

SEAFOOD HACCP

21 CFR 123

An Overview

Risk management  
done by the  
manufacturer

# ACKNOWLEDGEMENT

**Many of the slides (all the blue boxes) came from the Seafood Alliance HACCP Training Curriculum Manual, 4<sup>th</sup> Edition, November 2001.**

# HACCP - Hazard Analysis and Critical Control Point

It was developed by NASA around 1959 for the first manned space flights.

1. Food particles and water droplets in a zero gravity environment.
2. “[A]bsolute assurance of freedom from pathogens and biological toxins.”

***Can you imagine a case of “Staph Aureus” food poisoning in a zero gravity space capsule?***

**In the Late 90's US FDA adapted it to *fish and fishery products*.**

**FISH** - Fresh or saltwater finfish, crustaceans, and other forms of aquatic animal life (including but not limited to alligator, frog, aquatic turtle, jelly fish, sea cucumber, sea urchin and the roe of such animals) other than birds or mammals, and all mollusks, where such animal life is intended for human consumption.

**In the Late 90's US FDA adapted it  
to *fish and fishery products*.**

**FISHERY PRODUCTS** - Any human food product in which fish is a characterizing ingredient.

# PREQUISITES

- Good GMPS
- Standard Sanitary Operating Procedures
- A clearly defined product, storage, distribution, use and target consumer.
- A production flow chart and clearly defined manufacturing process.

