Slides prepared to support **Seafood HACCP Alliance** training courses approved by the Association of Food and Drug Officials (AFDO) which 'require' the accompanying training manuals:



Hazard Analysis and Critical Control Point Training Curriculum (SGR 137; Blue Book) 6th edition June 2020



FDA Fish and Fishery Products Hazards and Controls Guidance (Gold Book; SGR 129)
4th edition March 2020

Program Introduction

National Seafood HACCP Alliance for Training and Education





Introduction to the Alliance Course and HACCP

Slide 1

In this chapter, you will learn the:

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



Course Objective

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

Slide 3

Course Format:

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



Audience Role

Slide 4

Participants are encouraged to:

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



The Seafood HACCP Training Manual (blue book) provides:

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

The FDA Hazards Guide provides:

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





Definitions and Terms

Slide 6

Key Definitions and Terms used in the FDA Seafood HACCP regulation and Hazards Guide are provided for reference in Appendix 4

> Appendix 4 page 241

Glossary of Terms and Acronyms

As an aid to readers, a compilation of terms used in HACCP and food safety regulations and acronyms used in this book is provided below.

Definitions of HACCP Terms¹

Appendix 4

CCP Decision Tree: A sequence of questions to assist in determining whether a

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

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

Control Point: Any step at which biological, chemical, or physical factors can

Corrective Action: Procedures followed when a deviation occurs.



HACCP stands for Hazard Analysis and Critical Control Points

Slide 8

A HACCP system is:

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



Origins of HACCP:

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



OF SCIENCES

Slide 10

National Academy of Sciences Recommendation:

The HACCP approach should be adopted by all regulatory agencies and it should be mandatory for food processors.



7 Principles of HACCP

Slide 11

Seven principles of HACCP:

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



Layers of Controls

Slide 12

HACCP is not a stand-alone system.

HACCP is built on a foundation of Good Manufacturing Practices.







Prerequisite Programs and Sanitation Control Procedures

Slide 1

In this chapter, you will learn:

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



Prerequisites

Slide 2

Definition:

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



Federal, State or Local Requirements

- Food Defense and Biosecurity Requirements
- Food Safety Modernization Act (FSMA) Requirements
- Labeling Requirements
 - Food Allergen Labeling and Consumer Protection Act (FALCPA)
 - Country of Origin Labeling (COOL)
 - Nutritional Labeling and Education Act (NLEA)
- State and Local Licenses and Permits



Recommended programs

- Environmental Monitoring
- Shipping Controls
- Recall and Traceability Programs
- Supplier controls
- Preventive maintenance

Slide 5

Required Prerequisite Programs for Seafood HACCP

- Employee training and training records
- Current Good Manufacturing Practice (GMPs)
- Seafood HACCP Regulation-Sanitation Control Procedures



FSMA addition

Slide 6

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

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



Required Training Records

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Slide 7

Example of Training Records

Employee Training Record						
Employee: Anybody Jones		Position/Duty: Processing belt for shrimp cooker				
COURSES	LOCATION	DATE COMPLETED	SIGNED			
Basic Sanitation Course (Seafood HACCP Alliance)	Headquarters	Nov 01, 2015	Ben Smith			
GMP's 117	Plant Unit 3	Jan 15, 2017	85			
SCP Monitoring	Plant Unit 3	Jan 15, 2017	85			
Basic Sanitation Review	Headquarters	Feb 01, 2017	S Otwell			

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



GMP's 117

Slide 8

Good manufacturing practices (GMPs) are the basis for determining if process methods produce safe foods and whether products have been processed under sanitary conditions.

Slide 9

Good Manufacturing Practices (21 CFR Part 117 Subpart B)

- Describes requirements for food processors to ensure safe and sanitary production of foods.
- First released in 1969 (21 CFR Part 110), GMPs for food manufacturing were revised in 1986 and again in 2015 (21 CFR Part 117).
- The updated GMPs include prevention of allergen cross-contact.



GMP's 117

Slide 10

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

> Appendix 3 page 229



Current Good Manufacturing

Title 21 CFR Part 117 - Subpart B - Current Good

FDA source Dec. 2016: (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/

§117.10 Personnel.

The management of the establishment must take reasonable measures and

- a. Disease control. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, must be excluded from any operations which may be expected to result in such contamination until the condition is corrected, unless conditions such as open lesions, boils, and infected wounds are adequately covered (e.g., by an impermeable cover). Personnel must be instructed to report such health conditions to their supervisors.
- b. Cleanliness: All persons working in direct contact with food, foodcontact surfaces, and food-packaging materials must conform to hygienic



SCP's - Procedures

Slide 11

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

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



SSOP's - Written Procedures

Slide 12

Sanitation Control Procedures

Recommended:

Written Sanitation Standard Operating Procedures (SSOPs)

Required:

- Monitoring
- Corrections
- Recordkeeping



Examples of Sanitation Control Procedures

Control of bacterial cross contamination hazards

- Maintain product flow
- Location of hand washing stations
- Equipment cleaning and sanitizing

Control of chemical cross contamination and/or allergen cross-contact hazards

- Proper chemical storage
- Proper chemical labeling
- Correct use of chemicals
- Production scheduling to prevent allergen cross-contact.



8 Key Areas of Sanitation

Slide 14

Eight key areas of sanitation:

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



1) Safety of water:

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

Slide 16

2) Condition and cleanliness of food contact surfaces:

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



3) Prevention of cross-contamination:

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

Slide 18

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



5) Protection from adulterants:

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

Slide 20

6) Labeling, storage and use of toxic compounds



7) Employee health conditions:

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

Slide 22

8) Exclusion of pests:

Pests must not be present in the food processing facility.



SCP's in GMP's 117

Pages 21-22

Table 1

Seafood HACCP Regulation Sanitation Requirements (21 CFR 123.11(b)) and their relation to the current Good Manufacturing Practice Regulation (21 CFR 110) 21 CED 117

	Part 123.11(b) Monitoring Equipment	21 CFR Part 117 Subpart B – Current Good Manufacturing Practices	
1	Safety of Water	Water Supply .37(a) Water supply must be derived from adequate source and adequate for operations. Plumbing .37(b)(5) Prevention of contamination from plumbing .37(b)(5) Backflow prevention and cross-connections Processes and Controls .80(a)(1) Water used for washing, rinsing, or conveying food .80(c)(16) Ice	
2	Condition and cleanliness of food contact surfaces	Sanitation of Food Contact Surfaces 35(d)(2) Wet processing conditions must be cleaned and sanitized as necessary to preclude allergen cross-contact and cross contamination. Food contact surfaces, equipment and/or intensits: 40(a)(1) Designed and made from materials that are adequately cleanable and maintained to preclude cross-contact and cross contamination. 40(a)(2) Designed, constructed and used to avoid adulteration of food from all contaminants. 40(a)(3) Installed to facilitate cleaning and maintenance. 40(a)(3) Gorrosion resistant. 40(a)(5) Made of nontoxic materials and able to withstand environment of use, action of food, and cleaning conditions. 40(a)(5) Maintained to protect from cross-contact and cross contamination. 40 (b) Smoothly bonded seams. Processes and Controls. 80(c)(1) Equipment taken apart for thorough cleaning when necessary.	
3	Provention of cross- contamina- tion	Personnel 10(b) Employee cleanliness 10(b)(1) Outer garments 10(b)(2) Personal cleanliness 10(b)(3) Handwashing and sanitizing 10(b)(4) Insecured jewelry and other objects that cannot be sanitized 10(b)(7) Clothing and personal belonging storage 10(b)(7) Clothing and personal belonging storage 10(b)(8) Fating, drinking, gum, tobacco use 10(b)(9) Other precautions to preclude cross-contact and cross contamination Plant Construction and Design 20(b) Space sufficient for sanitary operations and food safety including prevention of allergen cross-contact .35(f) Storage & handling of cleaned portable equipment & utensits	
4	Maintenance of hand washing, hand sanitiz- ing, and toilet facilities	Plumbing 37(b)(2) Plumbing properly convey sewage and liquid waste 37(b)(3) Plumbing must not constitute a source of contamination 37(b)(5) Plumbing must protect against backflow or cross connections with waste water systems 37(c) Sewage disposal 37(d) Toilet facilities 37(e) Hand-washing facilities	

Examples of monitoring frequency and corrections

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

Monitoring SCP's

Pages 24-25



Monitoring SCP's

Slide 24

Required Elements of SCP Monitoring Records

- Name and address of the firm
- Date and time of the recorded activity
- Include all of the eight key sanitary concerns pertinent to the operation
- Monitoring procedure and appropriate frequency
- Monitoring results
- Corrections taken
- Signature or initials of person conducting the monitoring



A facility processes only chilled Atlantic Salmon and Pacific Cod fillets.

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

Page 27

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

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



SCP Requirements

Slide 26

Sanitation in the Seafood HACCP Regulations:

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



HACCP vs. SCP's

Slide 27

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



Example SSOP 'written program' and accompanying records

Table 2

Pages 30-40

The following is an example of a written SSOP for a fictitious company producing raw and cooked RTE seafood products: Table 2. Model Sanitation Standard Operating Procedure 1) Safety of water (FDA Key Sanitation Condition No. 1) Controls and Monitoring: a) All water used in the plant is from a reliable municipal water system. Municipal water bills indicate that the water source is safe. Monitoring Frequency: Annually. b) The water system in the plant was designed and installed by a licensed plumbing contractor, and meets current community building codes. All modifications to the plumbing system will be completed by a licensed plumbing contractor and will be inspected to ensure conformance with local building codes. Copies of building inspection reports indicate that the plumbing system is properly constructed. Monitoring Frequency: When plumbing is installed or modified. c) All water faucets and fixtures inside and out: controls. Water faucets and fixtures are insp antisiphoning controls. Monitoring Frequer Daily Sanitation Control Record with all 8 Key Sanitation Areas Corrections Daily Sanitation Control Record Report Date: Firm Name: a) In the event of municipal water treatment fa-Line 1: Raw seafood (not ready-to-eat Line 2: Ready-to-eat determine when the failure occurred, and hi Sanitation Area and Goal failure until product safety can be assured. F water meets state and federal water quality: b) Corrections will be made to the plumbing s¹ Safety of water (See Monthly Sanitation Control Record) problems. Production will resume only whe Back Siphonage - Hose (S/U)* quality standards. c) Water faucets and fixtures without antisipho 2) Condition and deanliness of food contact surface (See Monthly Sanitation Control Record antisiphoning controls have been implemer Equipment cleaned and sanifized Line 1: (S/LI) a) Municipal water bill and monthly sanitation (Sanitizer Strength b) Building plumbing inspection report and pe c) Daily Sanitation Control Record.

