

Training Modules on Food Safety Practices for Aquaculture

# Food Safety Practices for Aquaculture

# Introduction

This module is part of a training program on Food Safety Practices for the Aquaculture Industry.

This program was developed through a partnership facilitated by the Partnership Training Institute Network (PTIN) of the Food Safety Cooperation Forum (FSCF) of the Asia Pacific Economic Cooperation (APEC) Forum. The educational content was designed by faculty at Michigan State University. Funding for this effort was provided by The World Bank Group.

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# Food Safety Management Systems / HACCP

## Module Overview

Implementing an effective food safety management system is critical to the production of safe food. Management systems based on Hazard Analysis and Critical Control Points (HACCP) are the international standard as recognized by the Codex Alimentarius Commission. HACCP systems build upon effectively designed and implemented prerequisite food safety programs, and focus on three key concepts: 1) identifying significant food safety hazards, 2) controlling these significant hazards, and 3) documenting the system.

This learning module focuses on requirements for implementing HACCP systems as described in the Codex Alimentarius General Principles of Food Hygiene. The following topics will be discussed:

- Introduction to HACCP
- Preliminary Steps
- Principle 1 – Conduct a Hazard Analysis
- Principle 2 – Identify Critical Control Points
- Principle 3 – Determine Critical Limits
- Principle 4 – Determine Monitoring Procedures
- Principle 5 – Determine Corrective Actions
- Principle 6 – Determine Verification Procedures
- Principle 7 – Record-Keeping Procedures

## Definition of HACCP

**Hazard Analysis and Critical Control Points (HACCP)** is “a systematic approach to the identification, evaluation, and control of food safety hazards.” Proper implementation of HACCP systems provides the framework to produce foods safely and to prove they were produced safely.

HACCP systems:

- specifically focus on food safety, not all attributes constituting food quality,
- are applicable to all phases of food production,
- focus on prevention and control of potential food safety hazards rather than inspection, and
- emphasize the use of science and technology to ensure the production of safe food.



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## Prerequisite Programs and HACCP

Before a HACCP system can be implemented, the company must be operating in accordance with good hygiene and good manufacturing practices. These prerequisite programs (PRPs), which are discussed elsewhere in this curriculum, provide the strong foundation which is necessary to ensure the food facility is capable of producing safe food. These PRPs must be in place before effective HACCP programs can be implemented.

The importance of effective PRPs cannot be overstated, as they are the foundation of the HACCP plan. Inadequate PRPs may lead to additional critical control points that would have to be identified, monitored and maintained under the HACCP plan.



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## Prerequisite Programs and HACCP

The following are examples of common prerequisite programs :

- Building and equipment design, fabrication and maintenance
- Production line design and product flow
- Cleaning and disinfection programs
- Equipment calibration
- Management commitment
- Supplier approval
- Product Specifications
- Water quality
- Staff hygiene practices
- Staff training
- Staff health
- Pest control
- Waste control
- Storage and Distribution
- Product recall



Photo: Serfling US FDA

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# HACCP Plans

As stated previously, HACCP is “a systematic approach to the identification, evaluation, and control of food safety hazards.”

Key to the effective implementation is the written HACCP Plan, which is a document prepared in accordance with the principles of HACCP to ensure control of hazards that are significant for food safety in the segment of the food chain under consideration.

It is important to note that HACCP plans are specific to a food product and process. The plan is written by the HACCP team at the firm based upon the specific conditions in that facility. Any changes in product characteristics or processing steps will likely necessitate re-evaluation of the written HACCP plan.

The written HACCP plans at two facilities that are producing the same food product are likely to be different due to a variety of reasons including differences in types of equipment used, management of prerequisite programs, and other factors.

The diagram shows a HACCP Plan Form with the following structure:

HACCP PLAN FORM									
(1)	(2)	(3)	(4) MONITORING				(5)	(6)	(7)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARDS	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING			CORRECTIVE ACTIONS	RECORDS	VERIFICATION	
			WHAT	HOW	FREQUENCY				

Below the table, there are fields for 'SIGNATURE OF COMPANY OFFICIAL' and 'DATE'. The form is labeled 'FIGURE 3-1' and 'APPENDIX 3-1 FORM 1'.

Photo: 4<sup>th</sup> Edition FDA Hazards Guide



# HACCP – Getting Started

Design and implementation of effective HACCP systems requires systematic planning and execution. The preliminary steps necessary before implementing a HACCP plan include the following:

1. Assemble the HACCP Team
2. Describe the Food and its Distribution
3. Describe the Intended Use and Consumers of the Food
4. Develop a Flow Diagram Which Describes the Process
5. Verify the Flow Diagram

These steps must be completed prior to beginning work on HACCP Principle 1. Preliminary steps will be discussed in the following section.



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# 1. Assemble the HACCP Team

The HACCP team is the group of people who are responsible for developing, implementing and maintaining the HACCP system. Some considerations when identifying the HACCP Team include the following.

- The team should be multidisciplinary and its size proportionate to the size of the business.
- Team members should have skills and expertise in a wide variety of technical disciplines relative to the products covered by the HACCP system.
- HACCP expertise is not essential for all team members.
- Records must be maintained that demonstrate that the HACCP team has the required knowledge and experience to develop the food safety system.

One person should be designated as the HACCP Team Leader. Working with the rest of the team, this person has overall responsibility for the development, organization, and management of the HACCP program.



Image: Public Domain

## 2. Describe the Food and Its Distribution

The HACCP team first describes the food. This consists of a general description of the food, ingredients, and processing methods, packaging materials, etc. used in the formulation and preparation of the product. This description will assist the team in the identification of all possible hazards associated with the product.

In brief, the product description should include the name of the product, ingredients and composition, potential to support microbial growth (e.g. water activity, pH, etc.), brief details of the process and technology used in production, and description of the packaging used for the finished products.

The method of distribution of the finished product should be described along with information on whether the food is to be distributed frozen, refrigerated, or at ambient temperature.

The product description must be recorded for referral by the HACCP team during subsequent steps in HACCP system design and implementation.



Photo: Serfling US FDA

## 2. Describe the Food and Its Distribution

There are many factors to consider when developing your product description. The following are of examples of factors the HACCP team may need to consider as it gathers information about the product and process used in the facility.

- Suppliers
- Ingredient specifications
- Batches of ingredients
- Formulation
- Product specifications
- Facility and layout
- Types of equipment
- Equipment design
- Preparation procedures
- Processing parameters
- Employee practices
- Packaging materials
- Storage and warehousing
- Distribution
- Retail handling and display
- Product shelf-life
- Label instructions
- Operating conditions

## 2. Describe the Food and Its Distribution

When describing the product characteristics, you must describe 1) all raw materials, ingredients and product-contact materials, and 2) the characteristics of end products. These descriptions must be documented in detail sufficient to conduct the hazard analysis (HACCP Principle 1). The following are examples of considerations for each of these categories.