**Hazard Analysis**

**Critical Control Points**

**Critical Limits**

**Critical Control Point Monitoring**

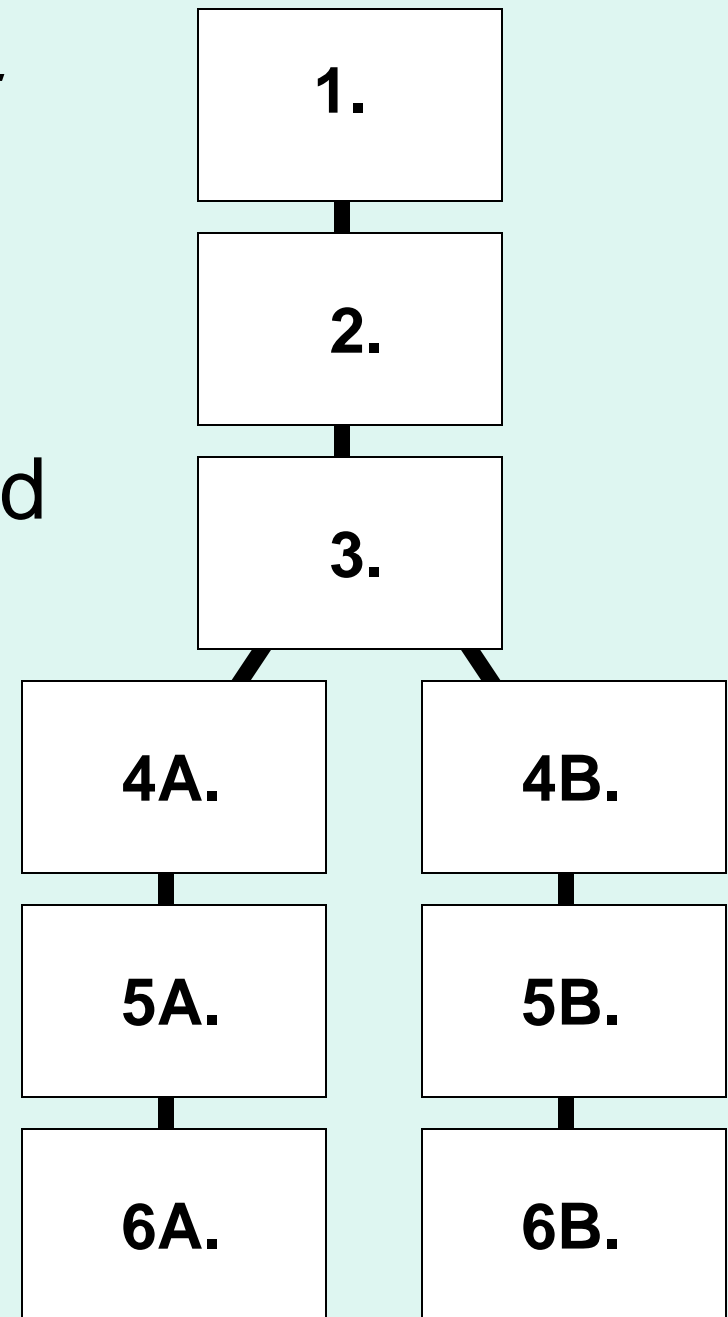
**Corrective Actions**

**Verification Procedures**

**Record Keeping**

# FLOW CHART

- Create a flow chart of the process.
- Each segment (box) should represent a step in the process
- The flow chart should go from receiving inputs (ingredients, packages, etc...) to shipping the finished product.



# **Hazard Analysis**

# Hazard Analysis

## **Definition:**

*Hazard:* a biological, chemical or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

Reasonably likely to ***cause illness or injury*** in the absence of its control....

***Remember: It's all about safety, HACCP doesn't get involved with issues that only effect product quality.***

# Hazard Analysis

Every processor must have a hazard analysis done.

You are looking for food safety hazards that are *reasonably likely to occur* and cause *unacceptable health risk to the consumer (severity)*.

# **Hazard Analysis**

Must consider factors beyond the immediate control of the processor.

Must think about things that can occur before you get the food(s) and things that can happen after you distribute it.

# Hazard Analysis

Create a flow chart of your process and identify every step in the process on the flow diagram. At each step:

1. Identify ***any possible hazard*** (Should not be limited to likelihood or severity).
2. After, evaluate each possible hazard to determine its ***likelihood of occurrence*** and whether it poses an ***unreasonable health risk to the consumer (severity)***.

# Hazard Analysis

Once you have determined something is a hazard, determine how it is controlled (mechanism of control).

Once you have determined how it is controlled, determine at what step in the process you can apply the control (critical control point).

**Hazard Analysis**

**Critical Control Points**

# Critical Control Points

For every hazard you identified, you must now establish/identify one or more, *critical control points*.

## **Definition:**

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

# Critical Control Points

Three general types of critical control points:

1. ***Prevent*** the occurrence/introduction of the risk.
2. ***Eliminate*** an existing risk.
3. ***Reduce*** an existing risk to a reasonable level.

# Critical Control Points

Examples of CCP's that Prevent the Hazard:

**Points may be identified as CCPs when hazards can be prevented.**

In some products and processes, the following may be true:

- Introduction of pathogens or drug residue can be prevented by control at the receiving step (e.g., supplier declaration).
- A chemical hazard can be prevented by control at the formulation or ingredient-addition step.
- Pathogen growth in the finished product can be prevented by control at the formulation or ingredient-addition step (e.g., pH adjustment or addition of preservatives).
- Pathogen growth can be controlled by refrigerated storage or chilling.

# Critical Control Points

Examples of CCP's that Eliminate the Hazard:

**Points may be identified as CCPs when hazards can be eliminated.**

In some products and processes, the following may be true:

- Pathogens can be killed during cooking.
- Metal fragments can be detected by a metal detector and eliminated by removing the contaminated product from the processing line.
- Parasites can be killed by freezing (e.g., *Anisakis* in fish destined for raw consumption).

# Critical Control Points

Examples of CCP's that Reduce the Hazard to an Acceptable Level:

**Points may be identified as CCPs when hazards are reduced to acceptable levels.**

In some products and processes, the following may be true:

- The occurrence of foreign objects can be minimized by manual sorting and automatic collectors.
- Some biological and chemical hazards can be minimized by obtaining shellfish from approved waters.

**Hazard Analysis**

**Critical Control Points**

**Critical Limits**

# Critical Limits

## 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 to an acceptable level the occurrence of a food-safety hazard.

For each ***critical control point***, you must establish a ***critical limit*** to control the ***hazard*** that has been identified.

# Critical Limits

In many cases, the appropriate critical limit is not readily apparent or easy to determine.