Line 2: (ppm)

Gloves and aprons clean and in good repair

*S = Satisfactory / U = Unsatisfactory



Comments and

2) Condition and cleanliness of food contact surf

a) Food contact surfaces are readily cleanable

overlapping joints, mineral scale, etc. that ar sanitize). The sanitation supervisor inspects they are readily cleanable. **Monitoring Frequency: Daily**

No. 2)

Controls and Monitoring:



Seafood Safety Hazards

Slide 1

In this chapter you will learn about:

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



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

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

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





Potential seafood safety hazards can be grouped into two categories:

- Species-related hazards
- Process-related hazards





Species-Related Hazards

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

Process-Related Hazards

- Pathogenic bacteria growth (includes general pathogens,
 C. botulinum and S. aureus)
- Pathogen survival through cooking or pasteurization
- Pathogen survival through processes that do not use heat
- Pathogen contamination after cooking or pasteurization processes
- Food allergens
- Food additives
- Metal and glass inclusion



Microorganisms that can be pathogenic and cause seafoodborne illnesses:

- Bacteria
- Viruses

Slide 6

Bacterial Hazards:

- Foodborne infection
- Foodborne intoxication



Pathogen Controls

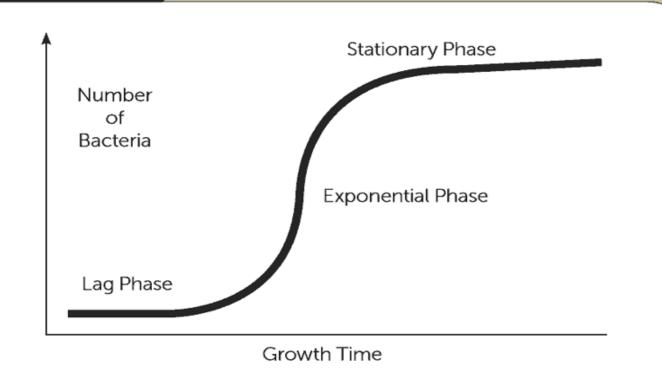
Slide 7

Control strategies for pathogens in seafood:

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



Pathogen Growth



Slide 9

What bacteria need for favorable growth:

- Food (nutrients from the seafood)
- · Water (moisture in the seafood)
- Proper temperature
- · Air, minimal air or no air (reduced-oxygen)



Primary Microbial Pathogens

Slide 10

Pathogens of Concern for Seafood Products:

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



Slide 11

Some controls for *Clostridium botulinum* in seafood:

- Destroy spores during processing (e.g., thermal processing [canning] or proper cooking to destroy the spores).
- Prevent potential growth by proper salting, drying, or pickling (acidification).
- Proper refrigeration, particularly for raw, non-frozen seafood packaged in anaerobic conditions (limited oxygen).
- Packaging refrigerated fishery products in permeable film that allows enough oxygen exposure to prevent anaerobic growth.



Slide 12

Some controls for *Bacillus cereus* in seafood:

- Proper sanitation to prevent product contamination (product source, process facilities and personnel)
- Proper chilling rates for warm prepared food
- Proper refrigeration for prepared, ready-to-eat (RTE) food with extended shelf lives



Slide 13

Some controls for *Listeria monocytogenes* in seafood:

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



Slide 14

Some controls for Salmonella spp. in seafood:

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



Slide 15

Some controls for Staphylococcus aureus in seafood:

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



Slide 16

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

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



Viruses

Slide 17

Hazards from viruses in foods

- Not truly "alive"
- Exist everywhere
- Do not grow in food
- Do not spoil food
- Transmitted by people, food and contaminated water
- Cause illness by infection



Viruses

Slide 18

Viruses:

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

Slide 19

Some controls for viruses in seafood:

- Product from approved sources
- Thorough cooking



Parasites

Slide 20

Parasites are organisms that need a host to survive.

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

Slide 21

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

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



Parasites

Slide 22

Parasitic Worms:

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

Slide 23

Some controls for *Anisakis simplex, P. decipiens* and *D. latum* parasites in seafood:

- Proper freezing
- Proper cooking



Species-Related Hazards from Harvest/Growing Waters

Slide 24

Species-Related Hazards Associated with the Harvest/Growing Area

- Natural Toxins
- Environmental Chemical Contaminants
- Aquaculture Drugs



Natural Toxins

Slide 25

Biotoxins – naturally occurring hazards:

- Shellfish Biotoxins
 - Amnesic Shellfish Poisoning (ASP; domoic acid)
 - Diarrhetic Shellfish Poisoning (DSP; okadaic acid)
 - Neurotoxic Shellfish Poisoning (NSP)
 - Paralytic Shellfish Poisoning (PSP; saxitoxins)
- Ciguatera Fish Poisoning (CFP)
- Tetrodotoxins (puffer fish poisoning)



Natural Toxin Controls

Slide 26

Control for shellfish biotoxins in seafood:

Only harvest approved shellfish products from approved waters

Slide 27

Control for ciguatera in seafood:

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



Natural Toxin Controls

Slide 28

Control for tetrodotoxin in seafood:

 Do not process certain fish (puffer fish) that have been designated as potentially tetrodotoxic

Slide 29

Control for *gempylotxin* in seafood:

Do not process certain potentially gempylotoxic fish



Environmental Chemical Contaminants

Slide 30

Controls for Environmental Chemical Contaminants (Pollutants)

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



Aquaculture Drugs: Illegal or Improper Use

Slide 31

Some controls for use of aquaculture drugs:

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



Scombrotoxin (histamine poisoning)

Slide 32

Control for potential scombrotoxin in seafood:

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



Process-Related Hazards

Slide 33

Other Process-Related Food Safety Hazards

- Food Additives
- Food Allergens
- Metal and Glass Inclusion



Process-Related Hazards

Slide 34

Examples of Food Additives

- Preservatives (e.g. nitrite, sulfites)
- Nutritional supplements (e.g. vitamins)
- Color additives

Slide 35

Controls for intentionally added ingredients in seafood:

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



Most common food allergens:

- Milk
- Peanuts
- Soybeans
- Eggs
- Tree Nuts
- Wheat
- Fish
- Crustaceans

Food Allergens

Slide 37

Control for potential allergens in seafood:

- Product labeling to inform consumers
- Institute proper pre-requisite programs and a strong sanitation program to avoid cross-contact for all allergens



Physical Hazards

Slide 38

Physical Hazard:

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

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



Physical Hazard Controls

Slide 39

Control for potential glass inclusion in seafood:

Examination of glass containers for breakage

Slide 40

Controls for potential metal inclusion in seafood:

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





Preliminary Steps in Developing a HACCP Plan

Slide 1

In this chapter, you will learn:

• The importance of preliminary steps in developing the HACCP plan



Get Ready!

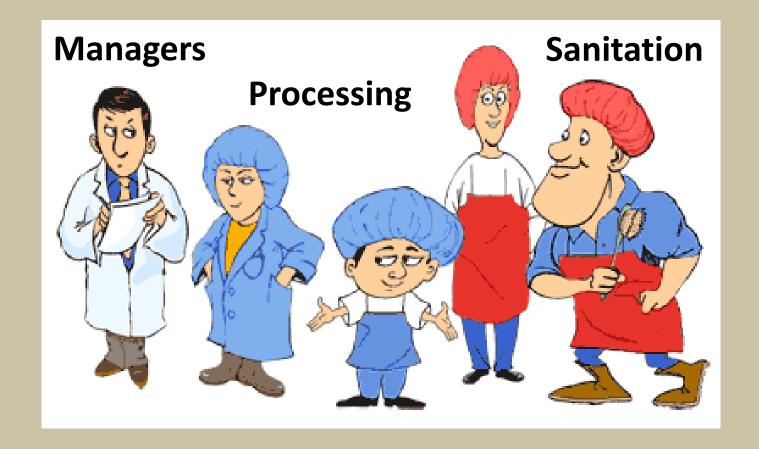
Slide 2

Preliminary steps:

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



HACCP TEAM ... Who's involved?





What's involved?

Slide 3

Product Description should include:

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



What's involved?

Slide 4

Product Description Form for Fish and Shellfish Species

Fish Farm Processori Desier Processori Desier Refrigerated Iced Iced Frozen Shelf-Stable Refrigerated Iced Frozen Shelf-Stable Refrigerated Refrigerated Iced Refrigerated Ref		ls	How Product Is Stored				Product How Product is chased urce) Received				re Pro Turcha Source	Acceptable Market Name & Species	
	Frozen Shefr-Stable Refrigerated Iced Iced Air Packed Air Packed Air Packed Air Packed Air Packed Raw, to be cooked, to be Cooked, RTE General Rubic	Shelf-Stable	Frozen	1000	Refrigerated	Shelf-Stable	Frozen	peol	Refrigerated	Processor? Dealer	Fish Farm	Fisherman	

Useful Product Description Chart

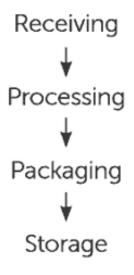
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Processing Steps involved?

Slide 5

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





Introduce XYZ Seafood Company (see pages 74 – 76)

XYZ Seafood Company Product Description Form for Fish and Shellfish Species

Acceptable Market Name & Species	19.5	re Pro turcha Source	sed	Н	ow Pro Rece	oduct rived	ls	How Product Is Stored				How Product Is Shipped				Pro	How oduct is ckaged	Intended Use			Intended Consumer	
	Fisherman	Fish Farm	Processor/ Dealer	Refrigerated	peol	Frozen	Shelf-Stable	Refrigerated	paoj	Frozen	Shelf-Stable	Refrigerated	loed	Frozen	Shelf-Stable	Air Packed	Reduced- Onygen/ Vacuum Packed	Raw, to be cooked	Raw, RTE	Cooked. RTE	General Public	At-risk Population
Mahi-mahi fillets (Coryphaena sp.)			х		×				х				Х			×		х			х	

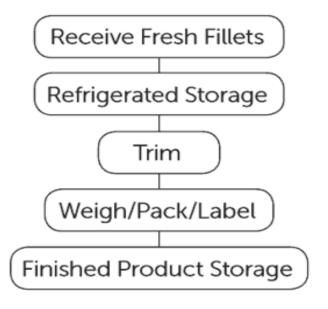


XYZ Processing Steps

Slide 7

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

Process Flow Chart







Principle 1: HAZARD ANALYSIS

Slide 1

In this chapter you will learn how to:

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



Key Definition

Slide 2

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

> **Food Safety** Hazards

BiologicaChemicalDL

Physical



Why conduct a Hazard Analysis?