### Raw Materials, Ingredients and Product-Contact Materials

- Biological, chemical and physical characteristics
- Ingredient composition, including additives
- Origin
- Method of production
- Packaging and delivery methods
- Storage conditions and shelf life
- Preparation and/or handling before use or processing
- Food safety-related acceptance criteria or specifications of purchased materials and ingredients

### Characteristics of End Products

- Product name or similar identification
- Composition
- Biological, chemical and physical characteristics relevant for food safety
- Intended shelf life and storage conditions
- Packaging
- Labeling relating to food safety and/or instructions for handling, preparation and usage
- Methods of distribution

### 3. Describe the Intended Use and Consumers of the Food

The third preliminary step is to describe the normal expected use of the product and the intended consumers. Intended use of the product refers to its normal use by end-users or consumers. The intended consumers may be the general public or a particular segment of the population (e.g., infants, the elderly, pregnant women, immune-suppressed individuals, etc.). The following is a list of questions the HACCP team should consider at this stage.

1. What is the intended use of the product? (e.g. retail, food service, further processing)
2. What is the potential for mishandling?
3. What handling and preparation procedures are required of the end users? (e.g. Is the product ready-to-eat, or does it require further preparation such as reheating, cooking, etc.)
4. Who are the intended consumers of the product?
5. Is the product intended for use by immune compromised individuals or other susceptible groups?

Consideration of these questions provides valuable information for the HACCP team as they proceed to the hazard analysis (HACCP Principle 1).



## 4. Develop a Flow Diagram Which Describes the Process

The next preliminary step is to develop a flow diagram for the products or process categories covered by the food safety management system. The purpose of a flow diagram is to provide a clear, simple outline of the steps involved in the process. The scope of the flow diagram must cover all the steps in the process which are directly under the control of the establishment. The flow diagram need not be as complex as engineering drawings. A block type flow diagram is sufficiently descriptive. It must be clear, accurate and sufficiently detailed.

The flow diagram provides a basis for the HACCP team to evaluate the possible occurrence, increase or introduction of food safety hazards in the product and process.



Illustration: Leslie Bourquin



## 4. Develop a Flow Diagram Which Describes the Process

The process flow diagram will identify the important process steps (from receiving to final shipping) used in the production of the specific product being assessed. Each process step should be considered in detail and the information expanded to include all relevant process data. Data may include but is not restricted to:

- All ingredients and packaging used (biological, chemical, physical data).
- Where raw materials, ingredients and intermediate products enter the flow.
- The sequence and interaction of all steps in the operation.
- Time/temperature history of all raw materials and intermediate and final products, including the potential for delay.
- Where product reworking and recycling take place in the process.
- Equipment design features.
- Any outsourced processes and subcontracted work
- Where end products, intermediate products, by-products and waste are released or removed.

## 5. Verify the Flow Diagram

Once the process flow diagram has been drafted, it must be confirmed by the HACCP team during an on-site inspection for accuracy and completeness. This will ensure that all the major process operations have been identified. It will also confirm the assumptions made with respect to the movement of product and employees on the premises.

During this on-site inspection of the facility, equipment and operations, the HACCP team should :

- check the accuracy and completeness of the flow diagram,
- identify any deficiencies, and
- correct the document.

The complete, verified flow diagram shall be maintained as a HACCP record.

It is important to note that HACCP plans are dynamic and must be updated to reflect any changes in process or food safety considerations. Therefore, any significant changes to the process must be accurately reflected in the product flow diagram.



Photo: Public Domain

# The Seven HACCP Principles

Following the effective completion of the HACCP preliminary steps, the team is ready to begin the process of writing the HACCP Plan. Writing the plan is a seven-step process which must occur in the following sequence.

1. Conduct a hazard analysis
2. Determine the CCPs
3. Establish critical limits
4. Establish monitoring procedures
5. Establish corrective actions
6. Establish verification procedures
7. Establish record keeping and documentation

In the following sections of this module, we will cover the basic concepts of each of these HACCP principles in sequence.



Photo: Chris&Rhiannon / Flickr

# HACCP Principle 1

## HACCP Principle 1 states:

- Conduct a hazard analysis. Prepare a list of steps in the process where significant hazards occur and describe control measures.

Hazard analysis is the process used by the HACCP team to determine which potential hazards present a significant health risk to consumers.

The purpose of the hazard analysis is to develop a list of hazards which are of such significance that they are reasonably likely to cause injury or illness **if not effectively controlled**. Only those hazards that pose **significant** risk to the health of consumers should be included in the HACCP plan.

It is important to consider in the hazard analysis the ingredients and raw materials, each step in the process, product storage and distribution, and final preparation and use by the consumer.

When conducting a hazard analysis, safety concerns must be differentiated from quality concerns. HACCP applies to food safety only, not food quality.

# Hazard Analysis Process

The process of conducting a hazard analysis involves two stages. These are:

## 1. Hazard Identification and Determination of Acceptable Levels

- First, the HACCP team develops a list of potential hazards that may be associated with a food.
- Following the identification of hazards, the team then determines the acceptable level for each identified food safety hazard.

## 2. Hazard Evaluation

- The HACCP team evaluates each identified hazard based on its **likelihood of occurrence** in that particular food product and the **severity of effects** of the specific hazard.
- Using this information, as well as information on acceptable levels for identified hazards, the HACCP team identifies which of the potential hazards pose a **significant risk** to the consumer.

## Hazard Identification

This is essentially a “brainstorming” exercise wherein the team generates a list of potential biological, chemical, and physical hazards that may be introduced, increased, or controlled at each step described on the product flow diagram.

The process of hazard identification should consider the following items.

- The preliminary information collected while developing the product description.
- Experience. For example, the establishment probably has considerable information on the likelihood of hazards being present in finished products based on results of product testing or information from consumer complaints.
- External information including, when possible, epidemiological and other historical data.
- Information from the food chain on food safety hazards that may be of relevance for the safety of the end products, intermediate products, and the food at consumption.