Tests may need to be conducted, or information obtained from scientific publications, ***regulatory guidelines***, ***experts***, trade organizations, experimental studies, etc....

# Critical Limits

General Source	Examples
scientific publications	journal articles, food science texts, microbiology texts
regulatory guidelines	state and local guidelines, tolerances and action levels; USDA guidelines, tolerances and action levels; FDA guidelines, tolerances and action levels
FDA	FDA Fish and Fisheries Products Hazards and Controls Guidance Manual (referenced in Chapter 13)
experts	NACMCF (National Advisory Committee on Microbiological Criteria for Foods), thermal process authorities; consultants, food scientists/microbiologists, equipment manufacturers, sanitarians, university extension, trade associations
experimental studies	in-house experiments; contract labs

# Critical Limits

Operating  
Limits...

**Hazard Analysis**

**Critical Control Points**

**Critical Limits**

**Critical Control Point Monitoring**

# Critical Control Point Monitoring

*Critical control points* must be *monitored* to assure that *critical limits* are adhered to and so that a record of manufacturing can be generated.

## **Definition:**

*Monitor:* to conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.

# Critical Control Point Monitoring

## MONITORING

### Purpose of Monitoring:

- To track the operation of the process and enable the identification of trends toward a critical limit that may trigger process adjustments,
- To identify when there is loss of control (a deviation occurs at a CCP).
- To provide written documentation of the process control system.

# **Critical Control Point Monitoring**

***What?***

***How?***

***When?***

***Who?***

# Critical Control Point Monitoring

## MONITORING

- **What:** usually a measurement or observation to assess if the CCP is operating within the critical limit.
- **How:** usually physical or chemical measurements (for quantitative critical limits) or observations (for qualitative critical limits).  
Needs to be real-time and accurate.
- **When (frequency):** can be continuous or intermittent.
- **Who:** someone trained to perform the specific monitoring activity.

**Hazard Analysis**

**Critical Control Points**

**Critical Limits**

**Critical Control Point Monitoring**

**Corrective Actions**

# Corrective Actions

Corrective actions must be taken when critical limits at a critical control point have been exceeded or not met.

When possible, these actions should be predetermined when developing the HACCP plan.

# Corrective Actions

These corrective actions should state

1. Procedures to restore process control and,
2. Determine the safe disposition of the affected product.

It may be possible, and is always desirable, to correct the problem on the spot.

# Corrective Actions

Effective corrective action plans must:

- Correct and eliminate the cause of the noncompliance to assure that the CCP is brought back under control.
- Segregate, assess and determine the disposition of the noncompliant product.
- **AND Address the systemic failure that caused the deviation to prevent its recurrence in the future (prevention).**

# Corrective Actions

Must be documented:

To identify recurring problems so that the HACCP plan can be modified.

Provide proof of the product disposition.

# Corrective Actions

## Corrective Action Components:

- To correct and eliminate the cause of the deviation and restore process control.
- To identify the product that was produced during the process deviation and determine its disposition.

# Corrective Actions

## Four Steps:

- A. Step One: Determine if the product presents a safety hazard:
  - a. Based on expert evaluation.
  - b. Based on physical, chemical or microbiological testing.
- B. Step Two: If no hazard exists based on the evaluations in Step 1, the product may be released.
- C. Step Three: If a potential hazard exists (based on the evaluations in Step 1), determine if the product can be:
  - a. Reworked/reprocessed.
  - b. Diverted for a safe use.
- D. Step Four: If potentially hazardous product cannot be handled as described in Step 3, the product must be destroyed. This is usually the most expensive option and is usually regarded as the last resort.

**Hazard Analysis**

**Critical Control Points**

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**Corrective Actions**

**Verification Procedures**

# VERIFICATION PROCEDURES

## **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.

***“trust what you  
verify”***

# VERIFICATION PROCEDURES

The purpose of verification is:

1. To provide a level of confidence that the plan is based on solid scientific principles,
2. Is adequate to control the hazards associated with the product and process and
3. Is is being followed.