Slide 3

The hazard analysis is conducted to identify:

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

PREVENT



ELIMINATE



REDUCE





How to Conduct a Hazard Analysis

Slide 4

There are five steps in a hazard analysis:

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





Use the Hazard Analysis Worksheet

Slide 5

Blank Hazard Analysis Worksheet

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



STEP 1 – Enter Processing Steps

Slide 6

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

Process Flow Chart

"Fresh Mahi-mahi Fillets"

Processing Steps

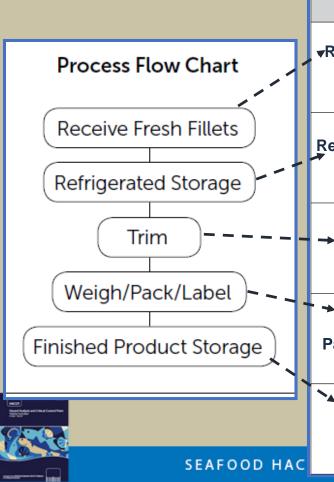
Flow Diagram from

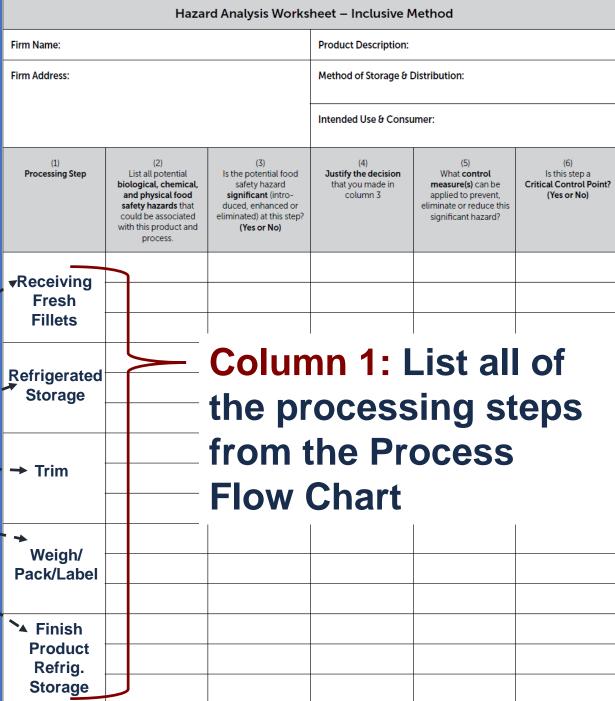
Chapter 4, Page 75





List all Processing Steps





STEP 2 – List Potential Food Safety Hazards

Slide 7

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

Slide 8

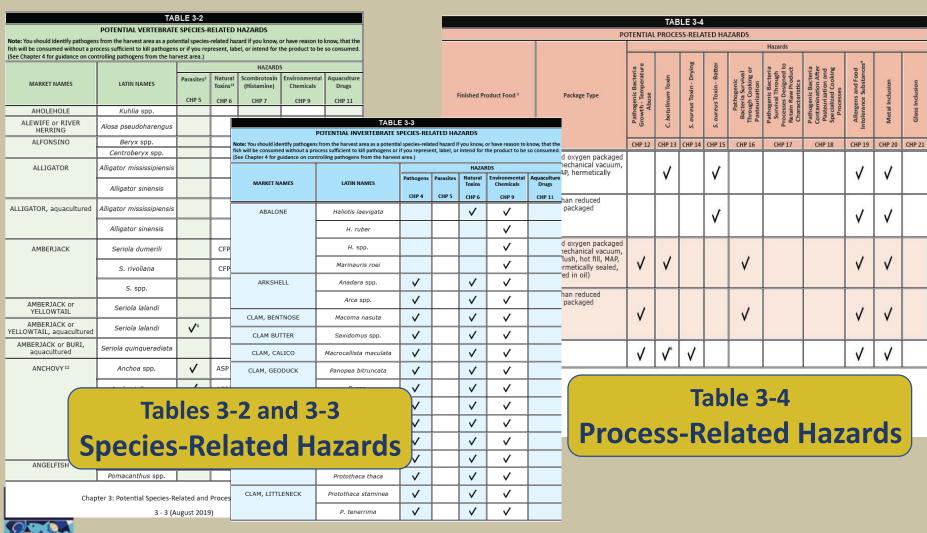
Use the FDA Hazards Guide as a tool to help identify **potential hazards**.







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





One Species-related hazard

Table 3-2

POTENTIAL VERTEBRATE SPECIES-RELATED HAZARDS

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

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

Notice two hazards in Chapter 19

Four Process-related Hazards

Table 3-4 POTENTIAL PROCESS-RELATED HAZARDS Hazards aureus Toxin - Drying aureus Toxin - Batter **Growth** - Temperature ntolerance Substances Processes Designed to Contamination After Pathogenic Bacteria Pathogenic Bacteria Food **Through Cooking or** Pathogenic Bacteria Retain Raw Product Specialized Cooking Pasteurization and Survival Through botulinum Toxin Characteristics Metal Inclusion Glass Inclusion Pasteurization and Abuse Finished Product Food 1 Package Type Allergens **CHP 12 CHP 13 CHP 14 CHP 15 CHP 20 CHP 16 CHP 17 CHP 18 CHP 19 CHP 21** Raw fish other than Reduced oxygen packaged oysters, clams, and (e.g. mechanical vacuum, mussels (finfish and non-MAP, CAP, hermetically sealed, or packed in oil) finfish) Other than reduced Raw fish other than oysters, clams, and oxygen packaged mussels (finfish and nonfinfish) Raw oysters, clams, and Reduced oxygen packaged (e.g., mechanical vacuum, mussels MAP, CAP, hermetically sealed, or packed in oil) Raw oysters, clams, and Other than reduced oxygen packaged mussels



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

Species-related Hazards

Table 3-2

1. Histamine formation (Chapter 7)



Process-related Hazards

Table 3-4

- 2. Pathogenic bacterial growth-temperature abuse (Chapter 12)
- 3. Allergens (Chapter 19)
- 4. Food Intolerance Substances (Chapter 19)
- 5. Metal inclusion (Chapter 20)





Inclusive Method

Hazard Analysis Worksheet						
Firm Name: XYZ Se	afood Company		Product Description: Fresh mahi-mahi fillets			
Firm Address: 238 Coastal Lane, Happy Beach, XX			Method of Storage of Stored and distribute			
			Intended Use & Cor the general public	nsumer: To be cooked	and consumed by	
(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) 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	Lis tha lik	olumn 2 st every hat is reasely to occur	nazard onably	n	
	Histamine Pathogen Growth-Temp. Abuse Undeclared Food Allergens Food	Eve	ery potent nsidered a ocessing st	ial hazard t each		
Refrigerated Storage	Intolerance Substances Metal Inclusion					



STEPS 3 & 4 - Hazard Evaluation & Justification

Slide 12

Steps 3 and 4: Hazard Evaluation and Justification. Determine

which hazards are significant and explain why.

Is This Significant??

Simply answer the questions in the Hazard Analysis



Exercise: Complete the Hazard Analysis Worksheet

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



Slide 13

To determine if a hazard is significant, consider two questions:

1) Is the hazard reasonably likely to occur in the finished product in the absence of control?

2) Is the hazard likely to cause consumer illness?

Is This Significant??

Slide 14

Example – Fresh Mahi-mahi

Which Hazards are Significant at the first process step, Receiving?

Histamine (Yes or No?)

Pathogen Growth - Temperature Abuse (Yes or No?)

Allergens (Yes or No?)

Food Intolerance Substances (Yes or No?)

Metal Inclusion (Yes or No?)



Justify your 'Yes or No' decisions

Slide 15

XYZ Seafood Company – Fresh Mahi-mahi Fillets

	Hazard Analysis Worksheet							
Firm Name: XYZ Seafo	Firm Name: XYZ Seafood Company			Fresh mahi-mahi fillets				
Firm Address: 238 Coastal Lane, Hap	ppy Beach, XX		Method of Storage & I Stored and distributed					
				ımer: To be cooked and	consumed by the			
(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 (intro- duced, enhanced or eliminated) at this step? (Yes or No)	(4) Justify the decision that you made in column 3	(5) What control measure(s) can be applied to prevent, eliminate or reduce this significant hazard?	(6) Is this step a Critical Control Point? (Yes or No)			
Receiving Fresh Fillets	Histamine	Yes	Time/temp. abuse during transit could cause histamine to form in the fish					
	Pathogen Growth - Temperature Abuse	No	Not likely to cause illness as the intended use for the product is to be cooked by or for the consumer prior to consumption					
	Food Allergens	Yes	Mahi is a food allergen					
	Food Intolerance Substances	No	No FIS are used on fresh fillets					
	Metal Inclusion	No	Not likely to occur at this step					

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

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

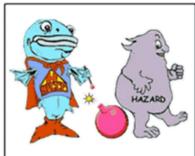
STEP 5 – Identify Control Measures (Column 5)

Slide 16

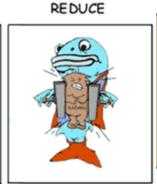
Step 5: Identify Control Measures for each significant hazard.



PREVENT



ELIMINATE



Slide 17

Control measures can be used to:

- Prevent a food safety hazard,
- Eliminate a food safety hazard, or
- Reduce a food safety hazard to an acceptable level.



Control Measures

Slide 18

Control Measures for Pathogenic Bacteria, Viruses, Parasites

Bacteria

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

Viruses

- 1) Cooking
- 2) Source controls

Parasites

- 1) Cooking
- 2) Freezing



Control Measures

Slide 19

Control Measures for Chemical and Physical Hazards

Chemical Hazards (Natural toxins, pesticides, drug residues, unapproved food and color additives, histamine)

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

Physical Hazards (Metal, glass, etc.)

- 1) Source controls
- 2) Production controls



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



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



Hazard Analysis Worksheet

Pages 95-97

Every 'Yes' in column 3 requires a response in column 5 and 6

Hazard Analysis Worksheet						
Firm Name: XYZ Se	afood Company		Product Description: Fresh mahi-mahi fillets			
Firm Address: 238 Coastal Lane, H	appy Beach, XX		Method of Storage & Distribution: Stored and distributed on ice			
			Intended Use & Cor the general public	nsumer: To be cooked	and consumed by	
(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)	
	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)		
	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			
Receiving	Undeclared Food Allergens	YES	Mahi is a food allergen	Containers of fillets will be labeled with market name at labeling step		
	Food Intolerance Substances	NO	No FIS used or added to the fresh fish			
	Metal Inclusion	NO	Not likely to occur at this step			
	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)		
	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		
	Food Intolerance Substances	NO	No FIS used or added to the fresh fish			
	Metal Inclusion	ŅΟ	Not likely to occur at this step			
Refrigerated Storage	Pathogen Growth-Temp. Abuse Undeclared Food Allergens Food Intolerance Substances	YES NO YES	this step Time/temp. abuse during transit could cause histamine to form in the fish Not likely to cause illness as the intended use of the product is to be cooked by or for the consumer prior to consumption Mahi is a food allergen No FIS used or added to the fresh fish	in ice & stored in a refrigerated cooler (proper icing) Containers of fillets will be labeled with market		



Hazard Analysis Worksheet

Pages 95-97

Every 'Yes' in column 3 requires a response in column 5 and 6

	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		
Trim	Undeclared Food Allergens	YES	Mahi is a food allergen	Containers of fillets will be labeled with market name at labeling step	
	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		
	Histamine	NO	Not likely to occur, time at this step is 30 min or less		
Weigh/Pack/	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		
Label	Undeclared Food Allergens	YES	Mahi is a food allergen	Fillets are labeled with market name at this step (proper labeling)	
	Food Intolerance Substances	NO	No FIS used or added to the fresh fish		
	Metal Inclusion	NO	Not likely to occur at this step		
	Histamine	YES	Time/temp. abuse could occur during storage	Mahi fillets are buried in ice & stored in a refrigerated cooler (proper icing)	
Finished Product Refrigerated Storage	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		





Be sure to identify all potential FOOD SAFETY Hazards

Slide 21

All food safety hazards must be considered in the Hazard Analysis, but it is not necessary to distinguish the hazards as biological, chemical or physical hazards.



End Chapter 5: Principle 1

HAZARD ANALYSIS







Principle 2: Determine Critical Control Points

Slide 1

In this chapter you will learn:

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



What's a Critical Control Point?