Appendix C in the document “Hazard Analysis and Critical Control Point Principles and Application Guidelines” which was published in 1997 by the U.S. National Advisory Committee On Microbiological Criteria For Foods (NACMCF) contains a thorough set of questions the HACCP team should consider when conducting hazard identification. This document is available at:

<http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/HACCPPrinciplesApplicationGuidelines/default.htm>



## Determination of Acceptable Levels

After conducting the “brainstorming” exercise to identify which food safety hazards may be associated with the product and process, the HACCP team must then determine the acceptable levels of each of these hazards. This determination typically can be completed by consideration of the following factors:

- Regulatory requirements
- Customer requirements
- Intended use by the customer
- Other relevant data

For those products that will be exported to other countries, it is vitally important that the HACCP team be cognizant of regulatory and customer requirements in the destination countries.

The HACCP team should record the result of these determinations and their justifications, and maintain these with other HACCP records.



Photo: Public Domain



## Hazard Evaluation

Following identification of hazards and determination of acceptable levels, the next step in the hazard analysis is to determine which hazards are sufficiently significant that they must be addressed by the HACCP plan.

The HACCP team decides which of the potential hazards listed during hazard identification stage present a **significant risk** to consumers.

Each potential hazard should be evaluated based on two factors:

1. **Severity** of the potential illness or injury
2. **Likelihood of occurrence**

We will consider each of these factors in sequence.



Photo: Serfling US FDA

## Evaluating Severity

Evaluation of the severity of a food safety hazard requires consideration of various factors, including:

- the magnitude and duration of the illness or injury,
- the possible impact of secondary problems (chronic sequelae), and
- the susceptibility of intended customers to foodborne illness (e.g. children versus adults).

The illnesses or injuries caused by foodborne hazards differ considerably in their magnitude and duration. For example, some foodborne pathogens can be deadly either due to the infection itself (e.g. *Listeria monocytogenes*), due to the actions of toxins formed by the pathogens after their consumption and outgrowth in the gastrointestinal tract (e.g. *E. coli* O157:H7), or due to the actions of toxins formed prior to ingestion of the food (e.g. *Clostridium botulinum*). Depending upon the hazard and its concentration, chemical hazards may cause acute intoxications or may only represent a hazard through chronic ingestion. Physical hazards commonly are associated with relatively minor injuries to the teeth and oral cavity, although some may represent choking hazards.

Some foodborne hazards have long-term adverse consequences, which are referred to as sequelae. For example, *Campylobacter jejuni* infection is associated with increased incidence of Guillain-Barré syndrome, a chronic inflammatory neuropathy. Several pathogenic bacteria, such as pathogenic *E. coli* and *Salmonella* spp., are known to initiate reactive arthritis.

We already have discussed the increased susceptibility of certain sensitive populations. It is also important to note that children typically consume greater quantities of food on a relative basis, so their exposure to foodborne hazards can be greater than that of adults.

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## Estimating Likelihood of Occurrence

The other factor the HACCP team must evaluate is the likelihood of occurrence of the foodborne hazard. Assessment of this factor can be complex and requires consideration of several factors, including the following.

1. Experience – The HACCP team should have considerable experience with the products the firm produces and the likelihood of occurrence of specific food safety hazards in these products.
2. Data from past foodborne illness outbreaks – Past outbreaks are tremendous learning opportunities, and the HACCP team must take into account lessons learned from these prior events.
3. Information in the scientific literature – Peer-reviewed scientific journals and other sources of technical literature contain a wealth of information on foodborne hazards, their occurrence, potential amplification in foods (in the case of biological hazards) and their control.
4. Historical information gathered by the establishment – The establishment likely has considerable information on the likelihood of occurrence of hazards in their food products. This information can be gleaned from previous laboratory tests on finished products, ingredients, or in-process materials. Consumer complaint records can be an outstanding source of information on physical hazards.

## Factors Influencing Likelihood of Occurrence

The HACCP team also should consider various other factors which can influence the likelihood of occurrence of food safety hazards. These factors include:

- Effectiveness of prerequisite programs
- Frequency of association of the potential hazard with the food or ingredient
- Method of preparation
- Conditions during transportation
- Expected storage conditions
- Likely preparation steps before consumption

Hazards identified in one operation or facility may not be significant in another operation producing the same or a similar product. For example, due to differences in equipment and/or an effective maintenance program, the probability of metal contamination may be significant in one facility but not in another.



Photo: Serfling US FDA

## Control Measures

Hazards that represent a significant risk based upon an assessment of their severity and likelihood of occurrence must be addressed in the HACCP plan.

Control Measures are “any action or activity that can be used to prevent or eliminate a food safety hazard, or reduce it to an acceptable level.”

In older HACCP documents, control measures are often termed “preventive measures.” The term control measure is now used in recognition of the fact that not all hazards can be prevented, but virtually all can be controlled.

For each significant hazard identified by the HACCP team, control measures must be described that will prevent, eliminate, or reduce the hazard to an acceptable level. As noted previously, significant hazards may be different for the same product produced at different facilities.



Photo: <http://www.vatpasteurizer.com>



## Control Measures

On the right is a partial list of possible control measures. These are provided as examples of the wide variety of methods which can be used to control the different hazards which may be present in foods.

For microbiological hazards, common control measures include those which either directly kill the microorganism (e.g. different types of thermal processing, irradiation) or prevent its germination and/or growth (e.g. acidification, fermentation, refrigeration, freezing, drying).

Control measures for chemical hazards include a variety of approaches such as testing and rejection of ingredients which contain excess concentrations of natural or artificial chemical hazards, following proper formulation procedures, correct application of GMPs in the facility, monitoring for allergens, and end product testing.

Likewise, physical hazards can be controlled by methods such as using equipment for straining or aspirating, mechanical separation, metal detection, or use of x-ray or other detection equipment.

- Cooking
- Pasteurization
- Thermal processing
- Irradiation
- Acidification
- Fermentation
- Disinfection
- Refrigeration
- Freezing
- Drying
- Filtering
- Metal detectors
- X-ray devices

## Summarize the Hazard Analysis

At the completion of the hazard analysis, the HACCP team must prepare a written summary of the hazard analysis. This summary must :

- Identify potential hazards for each step in the process flow diagram.
- Determine significance of identified hazards, and justify this decision.
- Identify control measures that can be applied at each step to control the identified hazards.

This written summary of the hazard analysis is an important record which must be retained. An example of a format for this written report is provided on the next page. Note that this example includes a column for identification of Critical Control Points. This concept will be addressed in the next section.



Photo: Public Domain



## Final Considerations

Remember that the hazard analysis, and subsequent HACCP plan, is specific to a product and process. However, it is reasonable to use a common hazard analysis for classes of products that are similar in formulation, have similar processing steps, and are otherwise prepared and packaged in a similar manner.