# **VERIFICATION PROCEDURES**

The must be verification procedures for:

1. Individual Critical Control Points and,
2. For the overall plan.

# VERIFICATION PROCEDURES

## Elements of Verification:

- Validation
- CCP verification activities
  - Calibration of monitoring devices
  - Calibration record review
  - Targeted sampling and testing
  - CCP record review
- HACCP system verification
  - Observations and reviews
  - Microbiological end-product testing
- Regulatory agencies

# VERIFICATION PROCEDURES

## **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.

**Validation of the plan occurs before the plan is actually implemented. The purpose of validation is to provide objective evidence that all essential elements of the plan have a scientific basis and represent a “valid” approach to controlling the food-safety hazards associated with the specific product and process.**

# VERIFICATION PROCEDURES

There are several approaches to validating the HACCP plan, among them are:

1. Incorporation of fundamental scientific principles,
2. Use of scientific data,
3. Reliance on expert opinion or
4. Conducting in-plant observations or tests.

# VERIFICATION PROCEDURES

## **Validation of the HACCP plan, who does it?**

- HACCP team
- Individual qualified by training or experience

## **What does validation involve?**

- A scientific and technical review of the rationale behind each part of the HACCP plan from hazard analysis through each CCP verification strategy.

# **VERIFICATION PROCEDURES**

Validation involves a scientific and technical review of the rationale behind each part of the HACCP plan from hazard analysis through each CCP verification strategy.

# VERIFICATION PROCEDURES

## Validation Frequency:

- Initially
- When factors warrant. The following may warrant validation of the plan:
  - changes in raw materials,
  - changes in product or process,
  - adverse review findings,
  - recurring deviations,
  - new information on hazards or control measures,
  - on-line observations, and
  - new distribution or consumer handling practices.

# VERIFICATION PROCEDURES

## **CCP Verification Activities:**

- Calibration
- Calibration record review
- Targeted sampling and testing
- CCP record review

Verification activities developed for CCPs are essential to ensure that the control procedures used are properly functioning and that they are operating and calibrated within appropriate ranges for food-safety control. Additionally, CCP verification includes supervisory review of CCP calibration, monitoring and corrective action records to confirm compliance with the HACCP plan. CCP verification may also include targeted sampling and testing.

# VERIFICATION PROCEDURES

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CCP verification may also include targeted sampling and testing.

# VERIFICATION PROCEDURES

In addition to the verification activities for CCPs, strategies should be developed for scheduled verification of the complete HACCP system.

## **HACCP System Verification Frequency:**

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

# VERIFICATION PROCEDURES

## **Verification Activities of the HACCP System:**

- Check the accuracy of the product description and flow chart.
- Check that CCPs are monitored as required by the HACCP plan.
- Check that processes are operating within established critical limits.
- Check that records are completed accurately and at the time intervals required.

**End product microbiological testing is also commonly used.**

# VERIFICATION PROCEDURES

## REGULATORY AGENCY FUNCTION

### **Verification procedures by an agency include:**

- Review of the HACCP plan and any modification.
- Review of CCP monitoring records.
- Review of corrective action records.
- Review of the verification records.
- Visual inspections of operations to determine if the HACCP plan is followed and records are properly maintained.
- Random sample collection and analysis.

**Hazard Analysis**

**Critical Control Points**

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**Record Keeping**

# RECORD KEEPING

**Four kinds of categories are kept as part of the HACCP system.**

1. HACCP plan and support documentation used in developing the plan
2. Records of CCP monitoring
3. Records of corrective action
4. Records of verification activities

# RECORD KEEPING

**All HACCP monitoring records should be on forms that contain the following information:**

- Form title,
- Firm name and location,
- Time and date,
- Product identification (including product type, package size, processing line and product code, where applicable),
- Actual observation or measurement,
- Critical limits,
- Operator's signature or initials,
- Reviewer's signature or initials, and
- Date of review.

# **RECORD KEEPING**

## **Record Review**

Monitoring records for CCPs and critical-limit deviations must be reviewed in a timely manner by a representative of plant management. All records should be signed or initialed and dated by the reviewer.