Slide 2

Definition: A Critical Control Point is a step at which control can be applied to prevent, eliminate a food safety hazard, or reduce it to an acceptable level.

Slide 3

CCP placement must be at the processing step or steps that adequately control the significant hazard.



Hazard Prevention

Slide 4

CCPs can be steps where hazards can be prevented.

Control Measures

Formulation

Time/Temp Control

Supplier Certificates

CCPs

Mixing Step

Refrigerated Storage Step

Receiving Step



Hazard Elimination

Slide 5

CCPs can be steps where hazards can be eliminated.

Control Measures

Cooking

Use of Metal Detection

Freezing Procedures

CCPs

Cook Step

Metal Detector Step

Freeze Step



Hazard Reduction

Slide 6

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

Control Measure

Source Controls

Time/Temp Control

CCP

Receiving Step

Cook Step



More than one ...

Slide 7

Multiple Hazards and Single CCP

Product = Live oysters (shellstock)

Hazards = Harvest site pathogens + Natural Toxins + Chemical

Contaminants

Single CCP = Receiving

Single Hazard and Multiple CCPs

Product = Fresh Tuna loins

Hazard = Histamine

Multiple CCPs = Receiving + Refrigerated Storage



Product & Process Specific ...

Slide 8

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

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



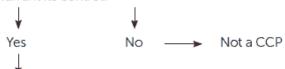
CCP Decision Tree (optional tool)

Page 99

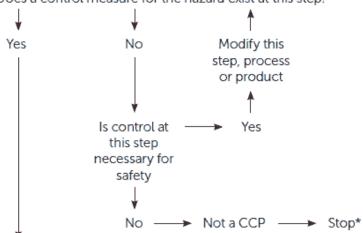
Slide 9

CCP Decision Tree

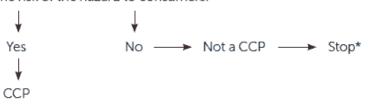
Q 1) Does this step involve a hazard of sufficient risk and severity to warrant its control?



Q 2) Does a control measure for the hazard exist at this step?



Q 3) Is control at this step necessary to prevent, eliminate or reduce the risk of the hazard to consumers?



*Proceed to the next step in process



Hazard Analysis Worksheet						
Firm Name: XYZ Se	afood Company		Product Description: Fresh mahi-mahi fillets			
Firm Address: 238 Coastal Lane, H	Firm Address: 238 Coastal Lane, Happy Beach, XX			Method of Storage & Distribution: Stored and distributed on ice		
			Intended Use & Cor the general public	nsumer: To be cooked	and consumed by	
(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)	
	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			
Receiving	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			
	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			
Refrigerated Storage	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			
	SI	EAFOOD HAC	CP ALLIANC	E FOR TRAIN	ING AND EDU	

Completed Hazard Analysis 105 - 107

CCP

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

CCP

	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		
Trim	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		
	Histamine	NO	Not likely to occur, time at this step is 30 min or less		
Weigh/Pack/	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		
Label	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		
	Histamine	YES	Time/temp. abuse could occur during storage	Mahi fillets are buried in ice & stored in a refrigerated cooler (proper icing)	YES
Finished Product Refrigerated Storage	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		

Completed Hazard Analysis 105 - 107

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

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
- Undeclared food allergen is a significant food safety hazard and there is one CCP for this hazard:
 - CCP 4. Weigh/Pack/Label



Remember to use the recommendations in the FDA Guide

For example, 'Likely CCPs' for histamine formation (FDA Guide, Chapter 7)

and food allergens (FDA Guide, Chapter 19)



SGR 129

Fish and Fishery Products
Hazards and Controls Guidance
Fourth Edition - APPIL 2011

- Receiving;
- Processing, such as:
 - Thawing;
 - Brining and salting;
 - Smoking;
 - Heading and gutting;
 - Manual filleting and steaking;
 - Fermenting;
 - Pickling;
 - o Drying:
 - Stuffing;
 - Mixing (e.g., salad preparation);
 - Portioning;
 - Packaging;
 - Final chilling after processing and packaging;
- Storing raw material, in-process product, and finished product under refrigeration.





"CCP either here or later"

Slide 10

XYZ Seafood Company - Fresh Mahi-mahi Fillets

		Hazard Analy	sis Worksheet					
Firm Name: XYZ Seafood Company Firm Address: 238 Coastal Lane, Happy Beach, XX			Product Description: Fresh mahi-mahi fillets					
			Method of Storage & Distribution: Stored and distributed on ice					
			Intended Use & Consu general public	umer: To be cooked and	consumed by the			
(1) Processing Step	List all potential food safety hazards that could be associated with this product and process.	(3) Is the potential food safety hazard significant (intro- duced, enhanced or eliminated) at this step? s 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)			
Rec. Haz	ard he	re	Time/temp. abuse during transit could cause histamine to form in the fish	Mahi-mahi Fllets are shipped in commers buried in ice (proper icing)	Yes			
	Food Allergens	Yes	Fish is a food allergen	Fillets will be labeled with market name at weigh/pack/label step (proper labelling)	No.			
	Metal Inclusion	No	Not likely to occur at this step					
Refrigerated Storage	Histamine	Yes	Time/temperature abuse during storage could cause histamine to form in the fish	Mahi-mahi fillets are buried in ice & stored in a refrigerated cooler (proper icing)	Yes			
	Food Allergens	Yes	Fish is a food allergen	Fillets will be labeled with market name at weigh/pack/label step (proper labelling)	No			
	Metal Inclusion	No	Not likely to occur at this step					

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

Slide 10 (cont.)

(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, eliminate or reduce this significant hazard?	(6) Is this step a Critical Control Point: (Yes or No)
Trim	Histamine	No	Not likely to occur, time at this and weigh/ pack/label step is 30 minutes or less		
'	Food Allergens	Yes	Fish is a food allergen	Fillets will be labeled with market name at weigh/pack/label step (proper labelling)	No
	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 and weigh/ pack/label step is 30 minutes or less		
	Food Allergens	Yes	Fish is a food allergen	Fillets are labeled with market name at this step (proper labelling)	Yes
	Metal Inclusion	No	Not likely to occur at this step	CCF	later
Finished Product Refrigerated Storage	Histamine	Yes	Time/temperature abused could occur during storage	Mahi-mahi fillets are buried in ice & stored in a refrigerated cooler (proper icing)	Yes
	Food Allergens	No	Fillets were labeled with market name at Weight/Pack/Label step.		
	Metal Inclusion	No	Not likely to occur at this step		



End Chapter 6: Principle 2 **Determine Critical Control Points**



Got it?



Principle 3: ESTABLISH CRITICAL LIMITS

Slide 1

In this chapter, you will learn:

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



What's a Critical Limit?

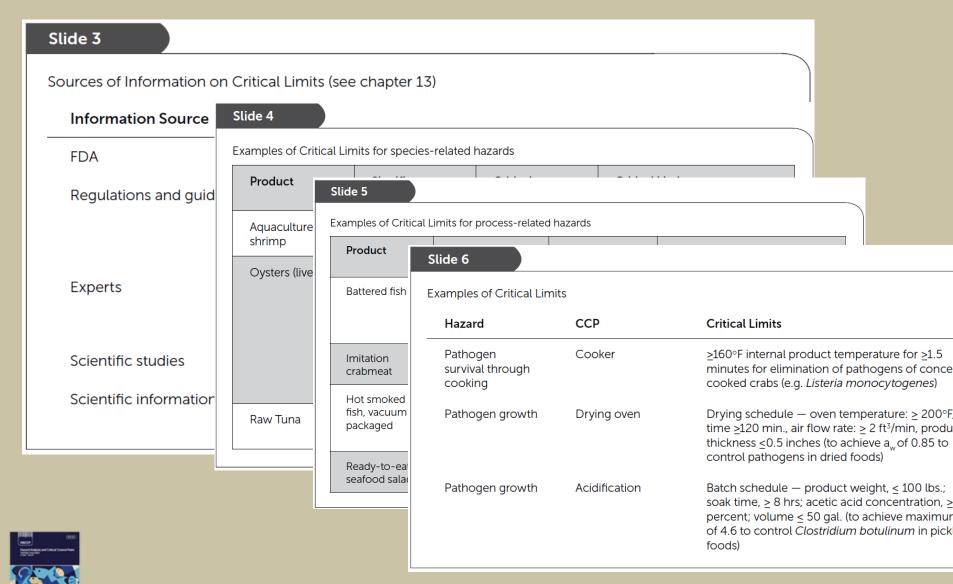
Slide 2

Definition:

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



Sources & Examples ...



Options and details ...

Slide 7

Option No. 1

Product: Fish cakes

Haza CCP Critic

Slide 8

Option No. 2

Product: Fish cakes

H

C

Slide 9

Option No. 3

Product: Fish cakes

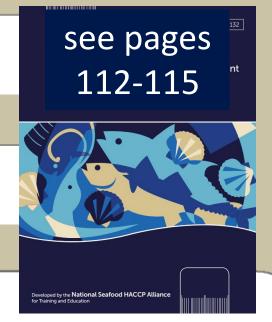
Hazard —pathogen survival

CCP — fryer

Critical limit — minimum fryer oil temperature of 350°F

Critical limit — maximum fish cake thickness of 3/4 inch

Critical limit — minimum cook time in the oil of two minutes





Using Operating Limits

Slide 10

Definition:

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



Using 'Lot' Designations

Page 109

Slide 11

Figure 1

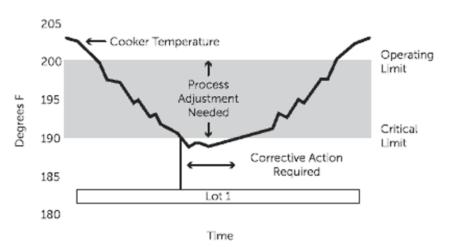
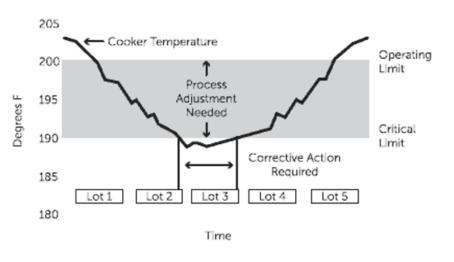


Figure 2



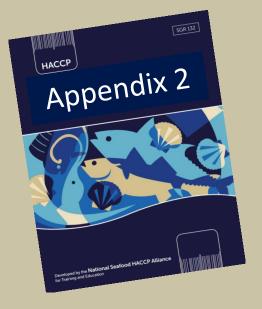


Critical Limits should be specified in the written HACCP Plan

Slide 12

lank HAC	0. 101111								
m Name:				H	ACCP Plan Fo	orm	P	woduct:	
Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control		Moni	itoring		Corrective Action	Verification	Records
POINT (OCP)	Hazarotty	Measure	What	How	Frequency	Who			





Optional HACCP Plan Forms

(both must contain same information)