The hazard analysis and HACCP plan will likely be different for the same product produced in different facilities. The HACCP team must take into account the unique characteristics, equipment and procedures used at their establishment when preparing the HACCP plan specific for their firm. However, it is perfectly reasonable for the HACCP team to refer to generic HACCP models to help guide their deliberations. Excellent sources of generic HACCP plans are available at the following web sites:

<http://seafood.ucdavis.edu/haccp/plans.htm>

Generic HACCP models from many other reputable sources also are available.

# Hazard Analysis Summary Sheet

HAZARD ANALYSIS WORKSHEET					
FIRM NAME:			PRODUCT DESCRIPTION:		
FIRM ADDRESS:			METHOD OF DISTRIBUTION AND STORAGE:		
			INTENDED USE AND CONSUMER:		
(1)	(2)	(3)	(4)	(5)	(6)
INGREDIENT/PROCESSING STEP	IDENTIFY POTENTIAL BIOLOGICAL, CHEMICAL, AND PHYSICAL HAZARDS ASSOCIATED WITH THIS PRODUCT AND PROCESS	ARE ANY POTENTIAL FOOD SAFETY HAZARDS SIGNIFICANT AT THIS STEP? (YES/NO)	JUSTIFY YOUR DECISION FOR COLUMN 3	WHAT PREVENTIVE MEASURE(S) CAN BE APPLIED FOR THE SIGNIFICANT HAZARDS?	IS THIS STEP A CRITICAL CONTROL POINT? (YES/NO)

Table: US Food and Drug Administration

## HACCP Principle 2

The second principle of HACCP is to identify the Critical Control Points (CCPs) in the process. This step also is sometimes referred to as the “Stop Sign” of the process, because the CCPs in the process are those steps which are essential to food safety.

A Critical Control Point is “a point or 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.”

CCPs are identified only after the completion of the hazard analysis (HACCP Principle 1). Any attempts by the HACCP team to identify CCPs without the benefit of a thorough hazard analysis often results in the identification of more CCPs than is necessary.

CCPs represent the steps in the process where a hazard can be controlled and control at this step is essential to ensure food safety.

CCP decision trees can be useful tools to help in the identification of CCPs. The use of decision trees will be discussed later in this section.

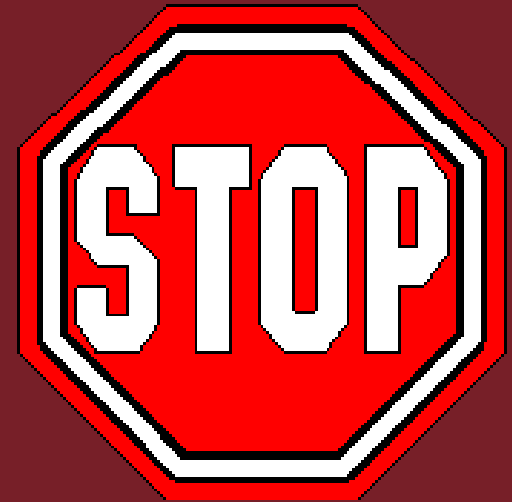


Illustration: Public Domain

## Assessment of Control Measures

To identify the CCPs in the process, the HACCP team must carefully assess the control measures identified during the hazard analysis. During this assessment, the HACCP team must:

- Identify control measures or combination of control measures capable of preventing, eliminating or reducing these food safety hazards to acceptable levels.
- Review each of the control measures with respect to its effectiveness against the identified food safety hazards.
- Categorize control measures as to whether they are managed by Prerequisite Programs, or need to be managed through the HACCP plan (i.e. as CCPs).

While there likely are several points in the process where hazards can be controlled to some extent, there are likely to be only a few steps where loss of control will result in the production of a potentially unsafe food. Those steps are the CCPs in the HACCP plan.