Firm Name: Address:					Product Description:					
Signature:					Method of Distrib	ution & Storage:				
(printed name)					Intended Use & Co	neumore				
Date:					intended ose & Co	Jiisuillers.				
(1)	(2)	(3) Critical Limits	(4)	(5)	(6)	(7)	(8)	(9)	(10)	
Critical Control Point	Significant Hazards	for each Preventative		Moni	toring		Corrective Action(s)	Verification	Records	
(CCP)		Measure	What	How	Frequency	Who				
			Lai	l nds	cap	pe				

Firm Name: XYZ Seatood Company			Product: Fresh Mahi-Mahi Fillets			
Address:	238 Coas	stal Lane, Happy Beach, XX	Method Storage & Distribution:			
			Stored and distributed on ice			
Signature:	Xxxx	xxxxxxx	Intended Use:			
1 - 1 - 1			To be cooked and consumed by			
Printed:	Xxxxxxx	rvvv	the general public			
I IIIICG.		2000	Date: (-signed date-)			
		CCP number 1				
Critical Co		RECEIVING				
Point (C	CP)					
Significant 1	Hazard	Histamine				
Critical Limi	ts					
Cincai Liiii						
			t			
	What	P	ortrait 🚃			
		<u> </u>				
	How					
Monitoring						
	When					
	Who					
Corrective A	ction					
Verifications						
, cinication						
D						
Records						



Expected Information in all HACCP Plans

				HACCP P	lan Form						
Firm Name:					Product Descrip	Product Description:					
Firm Address:	rm Address: Method of Storage and Distribution:										
					Intended Use and Consumer:						
(1) Critical	(2) Significant	(3) Critical		Mon	itoring		(8) Corrective	(9) Verification	(10) Records		
Control	Hazard(s)	Limits for	(4)	(5)	(6)	(7)	Action				
Point(CCP)		each Control Measure	What	How	Frequency	Who					
				насср	SGR 132						
				Apper	ndix 2						
		-		9							
				TO TO							
Signature:	-						Date:				
COSTO Studying and Control Control Halo To Control Control Control Halo To Control Control Control Halo To Control Control Control Control Halo To Control Control Control Control Control To Co				Developed by the National Seafood i for Training and Education	HACCP Alliance						



Building the HACCP Plan for each CCP

Hazard Analysis Worksheet

Firm Name: XYZ Sea	afood Company		Product Description: Fresh mahi-mahi fillets					
Firm Address: 238 Coastal Lane, Ha	appy 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	,		(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)			
	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		Not likely to cause illness as the intended use of the product is to be cooked by or for the consumer prior to consumption)			
Receiving	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					
	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			
Refrigerated	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					
Storage	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					

HACCP Plan form

X 72 00010	ou compe	arry -					
(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventative Measure	(4)	(5)	(6)		C.
			What	How	Frequency	Who	
RECEIVING	Histamine						
		Colum of the	_				
		and id	entif	ied h	azar	ds	





Recommended Critical Limits

REMINDER: The FDA Guide contains control strategies with recommended CL's



Processors may select alternative CL's 'however' equivalent effectiveness MUST be demonstrated and documented



Select a Control Strategy

Example: CCP = Receiving Hazard = Histamine



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



FDA Guide, Chapter 7

CONTROL STRATEGY EXAMPLE 3 - TRANSIT CONTROL

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

Set Critical Limits.

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



- For fish delivered under ice:
 - Fish are completely surrounded by ice at the time of delivery;



- For fish delivered under ice on an open-bed truck:
 - Fish are stored completely surrounded by ice;

AND

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



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



The internal temperature of the fish at the

Proceed through the selected Control Strategies

- Note all listed options to suit different situations
- When applicable, there can be different strategies for primary vs. secondary processors
- Note the details associated with OR's and AND's



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

TRANSIT CONTROL OPTIONS

- Transit temperature records
- Surrounded by ice on delivery
- Use of ice; AND internal fish temperature
- Frozen gel-packs; AND internal fish temperature
- Transit time (< 4 hours); AND internal fish temperature





HACCP Plan for XYZ Seafood Company

(5)

(6)

(8)

(4)

(1)

(2)

(3)

Critical Control Point (CCP)	Significant Hazards	Critical Limits for each Preventative Measure	(7)			FDA	A Guide, Ch	apter 7	Corrective ction(s)
		Mahi-mahi fillets are completely		•	OR For		ered under ic	•	
RECEIVING	Histamine	surrounded with ice at receipt	_	<u> </u>		Fish are co	ompletely su of delivery;	ırrounde	d by ice at
REFRIGERATED STORAGE	Histamine			•	OR For truc		ered under ic	e on an	open-bed
WEIGH/PACK/ LABEL	Undeclare d Food Allergens			-		ice; AND	tored comple nal temperati	•	•
FINISHED PRODUCT REFRIGERATED STORAGE	Histamine						elivery is 40°		

HACCP Plan for XYZ Seafood Company

Slide 13 **HACCP Plan Form** Firm Name: XYZ Seafood Company Product: Fresh mahi-mahi fillets Critical Control Corrective Action Signi ficant Critical Limits Monitoring Verification Records Point (CCP) Hazard (s) for each Control Measure What How Frequency Who Receiving Histamine Mahi-mahi fillets are completely surrounded with ice at receipt. **Critical Limits based on** Refrigerated Histamine Mahi-mahi fillets Storage are completely surrounded with ice throughout recommendations in the storage time. Weigh/Pack/ Label FoodAllergens All finished prod-**FDA Hazards Guide** uct containers will. be labeled with the correct market name of the fish. Finished Product Histamine Mahi-mahi fillets Refrigerated are completely Storage surrounded with ice throughout storage time. Firm Name: XYZ Seafood Company Product: Fresh mahi-mahi fillets Firm Address: Method of Storage and Distribution: Stored and distributed buried in ice 238 Coastal Lane, Happy Beach, XX Intended Use and Consumer: To be cooked and consumed by the general public Signature:







End Chapter 7: Principle 3

Establish Critical Limits





Principle 4: Critical Control Point Monitoring

Slide 1

In this chapter, you will learn:

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



What is a Monitoring?

Slide 2

Definition:

Monitoring: A planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record to demonstrate that critical limits have been met.

Slide 3

Purpose of Monitoring:

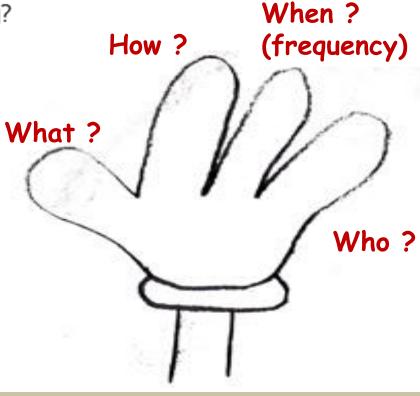
- To ensure that a critical limit is met,
- To provide documentation that critical limits have been met,
- To identify when there is loss of control (a deviation occurs at a CCP).



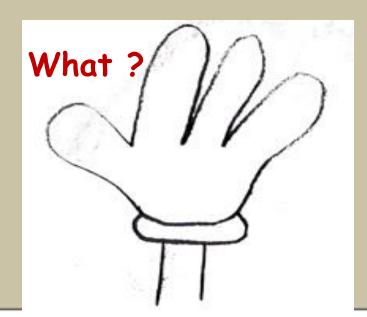
Elements of Monitoring

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

4 required parts for proper MONITORING



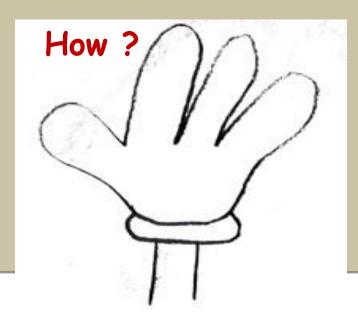




What will be monitored?

A **measurement** or **observation** to assess if the CCP is operating within the critical limit.



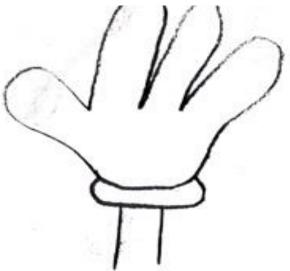


How will monitoring be performed?

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



When? (frequency)



Slide 7

What is the frequency of monitoring?

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





Who will monitor?

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



Monitoring requires training

Slide 9

Those responsible for monitoring a CCP should:

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



Monitoring Examples:

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

Slide 11

Examples of monitoring equipment could include:

- thermometers
- recorder charts
- clocks
- pH meters

- water activity meters
- data loggers
- metal detectors
- salometer



Monitoring for XYZ Seafood Company

Slide 12

HACCP plan form for XYZ Seafood Company completed through monitoring

Firm Name: XYZ Seafood Company **HACCP Plan Form** Product: Fresh mahi-mahi fillets Critical Control Significant **Critical Limits** Monitoring Corrective Action Verification Records Point (CCP) Hazard(s) for each Control Measure What How Frequency Who see page 127 Mahi-mahi fillets Receiving Histamine Adequacy of Visual check of Every Delivery Receiving are completely ice surrounding adequacy of ice Manager surrounded with mahi-mahi in a representa ice at receipt. fillets at delivery tive number of containers in each delivery Refrigerated Histamine Mahi-mahi fillets Adequacy of Visual check of At the begin-Cooler Storage are completely ice surroundadequacy of ice ning and end of Manager surrounded with ing mahi-mahi in a representathe work day ice throughout fillets tive number of storage time. containers in cooler storage Weigh/Pack/Label Food Allergens All finished prod-Visual check of Packing The market Each customer uct containers will name on each a representaorder Manager tive number of be labeled with container the correct market of finished containers and product their label Finished Product Histamine Mahi-mahi fillets Adequacy of Visual check Cooler Developed by the National Seafood HACCP Alliance Refrigerated are completely ice surroundof representabeginning and Manager Storage surrounded with ing mahi-mahi tive number of end of the work ice throughout fillets containers in storage time. cooler storage Firm Name: XYZ Seafood Company Product: Fresh mahi-mahi fillets Firm Address: Method of Storage and Distribution: Stored and distributed buried in ice 238 Coastal Lane, Happy Beach, XX Intended Use and Consumer: To be cooked and consumed by the general public Sign ature: Print name:



End Chapter 8: Principle 4

MONITORING





Principle 5: Corrective Actions

Slide 1

In this chapter, you will learn:

- The definition of corrective actions,
- Procedures for corrective actions, and
- Record-keeping requirements for corrective actions.



What are Corrective Actions?

Slide 2

Definition:

Corrective Action: Procedures to be followed when a deviation occurs.

Slide 3

Predetermined corrective actions are recommended.



Corrective action components:

- Identify the product that was produced during the process deviation, evaluate its safety and determine its disposition.
- Correct and eliminate the cause of the deviation and restore process control.

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



Is the involved product safe?