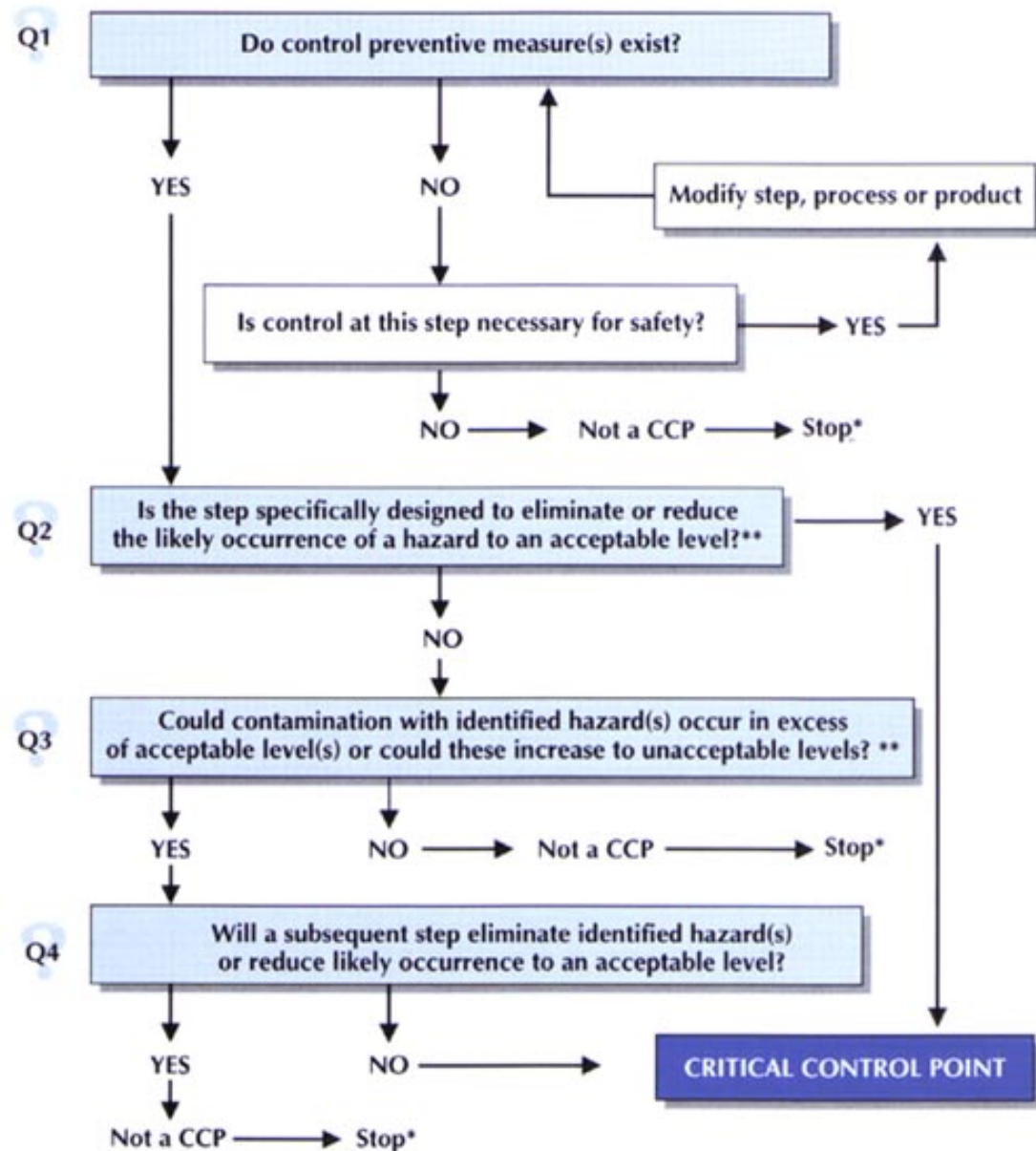
Photo: Serfling US FDA

## Food Safety Management Systems / HACCP CCP Decision Trees

The HACCP team can use **CCP Decision Trees** to assist in evaluation of each of the steps where food safety hazards can be prevented, eliminated, or reduced to acceptable levels. An example of a CCP decision tree is on the right (Source: FAO).

Do NOT use the CCP Decision Tree before completing the hazard analysis. Doing so may result in identifying CCPs that are not essential to controlling product safety.

Strictly following a CCP decision tree sometimes results in a decision that common sense says is incorrect. Therefore, the HACCP team should use CCP decision trees with caution.



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## CCPs and Hazard Control: Other Considerations

The number of CCPs required to control all significant food safety hazards depends on the product and process. Too few CCPs may not allow for adequate control of food safety hazards, whereas identifying too many CCPs may overburden the HACCP plan.

- A common saying among practitioners in the field is “If everything is significant (i.e. a CCP), then NOTHING is significant.” This refers to the fact that you cannot effectively manage too many CCPs in a single process. It is important to focus on those steps that are essential for food safety.

A single hazard may require control by multiple CCPs.

- Example: Acidification and thermal processing of fruit purees to control *Clostridium botulinum* growth and toxin formation.

Multiple hazards may be controlled by a single CCP.

- Example: Vegetative pathogenic bacteria and parasites in apple juice can be controlled by the same thermal process. [This also generally applies to the ability of thermal processes to control vegetative pathogenic bacteria and protozoan parasites.]



## HACCP Principle 3

The third principle of HACCP is to determine the Critical Limits (CLs) in the process. A critical limit is used to distinguish between safe and unsafe operating conditions at a CCP. Critical Limits must be established for each control measure important to manage food safety at a Critical Control Point.

A Critical Limit is defined by the Codex Alimentarius Commission as “a criterion which separates acceptability from unacceptability.”

The U.S. National Advisory Committee on Microbiological Criteria for Foods (NACMCF) has a more precise definition of a Critical Limit. The NACMCF definition is “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.”

CLs are identified only after the completion of the hazard analysis (HACCP Principle 1) and identification of the Critical Control Points (HACCP Principle 2).

Critical Limits are established only at Critical Control Points.



Photo: Public Domain



## Examples of Parameters that May Be Critical Limits

Critical limits must be scientifically based. For each CCP, there must be at least one criterion for food safety that is to be met. Critical limits may be based upon factors such as:

- Temperature
- pH
- Titratable acidity
- Humidity
- Moisture level
- Line Speed
- Time
- Flow rate
- Water activity
- Salt concentration
- Physical dimensions
- Weight
- Viscosity
- Available chlorine
- Preservative concentrations
- Sensory information such as aroma and visual appearance

In order to serve as effective critical limits at CCPs, these parameters must be:

- In place and operational
- Measurable and/or observable

## Establishing Critical Limits

Critical limits are defined based upon their ability to control (prevent, eliminate, or reduce to an acceptable level) the significant hazard(s) identified at a Critical Control Point.

The following list provides possible bases for selecting Critical Limits.

### Biological hazards

- Conditions necessary for inactivation of microorganisms, prevention of toxin formation, destruction of preformed toxins, prevention of growth of microorganisms.

### Chemical hazards

- Formulation and operating conditions necessary to control concentrations of chemical hazards below established safety limits. These safety limits for chemical hazards (such as regulatory Maximum Residue Levels) are often defined by toxicology studies in animal models or other methodologies.

### Physical hazards

- Criteria on foreign materials can be related to potential for causing injury (e.g. object size, hardness, sharpness).

## Establishing Critical Limits

The critical limits and criteria for food safety may be established by the HACCP team using information from sources such as:

- regulatory standards and guidelines,
- surveys of published research,
- experimental results (e.g. in-house experiments, contract laboratory studies), and
- experts (e.g. thermal process authorities, consultants, food scientists, microbiologists, equipment manufacturers, sanitarians, academics).

Regulatory standards are food safety criteria established by the responsible authority in a jurisdiction. The HACCP team must be aware of regulatory standards in the countries where they operate and, just as importantly, the countries where their company exports finished products.

## Deviations

In HACCP, a deviation refers to “a **failure to meet a critical limit.**” You also often see these events referred to as nonconformities.

Not meeting a critical limit could indicate:

- evidence that a direct health hazard **already exists** (e.g. bacterial contamination of a ready-to-eat food), or
- evidence that a direct health hazard **could develop** (e.g. under-processing of a low-acid food), or
- that a product was not produced under conditions **assuring safety** (e.g. metal detector calibrated incorrectly)

Appropriate steps to take when a deviation occurs will be discussed later in this section in Principles 5 (Corrective Actions).



Photo: Public Domain

## HACCP Principle 4

The fourth principle of HACCP is to establish CCP monitoring requirements and procedures for using the results of monitoring to adjust the process and maintain control. Properly designed and implemented CCP monitoring procedures are essential to demonstrating that the process is under control and establishes records to document compliance with the HACCP plan.

Monitoring is defined as “The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.”

In a HACCP system, monitoring procedures must be designed to accomplish the following objectives.

1. Track the operation of the process and enable the identification of trends toward a loss of process control that would necessitate process adjustments.
2. Identify when there is a loss of process control and a deviation occurs at a CCP.
3. Provide written documentation of the process control system.



Photo: Pacific Northwest National Laboratory / Flickr



## Types of Monitoring

There are many different types of monitoring procedures. Monitoring can be based on:

1. quantitative measurements (e.g. such as measurement of temperature, time, pH, water activity, etc.), or
2. observation by a trained individual (e.g. manual sorting)

Monitoring procedures also can either be continuous or discontinuous. Discontinuous monitoring is also commonly referred to as batch or attribute sampling.