Slide 5

Tools to help evaluate product safety:

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

CONTROLLING PATHOGEN GRO POTENTIALLY HAZARDOUS CONDITION GROWTH AND TOXIN FORMATION BY BACKLING	TABLE A.: E AND TEMPERATURE OWTH AND TOWN	2 GUIDANCE E	
POTENTIALLY HAZARDOUS CONDITION	N PRODUCTION FO	RMATION IN	FISH AND FISHERY PRODUCTS
GROWTH AND TOXIN FORMATION BY BACILLUS CEREUS	39.2-430p (MAXIMUM CUMULATIVE EXPOSURE TIME
GROWTH OF CAMPYLOBACTER JEJUNI	60-70°F (7-1	5°C)	5 days
GERAIN	86-930F (20	21°C)	1 day 6 hours 3 hours
GERMINATION, GROWTH, AND TOXIN FORMATION BY CLOSTRIDIUM BOTULINUM TYPE A, AND PROTECLYTIC TYPES B AND F GERMINATION, GROWTH.	50-70°F (10 2)	4°C)	48 hours 12 hours
FORMATION, GROWTH, AND TOWN	70°F (21	°C)	11 hours 2 hours
TYPES B AND NON-PROTEOLYTIC	37.9-41°F (3.3-5° 42-50°F (6-10°C		7 days
GROWTH OF CLOSTRIDIUM PERFRINGENS	51-70°F (11-21°C Above 70°F (21°C	3	2 days 11 hours
GPOWER	50-54°F (10-12°C) 55-57°F (13-14 °C) 58-70°F (15-21°C) Above 700°C		6 hours 21 days
GROWTH OF PATHOGENIC STRAINS OF ESCHERICHIA COLI			1 day 6 hours
GROWTH OF LISTERIA MONOCYTOGENES	43.7-50°F (6.6-10°C) 51-70°F (11-21°C) Above 70°F (21°C)		2 hours 2 days
- NOCYTOGENES	31.3-41°F (-0.4-5°C)		5 hours 2 hours
GROWTH OF THE	71-86°F (22-21°C)		7 days 1 day
4	1.4-50°F (5.2 co		7 hours 3 hours 1 hour
OKOWIH OF SHIGELLA SPECIES	bove 70°F (210°C)		2 days 5 hours
GROWTH AND 2	1-70°F (11-20°C)		2 hours 2 days
51 ₂	50°F (7-10°C)		5 hours 2 hours
Abo	ove 70°F (21°C)		14 days 12 hours ¹

Helpful Sources: GROWTH AND TOWN FORMA STAMFHIOCOCCUS AUREL FDA Guide-Appendix 4



Is the involved product safe?

Slide 6

Steps to determine the disposition of product:

Step 1: Determine if the product presents a safety hazard.

Step 2: If no hazard exists, the product may be released.

Step 3: If a potential hazard exists, determine if the product can be:

- a) Reworked/reprocessed, or
- b) Diverted for a safe use.

Step 4: If a food safety hazard does exist, the product must be rejected or destroyed.

Slide 7

Corrective actions must identify the cause of the deviation and restore process control.



Using the FDA Guide for CA's

Optional CA's

FDA Guide Example Chapter7, page 143



In some cases, the final option to reject or destroy product is more logical than trying to produce evidence for other options



Take the following corrective action to a product involved in a critical limit deviation:

histamine analysis is performed on a minimum of 60 fish representatively collected from throughout the affected lot. Destroy the lot or divert it to a non-food use if any fish is found with histamine greater than or equal to 50 ppm. The fish collected for analysis may be composited if the action plan is reduced accordingly. For example, a sample of 60 fish may be composited into 20 units of 3 fish each, provided the action point is reduced from 50 ppm to 17 ppm for each unit;

OR

Destroy the product;

OR

• Divert the product to a non-food use.



Slide 8

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

Information for documenting Corrective Actions

Page 127

Slide 9

Sample Corrective Action Report

Company Name: Street Address, City Name, State:

Product Identification:

Date: Code or Lot Number:

Date and Time of Deviation:

Description of Deviation:

What Actions were taken to Restore Order to the Process:

Person (name and signature) of Person Taking Action:

Amount of Product Involved in Deviation:

Evaluation of Product involved with Deviation:

Final Disposition of Product:

Reviewed by (Name and

Date:

Signature):



Example Corrective Actions see pages 128 -129

Slide 10

Corrective action examples for species-related hazards

Critical Control Point	Significant Hazard	Critical Limit
Receiving aquacultured shrimp from the farm	Aquaculture drugs	Supplier certificate of (indicating proper dr
Receiving live oysters from the harvester	Natural toxins	All shellstock tagged the date and place o harvest, type and qu of shellfish, and nam registration number harvest vessel and
		All shellstock from w approved by State Sh Authority and
		All shellstock from a harvester.

Slide 11

Corrective action examples for process-related hazards

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



Corrective Actions for XYZ Seafood Company

Slide 12

HACCP plan form for XYZ Seafood Company completed through corrective action

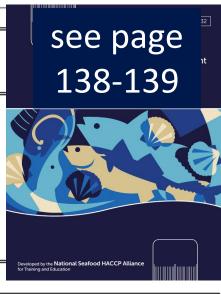
Firm Name: XYZ Seafood Company Product: Fresh mahi-mahi fillets

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits		Moni toring			Corrective Action	Verification	Records
rollit (ccr)	Hazardysy	Measure	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 representa- tive number of containers in each delivery	Every Delivery	Receiving Manager	If: the amount of ice is not adequate; Therr 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.		page 3-139
Refrigerated Storage	Histamine	Mahi-mahi fillets are completely surrounded with ice throughout storage time.	Adequacy of ice surround- ing mahi-mahi fillets	Visual check of adequacy office in a representa- tive number of containers in cooler storage	At the begin- ning 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.		
Weigh/Pack/ Label	Food Allergens	All finished prod- uct containers will be labeled with the correct market name of the fish.	The market name on each container of finished product	Visual check of a representa- tive number of containers and their label	Each customer order	Packing Manager	If a container is improperty labeled, Then: segregate it and property label it before the customer order is placed in the finished product cooler, and modify labeling procedure and conduct training as necessary to ensure that all products are properly identified.	Developed by the National Seafood for Training and Education	HACCP Alliance

Corrective Actions for XYZ Seafood Company

Slide 12 (cont.)

Critical Control Point (CCP)	Significant Hazardís)	Critical Limits		Moni	toring	Corrective Action	
POIR CCP/	TBZald by	Measure	What	How	Frequency	Who	
Finished Product Refrigerated Storage	Histamine	Mahi-mahifillets are completely surrounded with ice throughout storage time.	Adequacy of ice surround-ing ma hi-ma hi fillets	Visual check of representa- tive number of containers in coolers to rage	At the beginning and end of the work day	Cooler Manager	If: finished product containers do nothave 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.



Firm Name: XYZ Seafood Company	Product: Fresh mahi-mahi fillets	
Firm Addre ss:	Method of Storage and Distribution: Stored and distributed buried in ice	
238 Coastal Lane, Happy Beach, XX	Intended Use and Consum er: To be cooked and consumed by the general public	
Signature:	Date:	
Print name:		



End Chapter 9: Principle 5

CORRECTIVE ACTIONS





Principle 6: Establish Verification Procedures

Slide 1

In this module, you will learn:

- The definition of verification
- Validation is part of verification
- Verification procedures



What is Verifications?

Slide 2

Definition:

Verification: Those activities, other than monitoring, that determine the validity of the HACCP plan and that verify the system is operating according to the plan.

Slide 3

"Trust what you can verify."



Various types of Verifications

Slide 4

Types of Verification Procedures:

- 1) Validation (before the HACCP plan is implemented)
- 2) CCP verification (regularly scheduled activities):
 - Calibration of process-monitoring devices,
 - Record review,
 - Targeted sampling and testing.
- 3) HACCP system verification (periodic activity):
 - HACCP plan reassessment
 - Microbiological end-product testing and third party audits
- 4) Regulatory verification (periodic activity)



Validation 'before' operations

Slide 5

Definition:

Validation: The element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the hazards.

'Will it work'



Before operations...'Validate the HACCP controls and plan will work'

Slide 6

Validation involves establishing the scientific basis for the HACCP plan.

Strategies that can be used to validate the HACCP plan include:

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



When to Validate

Slide 7

Validation frequency:

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



Verification 'during' operations

Slide 8

CCP verification activities:

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

Slide 9

'Is it working'

Accuracy checks and calibrations are performed:

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



'Is it working' ... see page 140

Slide 10

Examples of calibration and accuracy activities

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

^{*}NIST = National Institute of Standards and Technology



Record Accuracy and Calibration

Slide 11

Frequency of accuracy checks and calibration can depend on:

- Design of the monitoring device
- Reliability and sensitivity of the device
- The environment or conditions in which it is used

Slide 12

Accuracy checks and calibration records must:

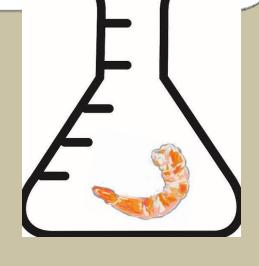
- 1) Document results of accuracy checks and calibration procedures
- 2) Provide a reference to the standard
- 3) Be reviewed by qualified, trained personnel



Verify through periodic testing

Slide 13

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





Must Review Monitoring and Corrective Action Records

Slide 14

Verification through Record Reviews:

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



Total HACCP Program Verification

Slide 15

HACCP system verification or reassessment frequency:

- Annually,
- Occurrence of a system failure or significant change in product or process.

Slide 16



System-wide HACCP plan verification reviews include:

- Verifying that the hazard analysis and HACCP plan are still accurate, and
- Reviewing records to determine trends and verify that the plan is being followed.



Total HACCP Program Verification

Slide 17

Other system-wide verification strategies

- Finished product testing for microbiological, chemical or physical hazards
- Third-party audits

Slide 18

Situations that may trigger a HACCP plan reassessment:

- A change in products or the process
- A change in the critical limit at a CCP
- Relocation of your plant
- Installation of a new piece of equipment
- A HACCP system failure
- Adverse findings from a regulatory inspection or third party audit



Ultimate Verification

Slide 19

Regulatory agencies conduct inspection to verify that a processor:

- Has developed a HACCP plan that controls all significant food safety hazards;
- Has implemented the HACCP plan and it is consistently being used; and
- Is in compliance with HACCP and other regulations.



Verification Summary ...

Pages 146-147

Slide 20

Example of a company-established HA(

Activity	F
Verification activities scheduling	p
Initial validation of HACCP plan	P ir
Reassessment of HACCP plan	Cl cl e sy
Verification of CCP monitoring as described in the plan (e.g., monitoring of patty cooking temperature)	A (∈
Review of monitoring, corrective action records to show compliance with the plan	V
Comprehensive HACCP system verification	Y

^aMay require additional technical expertise as well as labor

Slide 21

Examples of verification activities for specific critical limits

Significant Hazard	Critical Control Point	Critical Limits	Verification
Aquaculture drugs	Receiving (from farm)	Suppliers certificate on file (indicating proper drug use).	Visit new suppliers within a year and existing suppliers on a pre-determined schedule to review drug use policies; and
			Conduct quarterly sampling of raw material and test for drug residue likely to be present; and
			All records will be reviewed by a HACCP trained person once per week.
Natural toxins	Receiving (from harvester)	All shellstock tagged with the date and place of harvest, type and quantity of shellfish, and name or registration number of harvest vessel; and all shellstock from waters approved by State Shellfish Authority; and all shellstock from a licensed harvester.	Review all monitoring and corrective action records once per week.
Histamine	Receiving (from supplier)	Fish are completely surrounded by ice.	Check the accuracy of new thermometers before they are used and daily thereafter and calibrate thermometers once per year; and Check internal temperature of iced fish at receipt before accepting fish from new suppliers and quarterly for existing suppliers to verify adequacy of ice; and All records will be reviewed by a trained person once per week.
C. botulinum toxin forma- tion (in finished product)	Hot smoking	Internal fish temperature held at or above 145°F for at least 30 minutes.	Check the accuracy of the smokehouse temper- ature sensor before it is used and daily thereafter and calibrate at least once per year, and all records will be reviewed by a trained person once per week.
Pathogen growth	Cooler storage	Cooler temperature not to exceed 40°F.	Check the accuracy of the cooler temperature sensor before it is used and daily thereafter and calibrate at least once per year; and All records will be reviewed by a trained person once per week.