Each of these approaches will be discussed in turn.



Photo: SEAFDEC/AQD / Flickr



## Continuous Monitoring

**Continuous monitoring** using automated equipment or sensors, where feasible, is preferable to discontinuous methods. This is due to the fact that continuous monitoring provides assurance that all products produced have met the criteria for acceptability (i.e. have met the designated critical limit). Continuous monitoring also allows for the effective use of operating limits (as described previously) which enable the operator to apply adjustments if monitoring indicates a trend toward loss of process control.

Continuous monitoring is commonly used for processes that are readily amenable to automated measurement. This includes measurement of parameters such as temperature, time, acidity, etc.

It is critical to recognize that continuous monitoring systems require routine calibration and supervision by trained personnel to verify that these systems are functioning as intended.



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## Discontinuous Monitoring

**Discontinuous monitoring** also is perfectly acceptable in HACCP systems, and in many cases is the only monitoring approach possible. However, when discontinuous monitoring is used the amount and frequency of monitoring should be sufficient to provide an acceptable level of assurance that the CCP is under control. The higher the frequency of monitoring (i.e. the less time between each instance of monitoring), the less product will be affected when there is a loss of control at the CCP.

When discontinuous monitoring is used, a sampling plan must be devised which will provide reasonable assurance that the process is under control and the designated critical limits have been met. The International Commission on Microbiological Specifications for Foods (ICMSF) has published extensively on statistical sampling methodologies for the food industry and has several useful publications on its web site:

<http://www.icmsf.iit.edu/main/home.html>



Photo: CIMMYT / Flickr

# Monitoring Procedures

A well-designed monitoring procedure will address each of the following points.

1. **Who** is responsible for the monitoring activity (usually by position or job title, not name of an individual)
2. **What** is to be monitored
3. **How** it is to be monitored
4. **When** monitoring will take place, and how often (frequency)

A monitoring procedure that meets each of these requirements and is appropriately implemented will enable the establishment to document that critical limits in the process are being met.



Photo: Serfling US FDA

## Monitoring Records

Monitoring procedures performed during the operation should result in written documentation which will serve as an accurate record of the operating conditions.

These records must include the:

- actual monitoring information,
- date and time the activity took place, and
- the signature or initials of person conducting the monitoring procedure.

Accurate monitoring procedures and associated records allow the operator to make decisions on the acceptability of the lot. To complete the monitoring process, data derived from monitoring should be reviewed and evaluated by a designated person (or persons) with knowledge and authority to carry out corrective actions when indicated.



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## HACCP Principle 5

The fifth principle of HACCP is to establish corrective actions to be taken when monitoring indicates that there is a deviation from an established critical limit. Taking appropriate corrective actions in the event of a deviation at a critical control point is essential to producing safe food. If corrective actions are not properly conducted, potentially unsafe food could leave your establishment and cause illness in consumers of your food products.

The Codex defines corrective action as “Any action to be taken when the results of monitoring at the CCP indicate a loss of control.”

In a HACCP system, corrective actions taken in the event of a deviation at a CCP must accomplish the following:

1. determine and correct the cause of non-compliance,
2. identify the product that was produced during the process deviation and determine its disposition, and
3. Record the corrective actions that have been taken.





## Definition and Preliminary Considerations

Specific corrective actions must be developed for possible deviations at each CCP in the HACCP plan for a product.

To the extent possible, corrective actions should be pre-planned. However, it is not possible to pre-plan for all corrective actions. You need to have a process in place to control nonconforming product and evaluate it to determine its ultimate disposition.

As a minimum, the HACCP plan should specify:

- what is done when a deviation occurs,
- who is responsible for implementing the corrective actions, and
- what records will be developed and maintained of the actions taken.

Individuals who have a thorough understanding of the process, product and HACCP plan should be assigned the responsibility for oversight of corrective actions. As appropriate, experts may be consulted to review the information available and to assist in determining disposition of non-compliant product.



Photo: Public Domain



## Determining and Correcting the Cause of Non-compliance

The first corrective action to be taken in the event of a deviation at a CCP should be to bring the process back under control.

This corrective action may simply require a process adjustment to bring the process back into compliance with the established critical limits. For example, if monitoring of a cooking process indicates that the product has not achieved an appropriate internal temperature, an appropriate corrective action might be to increase the cooking time and/or temperature until the appropriate internal temperature is met.

In some cases, it may not be possible to immediately bring the process back under control. In these instances, an appropriate corrective action may be to stop the processing line and hold all affected product (and products in process) until the cause of the non-conformity can be assessed and corrected.

Corrective actions may require root cause analysis to determine the cause of the non-conformity and provide assurance that continued deviations do not occur.



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## Identifying Affected Product and Determining its Disposition

The second important task a corrective action must accomplish is to identify product affected by the deviation and determine its final disposition.

With regard to identification and isolation of the affected product, the following steps must be accomplished:

1. All affected product (i.e. that processed since the last point at which the CCP was known to be under control) must be isolated.
2. Isolated product must be clearly marked (e.g. with firmly attached tags) with information including: hold number, product, amount, date held, the reason for the hold, and the name of the person holding the product.
3. The producer must maintain control of the product from the hold date to the date of final disposition.

Furthermore, the product must be held under conditions that minimize its further deterioration (e.g. refrigeration or freezing where necessary).

If products that have left control of the organization are subsequently determined to be unsafe, the organization must initiate a withdrawal.

## Identifying Affected Product and Determining its Disposition

After the affected product has been identified and isolated, the establishment must evaluate these products to determine their final disposition.

Product evaluation should be conducted by a qualified person. For example, thermal process deviations should be evaluated by a competent process authority or someone having similar expertise.

The evaluation of affected product should be adequate to detect potential hazards. It should be ensured that sampling is adequate to identify the extent of the problem, that the tests are appropriate, that the judgment is based on sound science, and that the product is not released until the evaluation has determined that no potential hazard exists.

Each lot of nonconforming product can only be released as safe when any of the following apply:

- Other evidence demonstrates that the control measures have been effective.
- Evidence shows that the combined effect of the control measures for that particular product complies with the performance intended.
- Sampling, analysis and/or other verification activities demonstrate that the affected product complies with the identified acceptable levels for the food safety hazard(s) concerned.

## Recording Corrective Actions

Records for corrective actions and nonconformities must include the following information:

- The actual production records for the product
- A standard form listing the following:
  - Hold number, deviation, reason for hold, date and code of product held, quantity of product held, name and signature of responsible individual
- Results of product evaluation: Authority recommendations, product testing results, decision on final disposition of product in question
- Accurate accounting of all units in question
- Statement of the procedure for handling the nonconformity
- Cause of deviation identified
- Corrective action taken to prevent recurrence of deviation

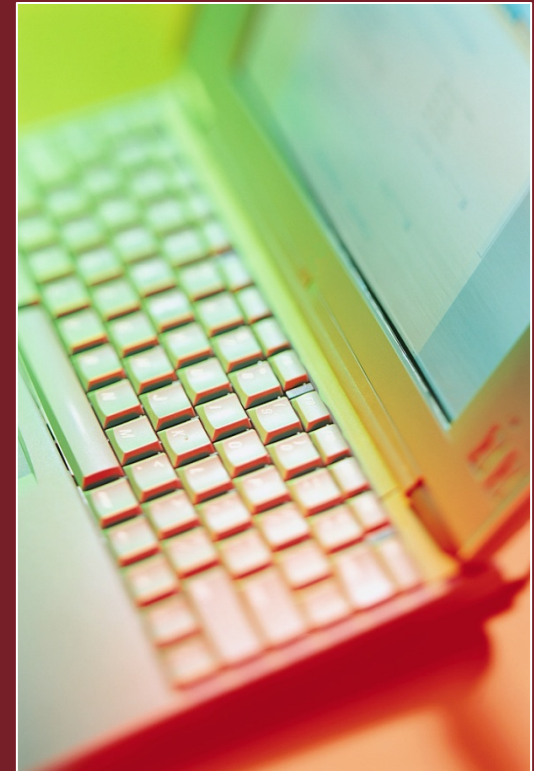


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## HACCP Principle 6

The sixth principle of HACCP is to establish HACCP plan verification procedures. Verification procedures for HACCP plans are critical because these activities demonstrate that the written HACCP plan is able to control the appropriate hazards in the product, and that the HACCP plan is being implemented as written.

The Codex guidelines define verification as “the application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan.”

The U.S. NACMCF uses a slightly different definition of verification, describing it as “those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan.” This definition is useful because it emphasizes the two critical aspects of verification.

1. Is the HACCP plan valid?
2. Is the system in compliance with the written HACCP plan?

These aspects will be discussed in the following sections.



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## Validation

Validation is defined by the Codex guidelines as “Obtaining evidence that the elements of the HACCP plan are effective.”

The U.S. NACMCF definition is more detailed: “That 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 essentially is the part of HACCP plan verification that asks the question *“Am I doing the right thing?”*

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. This is conducted by the HACCP team, with assistance by additional experts as necessary.





## Initial Validation

Initial validation is conducted within the first weeks or months of implementation of the HACCP plan. During initial validation, the team should aim to achieve the following:

- assure that the plan is valid for controlling food safety hazards associated with the ingredients, process, and product, and
- verify that the plan can be implemented as written.

HACCP plan validation should include:

- a review of the hazard analysis,
- CCP determination,
- justification for critical limits, based for example on current good science and regulatory requirements, and
- determination of whether monitoring activities, corrective actions, record keeping procedures and verification activities are appropriate and adequate.

If deficiencies are noted in any of these areas, the HACCP team must revise the HACCP plan. These changes must be implemented as rapidly as is practicable

## Revalidation

Revalidation, or reassessment, also is a required element of the HACCP system. It is necessary:

- after any changes are made that could affect the hazard analysis or the HACCP plan,
- when any changes are made to the HACCP system, and
- when specifically required by regulatory authorities or private standards bodies (e.g. in the United States, the federal regulatory authorities require annual reassessments of HACCP plans).

Revalidation of the HACCP plan may also be necessary when:

- new information arises concerning the safety of a product or ingredient,
- the product or product category is linked to a foodborne disease outbreak,
- the regulatory agency issues alerts related to the product or process,
- multiple deviations from a Critical Limit occur,
- inadequate record-keeping is followed,
- recalls or product withdrawals occur, or
- consumer complaints occur.

When the reassessment is complete, the HACCP team should issue a report detailing their findings. This report must be maintained as a HACCP record.

The HACCP plan must be modified immediately if reassessment indicates the HACCP plan is no longer adequate.

## Verification

The second important element of verification procedures is to confirm that the HACCP system is being implemented according to the written plan.

This is the part of HACCP plan verification that asks the question *“Am I actually doing what I say I should be doing?”*

HACCP plan verification activities are designed to ensure that the HACCP plan is being implemented properly. This includes:

- Verification of prerequisite programs
- Verification of CCPs
- Verification of the HACCP plan

Verification activities can be carried out by individuals within the company, third party experts, and regulatory agencies. It is important that individuals conducting verification activities have appropriate technical expertise to perform this function.



## Recording Verification Activities

Verification activities for the HACCP system must be documented. Examples of verification records include the following:

- Records documenting the accuracy and completeness of the written HACCP plan
- Records demonstrating that the written HACCP plan is being effectively implemented
- Results of verification audits conducted by the HACCP team and by external agencies
- Reports summarizing HACCP plan reassessment activities
- Equipment testing and evaluation
- Calibration records for monitoring equipment



Photo: Wael Attili / sah3teely.com

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## HACCP Principle 7

The seventh and final principle of HACCP is to establish effective record-keeping procedures that document the HACCP system. Maintaining complete and accurate records is essential to ensure effective monitoring of the HACCP system and demonstration of compliance with food safety requirements.

Efficient and accurate record keeping is essential to the application of a HACCP system. According to the Codex guidelines, “documentation and record keeping should be appropriate to the nature and size of the operation and sufficient to assist the business to verify that the HACCP controls are in place and being maintained.”

Although it requires considerable effort, the record-keeping program should be viewed as a **benefit** rather than a burden for the following reasons.

- Records are the only references available to trace the production history of a finished product.
- Records can be used as a tool to alert the operator to potential problems before they lead to the violation of a critical limit.
- Records can serve as evidence that proper procedures are being followed.

## Types of HACCP Records

Several different types of records are required to properly document the HACCP system. These include:

- Support documentation for developing the HACCP plan
- Records generated by the HACCP system
- Documentation of methods and procedures used
- Records of employee training programs

These types of records will be discussed in the following sections.



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# HACCP System Support Documents

The HACCP plan support documents include information and supporting data used to establish the HACCP plan such as the hazard analysis and records documenting the scientific basis for establishing the CCPs and critical limits. Examples include:

- A summary of the hazard analysis, including the rationale for determining hazards and control measures.
- Data used to establish the control measures to prevent microbiological growth.
- Data used to establish the shelf-life of the product (if age of the product can affect safety).
- Data used to establish the adequacy of critical limits in ensuring the safety of the product.