Verifications for XYZ Seafood Company

Slide 22

Firm Name: XYZ Seafood Company HACCP Plan Form Product: Fresh mahi-mahi fillets

Critical Control Point (CCP)	Significant Critical Limits Hazard(s) for each Control		Monitoring				Verification	Records	
Polit (CCP)	nazaruş)	Measure	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 representa- tive number of containers in each delivery	SE 1	Receiving Manager	If: the amount of ice is not adequate; Then: reject product, and call a polier to let was not de product cations, ie use of teir the reject product cations are used to the reject product prod	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	Mahi-mahi fillets are completely surrounded with ice throughout storage time.	Adequacy of ice surround- ing mahi-mahi fillets	Visual check of adequacy of ice in a representa- tive number of containers in coolers to rage	At the Developed by the N for Training and Edu	ational Seafood HACCP Allian	ce is in chill lect a ted me possures ling operations, and add loe 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.	

Verifications for XYZ Seafood Company

Slide 22 (cont.)

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control		Monitoring			Corrective Action	Verification	Records
rollik(ccr)	riazai u(s)	Measure	What	How	Frequency	Who			
Weigh/Pack/ Label	Food Allergens	All finished prod- uct containers will be labeled with the correct market name of the fish.	The market name on each container of finished product	Visual check of a representa- tive number of containers and their label	ord	ee pa	If a container is improp- and labeled. Then: segre- viabel mer ne nooler, ng nduct ary to oducts tilled.	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	Mahi-mahi fillets are completely surrounded with ice throughout storage time.	Adequacy of ice surround- ing mahi-mahi fillets	Visual check of representa- tive number of containers in cooler storage	Developed by the National Sec for Training and Education	of Good HACCP Alliance	duct not have The n: chill reduct evaluated btal time ure luding into prior perations, he if there is a higher cooler	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 loe maintains product temperature. Check the accuracy of the thermometer before each use. Annual calibration of thermometer used to check internal temp.	

Firm Name: XYZ Sea food Company	Product: Fresh mahi-mahi fillets		
Firm Address:	Method of Storage and Distribution: Stored and distributed buried in ice		
238 Coastal Lane, Happy Beach, XX	Intended Use and Consumer: To be cooked and consumed by the general public		
Signature:	Date:		
Print name:			

End Chapter 10: Principle 6

VERIFICATIONS





Principle 7: Record-Keeping Procedures

Slide 1

In this chapter you will learn:

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



Records support the HACCP Program

Slide 2

Six types of records are needed in a HACCP system:

- 1) The HACCP plan and supporting documentation
- 2) CCP Monitoring records
- 3) Corrective Action records
- 4) Verification records
- 5) Sanitation Control records
- 6) Importer Verification records

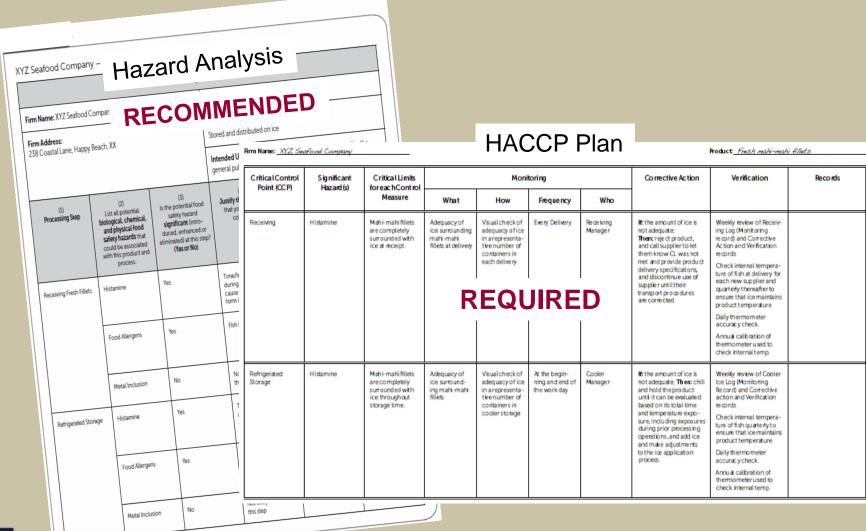
Required Records

Slide 3

1) The HACCP plan and its supporting documentation



Recommended and Required Records





Additional Record support for HACCP

Slide 4

Examples of HACCP Plan Support Documents:

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



Slide 5

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

Slide 6

Required information on required records

Information required on CCP monitoring records:

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



Example Monitoring Records

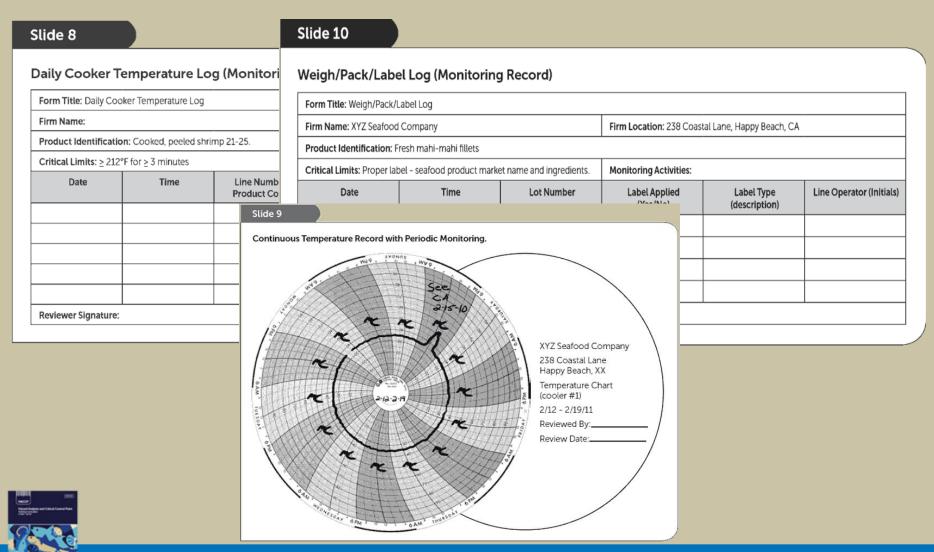
Slide 7

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



Example Monitoring Records ...

Pages 161-163



Slide 11

3) Corrective action records

Information for CA records

• • •

Pages 163-164

Slide 12

Corrective Action Report (Corrective Action Record)

Form Title: Corrective Action Report Form						
Firm Name:		Firm Location:				
Product Description:						
Date:	Line Number:	Lot Number:	Code Number:			
Date and time of process deviation:						
Describe the process deviation and who	at happened to the product?					
What action(s) was taken to restore ord	er to the process?					
Name and signature of person reportin	g deviation and responsible for taking the	correction action:				
Amount of product affected by the pro	cess deviation:					
Evaluation of product involved by the p	rocess deviation:					
Final disposition of the affected produc	t.					
Reviewer Signature:		Date of Review:				



Slide 13

4) Verification records

Slide 14

Verification Records document the results of:

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



Additional Record Examples ... Pages 161-163

Slide 15

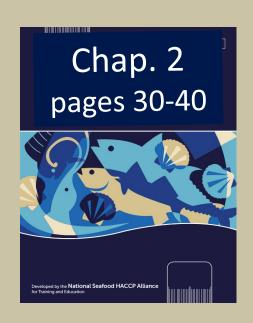
Form Title: Daily Thermor	neter Accuracy Log			
Firm Name:		Firm Location:	Firm Location:	
Product Identification:		·		
Verification:	Slide 21			
Date	Annual HACCP Plan V	/erification Report (Verificatio	n Record)	
	Annual HACCP Plan Verificatio	n Checklist	Date Task Completed:	Signature of Person who Completed the Task
	List of HACCP Team with Individ	dual Responsibilities Updated.		
	List of Seafood Products and Pr	ocesses in Place at Facility.		
	Product Flow Diagrams Update	d		
	Hazard Analysis Updated			
Reviewer Signature:	HACCP Plan Updated			
	Good Manufacturing Practice P	lan Updated		
	Sanitation Standard Operating F	Practices Plan Updated		
	HACCP Plan Implemented			
	Reviewer Signature:		Date of Annual Review:	



Do Not Forget Records for required SCP monitoring

Monthly	anitation Control Record		
Firm Name:	Date:		
Firm Address:		Comments/	Sa
Sanitation Area	Decision		
1) Safety of water			
Safe and sanitary source (S/U) (Annual)			
No cross-connections in hard plumbing (S/U)			
Condition and cleanliness of food contact surfaces			
 Processing equipment and utensils in suitable condition (S/U) 			
3) Prevention of cross-contamination			
Physical conditions of plant and layout equipment (S/U)			
S = Satisfactory / U = Unsatisfactory			

Remember SCP records for the 8 Key
Sanitation Conditions





Do Not Forget Employee Training Records in GMP's 117

Page 171

Slide 22

Example of Training Report (Pre-requisite Document)

Employee Training Record							
Employee: Anybody Jo	nes	Position/Duty: Processing belt for shrimp cooker					
Firm Name: XYZ Seafo	od Company	Firm Location: 238 Coastal Lane, Happy Beach, XX					
COURSES	LOCATION	DATE COMPLETED	SIGNED				
Basic Sanitation Course (Seafood HACCP Alliance)	Headquarters	Nov 01, 2015	Ben Smith				
GMP's 117	Plant Unit 3	Jan 15, 2017	85				
SCP Monitoring	Plant Unit 3	Jan 15, 2017	85				
Basic Sanitation Review Headquarters		Feb 01, 2017	S Otwell				

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



Slide 23

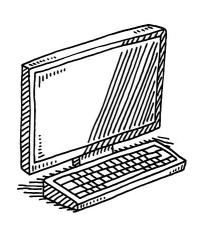
Electronic or computerized monitoring records must be equivalent to paper records and handwritten signatures.