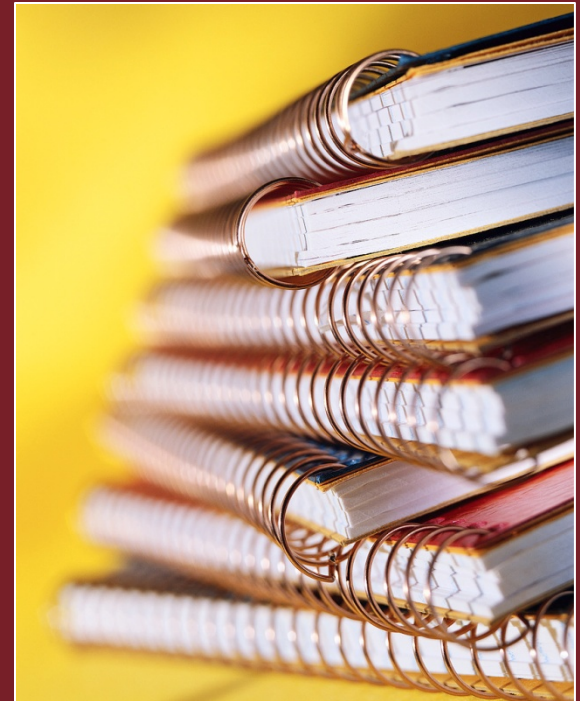


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## HACCP System Support Documents

The HACCP plan support documents should also include the written HACCP plan and systems which support its implementation. Examples of these records include:

- Listing of the HACCP team and assigned responsibilities.
- Description of the food, its distribution, intended use, and consumers.
- Verified flow diagram.
- HACCP Plan Summary Table that includes information for:
  - Steps in the process that are CCPs
  - The hazard(s) of concern
  - Critical limits
  - Monitoring procedures
  - Corrective actions
  - Verification procedures and schedule
  - Record-keeping procedures

Support documents may also include correspondence with consultants and other documents detailing how the HACCP plan was developed.

## Records Generated by the HACCP System

The records generated by the HACCP system include all activities and documentation required by the plan, including:

- monitoring records for all CCPs,
- deviation and corrective action records, and
- verification/validation records.

Routine CCP monitoring records should include the following information:

1. Form title
2. Firm name and location
3. Time and date
4. Product identification (including product type, package size, processing line and product code, where applicable)
5. Actual observation or measurement
6. Critical limits
7. Corrective action taken, where applicable
8. Operator's signature or initials
9. Reviewer's signature or initials
10. Date of review

## Records Generated by the HACCP System

Deviation and corrective action records should include:

- identification of the deviant lot/product,
- amount of affected product in the deviant lot,
- nature of the deviation,
- information on the disposition of the lot, and
- description of the corrective action.

Examples of verification and validation records include:

- in-house on-site inspection,
- equipment testing and evaluation,
- accuracy and calibration of monitoring equipment, and
- results of verification activities, including methods, date, individuals and/or organizations responsible, results or findings and action taken.

## Documentation of Methods and Procedures

Methods and procedures used in implementing the HACCP system also must be documented. Examples include:

- Description of procedures used to implement key prerequisite programs, such as employee hygiene and sanitation of equipment and facilities. In certain cases, records of these procedures are required by regulation (e.g. as in certain U.S. HACCP regulations).
- Description of the monitoring system for the critical limits of each CCP, including the methods and equipment used for monitoring, the frequency of monitoring and the person performing the monitoring.
- Plans for corrective actions for critical limit violations or situations resulting in potential hazards.
- Description of record keeping procedures, including copies of all record forms.
- Description of verification and validation procedures.



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## Retention of Records

Records documenting the HACCP system should be stored for a predefined period. The duration of record retention is generally linked to the anticipated shelf life of the product.

The HACCP team must familiarize themselves with the legal and/or customer requirements for maintenance and retention of records in the countries where they operate and where their products are sold.

For example, regulatory agencies in the United States require that HACCP records be retained for at least the following durations:

- One year, for perishable or refrigerated products.
- Two years (or shelf life of the product, if longer), for frozen, preserved, or shelf-stable products.

Records must be readily accessible. Off-site storage is often permitted by regulatory authorities provided that records can be retrieved within a reasonable period of time (e.g. 24 hours).



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## Electronic Records

Electronic, or computerized, records are an increasingly common option to traditional written record keeping on printed forms. When using computerized records, it is important to include controls to ensure that records are :

- authentic,
- accurate, and
- protected from unauthorized changes.

The HACCP team should ensure that any electronic record-keeping procedures used in their system comply with the regulatory requirements in the jurisdictions where they operate.



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## Records – Other Considerations

Employees with record-keeping responsibilities must be trained on the importance of accurate and timely record-keeping.

Records must be taken at the times and frequencies stipulated in the HACCP plan. They should never be completed prior to or long after the scheduled frequency.

The employee must record the actual measurement or observation, not the critical limit specified in the HACCP plan.

Written records typically must be recorded in ink, not pencil.

Corrections to written records should be completed by crossing out the mistaken reading with a single line and replacing it with the correct reading. It is good practice to have these edits approved and initialed by supervisory personnel.

Records must be readily accessible and maintained in a secure location.



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## HACCP Plan Form

Below is an example of a blank standard HACCP plan summary table. The purpose of the summary table is to aggregate all of the key information regarding implementation of the HACCP plan in a single document. The completed summary table should be supported by a variety of other records, including records of the hazard analysis, determination of CCPs, maintenance of prerequisite programs, methods and procedures, daily operational records, corrective action records, verification and validation records and other supporting documentation.

1. CCP	2. Hazards	3. Critical limits	Monitoring				8. Corrective actions	9. Verifica- tion	10. Record keeping
			4. What	5. How	6. Frequency	7. Who			

## HACCP Final Considerations

Design and maintenance of a valid and effective HACCP system requires a significant and lasting commitment by the establishment. Management support is essential.

The HACCP team should be multidisciplinary and have a complete understanding of the firm's products and processes, as well as the likely hazards in these products and methods for controlling these hazards.

HACCP systems are dynamic. At a minimum, HACCP plans must be revalidated annually. Revalidation is also triggered by a host of other factors, including changes in product formulation, processing steps, understanding of potential hazards in the products, recalls or other food safety incidents, or other information that may impact food safety hazard incidence or severity.

Finally, once written and validated the establishment must treat the HACCP system as the "law" in their establishment. Once implemented, all operations must be in accord with the plan.



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