Slide 24

Computer Recordkeeping allowed ... **IF**

An effective electronic record-keeping system must:

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





Records for XYZ Seafood Company

Slide 31

Firm Name: XYZ Seafood Company			HACCP Plan Form					Product: Fresh mahi-mahi fillets		
CriticalControl	Critical Control Significant Critical Limits Point (CCP) Hazard(s) for each Control		Monitoring				Corrective Action	Verification	Records	
Polit (CCP)	Politi (CCP) Hazardis) To	Measure	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 representa- tive number of containers in each delivery	EveryDelivery	Receiving Manager See 179	If: the amount of ice is not adequate; Then: reject product, and call supplier to let them know CL was not Pages 1 -180	Weekly review of Receiving Lo g (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-mahifillets are completely surrounded with ice throughout storage time.	Adequacy of ice surround-ing ma hi-ma hi fillets	Visual check of adequacy of ice in a representative number of containers in coolers to rage	Atthe begin- ning and end the work day	eveloped by the National Seafood Trialning and Education	to the ice a pplication 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 loe Log that documents: the number of containers examined, the approximate number of containers in storage, and the results of checks for adequacy of ice. Corrective Action records Verification Records Accuracy Check Record Annual Calibration Log	

Records for XYZ Seafood Company

Slide 31 (cont.)

Critical Control			toring			Corrective Action	Verification	Records		
Point (CCP) Hazard(s)	for each Control Measure	What	How	Frequen	псу	Who				
Weigh/Pack/Label	FoodAllergens	All finished prod- uct containers will be labeled with the correct market name of the fish.	The market name on each container of finished product	Visual check of a representa- tive number of containers and their label	Each custor 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, and modify labeling procedure and conduct training as necessary to ensure that all products are properly identified.	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 a liergenic or food intolerance substance ingredients against a w materials ingredients' label declarations at least annually and when changes to applicate of formula tion e.	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
Finished Product Refrigerated Storage	Histamine	Ma hi-ma hi fillets are completely surrounded with ice throughout storage time.	Adequacy of ice surround- ing mahi-mahi fillets	Visual check of representa- tive number of containers in cooler storage	At the beginning a end of the v day		Cooler Manager	see pa 179 -1	ges	Cooler Ice Log that documents: the number of containers examined, the approximate number of containers in storage and the results of checks for a dequacy of ice. Corrective Action records Verification Records • Accuracy Check Record • Annual Calibration
Firm Name: XYZ Seafood Company					P	Product:	Fresh mahi-n			
Firm Address: 238 Coastal Lane, Happy Beach, XX						Method of Storage and Developed by the National Seafood HACCP Alliance for Training and Education Intended Use and Consumer: To be cooked and consumed by the general public				
Signature: John Doe Print name:						Date:		arret. 15 de cooked and consum	iou sy riie general public	

SPECIAL NOTE

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

XYZ Seafood Company

Pages 181-184

Blank forms are in Appendix 2



Slide 32

HACCP Plan Form

Firm Name: XYZ Seafood Company			Product: Fresh mahi-mahi fillets			
Firm Address: 238 Coastal Lane, Happy Beach XX			Method of Storage & Distribution: Stored and distributed buried in ice			
			Intended Use and Consumer: To be cooked and consumed by the general public			
Critical Control Point (CCP)		CCP 1: Receiving				
Significant Hazard(s)		Histamine				
Critical Limits for each Control Measure		Mahi-mahi fillets are completely surrounded with ice at receipt.				
	What	Adequacy of ice surrounding mahi-mahi fillets at delivery				
Monitoring	How	Visual check of a representative number of containers and their label				
Monitoring	When	Every Delivery				
	Who		Receiving Manager			
Corrective Action		If: the amount of ice is not adequate; Then: reject product, and call supplier to let them know CL was not met and provide product delivery specifications, and discontinue use of supplier until their transport procedures are corrected.				
Verification		Weekly review of Receiving Log (Monitoring record) and Corrective Action and Verification records Check internal temperature of fish at delivery for each new supplier and quarterly thereafter to ensure that ice maintains product temperature Daily thermometer accuracy check. Annual calibration of thermometer used to check internal temp.				
Records		Receiving Log that documents: the number of containers examined; the number of containers in each delivery; and the results of checks for adequacy of ice. Corrective Action records Verification records				
Signature: John D	oe		Date: 5/9/17			

End Chapter11: Principle 7

Record-Keeping





The Seafood HACCP Regulation

Slide 1

In this module, you will learn:

- The requirements of the regulation
- How to reference the specific requirements



Copies of the Official Published Regulation 21 CFR Part 123 Seafood HACCP Regulation

- SHA Training Manual
- Appendix 1 (p. 205)



- FDA Guide
- Appendix 8



Stay aware for periodic additions



Regulation Outlined in Parts

Slide 2

Regulation Format

Subpart A — General provisions

- 123.3 Definitions
- 123.5 Current GMPs
- 123.6 HACCP plan
- 123.7 Corrective actions
- 123.8 Verification
- 123.9 Records
- 123.10 Training
- 123.11 Sanitation control procedures
- 123.12 Special requirements for imported products

Subpart B — Smoked and smoke-flavored fishery products

- 123.15 General.
- 123.16 Process controls

Subpart C — Raw molluscan shellfish

- 123.20 General
- 123.28 Source controls



Key Definitions in the Regulation

Slide 3

- certification number
- critical control point
- critical limit
- fish
- fishery product
- hazard
- importer
- molluscan shellfish
- preventive measure instrument
- processing
- processor

- scombroid toxin-forming species
- shall
- shellfish-control authority
- shellstock
- should
- shucked shellfish
- smoked or smokeflavored fishery
- process-monitoring products
- tag



Key Definitions in the Regulation

Slide 4

Regulatory terms "shall" and "should"

Slide 5

Products that are subject to the regulation:

- Fish
- Fishery Product



Who must comply?

Slide 6

Who must comply with the regulation:

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



Define Processing

Slide 7

What constitutes processing:

• Processing 123.3 (l)



Regulation does not apply to:

Slide 8

This regulation does not apply to:

- The harvest or transport of fish or fishery products
- Practices such as heading, eviscerating or freezing intended solely to prepare a fish for holding on a harvest vessel
- The operation of a retail establishment



Foundation for the Regulation

Slide 9

Current Good Manufacturing Practices:

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



Current Good Manufacturing Practices

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

FDA source Dec. 2016: (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/

Copy of the current GMP's Part 117

Appendix 3, Page 235



Determine hazards likely to occur...

Slide 10

Hazard Analysis 123.6(a)

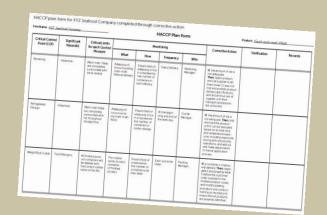
Every processor shall conduct, or have conducted for it, a hazard analysis.

Slide 11

Determining those hazards that are "reasonably likely to occur:" Those "for which a prudent processor would establish controls."



Written HACCP plans ...



Slide 12

HACCP Plan 123.6(b)

Every processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food-safety hazards that are reasonably likely to occur.

The plan shall be specific to:

- · Each processing location.
- Each species of fish and type of fishery product.



HACCP plans 'shall' contain ...

Slide 13

The HACCP plan shall list:

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



HACCP plans 'shall' be signed and dated ...

Slide 14

The HACCP plan shall be signed and dated:

- By the most responsible individual at the processing facility or a higher level official.
 - Signed and dated:
 - Upon initial acceptance.
 - Outpoin Upon any modification.*
 - At least annually.*

*This is a verification requirement.



Slide 15

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

Special considerations for seafood canning operations ...



Sanitation or HACCP Controls?

Slide 16

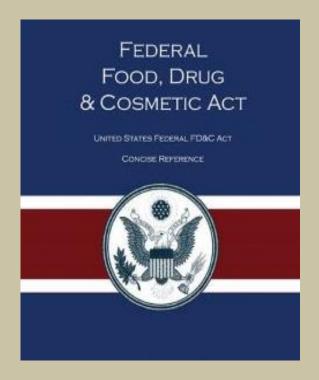
Sanitation controls may be difficult to manage in a HACCP plan.





Slide 17

It is unlawful to process food under conditions that may render it injurious to health.





Processors 'shall' take 'corrective actions'

Slide 18

Corrective Action 123.7

Whenever a deviation from a critical limit occurs, a processor shall take corrective action.

Slide 19

Corrective Actions — Two Choices:

- 1) Predetermined
- 2) Alternate Procedure outlined in the regulation
 - Segregate and hold product
 - Determine product acceptability
 - Apply corrective action to product and process
 - Reassess the HACCP plan



Verifications are required ...

Slide 20

Every processor shall verify:

- That the HACCP plan is adequate to control the food-safety hazards that are reasonably likely to occur; and
- That the HACCP plan is implemented effectively.

Slide 21

Ongoing verification:

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



Required records ...

Slide 22

Records required by the regulation:

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





Information required on each record ...

Slide 23

Required information on each record:

- Name and location of the processor or importer
- Date and time of the activity being recorded
- Signature or initials of the person making the record
- Identity of the product and the production code where appropriate





Record Reviews and Retention ...

Slide 24

Review of records:

- CCP monitoring and corrective action records within one week
- Calibration and in-process or end-product testing records timely manner

Slide 25

Record retention:

- One year for refrigerated products
- Two years for frozen or preserved products



HACCP training to ...

Slide 26

The HACCP-trained individual shall:

- Develop the HACCP plan.
- Reassess and modify the HACCP plan and hazard analysis.
- · Review HACCP records.



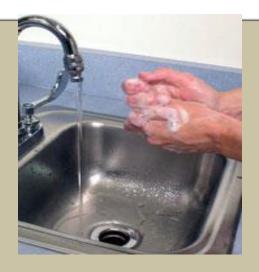
Trained



SCP's – Sanitation Control Procedures

Slide 27

- Processors should have written SCPs.
- Processor shall monitor and document sanitation control procedures.
- Processors shall correct sanitation deficiencies in a timely manner.







8 Key Sanitation Control Areas

Slide 28

Eight key sanitation areas:

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



HACCP with Imported Seafood

Slide 29

Importer Verification:

- Import from countries with a memorandum of understanding (MOU) or
- Implement verification procedures.

Slide 30

Importer Verification Procedures Importers must have:

- 1) Written verification procedures
- 2) Product specifications
- 3) Affirmative steps



HACCP with Imported Seafood

Slide 31

Affirmative steps may include any of the following:

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



HACCP with Smoked Seafood

Slide 32

Smoked and Smoke-Flavored Fishery Products

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



HACCP with Raw Molluscan Shellfish

Slide 33

Raw Molluscan Shellfish 123.20

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



HACCP with Raw Molluscan Shellfish

Slide 34

Raw Molluscan Shellfish 123.28

Processors shall only process molluscan shellfish from:

- Growing waters approved by a shellfish-control authority
- Federal growing waters not closed by an agency of the federal government

Slide 35

Raw Molluscan Shellfish 123.28 Shellstock Receiving:

- If source is a harvester, harvester must be in compliance with any license requirement.
- If source is another processor, processor must be certified by a shellfish-control authority.
- Containers of shellstock must be properly tagged.



Slide 36

Raw Molluscan Shellfish 1240.60 (b)

Required information on tag:

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

Slide 37

Raw Molluscan Shellfish 123.28 Records for shellstock receiving must document:

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





Slide 38

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

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

Slide 39

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

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





Resources for Preparing Seafood HACCP Plans

Recommended websites:

- FDA Seafood HACCP Regulations
- AFDO Seafood HACCP Alliance (Association of Food and Drug Officials)
- Numerous State based Sea Grant Programs via Seafood Safety and HACCP
- USDC/National Marine Fisheries Services via Seafood HACCP
- USDA Catfish HACCP

