

**CARIFORUM Regional Framework for Good Fisheries Hygiene and Production Standards**

Guidelines and models on developing and implementing plans for applying HACCP in fishery production establishments and facilities. Updated August 2015.

**Guidelines on Developing and Implementing HACCP Plans for Fish and Fishery Products**

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## Contents

Contents i

About this Guidance ii

Part A | Definitions 1

Part B | Introduction to HACCP 4

1] Definition of HACCP and its Role in Food Safety 4

2] HACCP versus the traditional food inspection system 4

3] Staff 5

Part C | The HACCP Principles and Guidelines 6

1] Overview 6

2] The 7 HACCP Principles 6

Part D | Developing a HACCP Plan 8

1] Preliminary steps 8

2] Applying the HACCP Principles 10

Part E | Implementation and Maintenance of the HACCP Plan 18

Forms 19

Appendices 24

Appendix 1 | Model Process Flow for Frozen Conch 24

Appendix 2 | Examples of Questions to be Considered When Conducting a Hazard Analysis 26

Appendix 3 | Examples of How the Stages of Hazard Analysis are used to Identify and Evaluate Hazards 30

Appendix 4 | Example of a CCP Decision Tree 31

Appendix 5 | Examples of Verification Activities 32

Appendix 6 | Examples of HACCP Records 34

## About this Guidance

This guidance is intended to assist processors of fish and fishery products in the development of their Hazard Analysis Critical Control Point (HACCP) plans. It is part of the **Additional Guidance on Good Fish and Fishery Product Hygiene Practices** provided within the **Caribbean Regional Fisheries SPS Framework** produced under the Sanitary and Phytosanitary Measures programme, one component of the 10th EDF Programme titled “*Support to the Caribbean Forum of ACP States in the Implementation of Commitments Undertaken Under the Economic Partnership Agreement (EPA): Sanitary and Phytosanitary Measures (SPS)*”, implemented by the Inter-American Institute for Cooperation on Agriculture (IICA), with the fisheries sub-component being executed by the CRFM Secretariat.

The Guidance is designed to walk users through a series of steps that will result in a completed HACCP plan. A separate HACCP plan should be developed for each location where fish and fishery products are processed and for each kind of fish and fishery product processed at that location. Products may be grouped together in a single HACCP plan if the food safety hazards and controls are the same for all products in the group.

Processors of fish and fishery products will find information in this guidance that will help them identify hazards that are associated with their products, and help them formulate control strategies. The guidance will also help consumers and the public generally to understand commercial seafood safety in terms of hazards and their controls.

The control strategies and practices provided in this guidance are recommendations to the fish and fishery products industry unless they are required by national regulations or rules. This guidance provides information that would likely result in a HACCP plan that is acceptable to national Competent Authorities.

Processors may choose to use other control strategies, as long as they comply with the requirements of the applicable food safety laws and regulations. However, processors that chose to use other control strategies (e.g., critical limits) should scientifically establish their adequacy.

# Part A | Definitions

**CCP Decision Tree**

A sequence of questions to assist in determining whether a control point is a CCP.

**Control**

(a) To manage the conditions of an operation to maintain compliance with established criteria.

(b) The state where correct procedures are being followed and criteria are being met.

**Control Measure**

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 be controlled.

**Corrective Action**

Procedures followed when a deviation occurs.

**Criterion**

A requirement on which a judgement or decision can be based.

**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 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.

**Deviation**

Failure to meet a critical limit.

**HACCP**

A systematic approach to the identification, evaluation, and control of food safety hazards.

**HACCP Plan**

The written document which is based upon the principles of HACCP and which delineates the procedures to be followed.

**HACCP System**

The result of the implementation of the HACCP Plan.

**HACCP Team**

The group of people who are responsible for developing, implementing and maintaining the HACCP system.

**Hazard**

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

**Hazard Analysis**

The process of collecting and evaluating information on hazards associated with the food under consideration to decide which are significant and must be addressed in the HACCP plan.

**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.

**Prerequisite Programs**

Procedures, including Good Manufacturing Practices, that address operational conditions providing the foundation for the HACCP system.

**Severity**

The seriousness of the effect(s) of a hazard.

**Step**

A point, procedure, operation or stage in the food system from primary production to final consumption.

**Validation**

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.

**Verification**

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

# Part B | Introduction to HACCP

## 1] Definition of HACCP and its Role in Food Safety

HACCP is an abbreviation for the **Hazard Analysis Critical Control Points System**. The current principles and guidelines governing HACCP are established through CODEX (Committee for Food Hygiene on the Codex Alimentarius), a Joint Food Standards Programme of the UN Food and Agriculture Organization (FAO) and the World Health Organization (WHO).

It is the universal standard approach for a “total food safety system”. HACCP as a system:

* **Identifies hazards** which are important to food safety
* **Evaluates hazards** which are important to food safety
* **Controls hazards** which are important to food safety.

As a system it identifies any point at which a potential food safety hazard may occur thereby adversely impacting food safety and implements controls to either eliminate or significantly reduce the hazard to tolerable levels.

HACCP is a science-based system which operates on the concept that the hazards affecting or impacting the safety of food supplies can identified at any of the critical point along the food chain. Further, that these potential hazards can be eliminated, minimized or significantly reduced during production or processing at any stage or critical point along the food chain.

HACCP as a system can be applied to any food production or processing activity or at any point along the food chain-from point of harvest to consumption.

**HACCP is not a stand-alone system.** The application of HACCP does not stand alone in a food processing facility. The plan must be built on pre-requisite and other food safety programs. Good Manufacturing Practices (GMP) that are practised by the processing facility will support HACCP plan and will address food safety and food quality issues that are not critical for the reduction of food safety hazards. Sanitation Standard Operating Procedures (SSOP's) are required in fishery production operations and address procedures for clean facilities, equipment and personnel that are necessary for all products produced in a facility.

## 2] HACCP versus the traditional food inspection system

The traditional food safety inspection system is primarily geared towards inspection of end products. This requires excessive effort in terms of time, cost and personnel. HACCP is a risk-based system, as compared to the pre-specified physical parameter approach in traditional food inspection systems. The application of HACCP may require fundamental change in the culture and attitudes of both management and line staff in processing establishments.

The idea of **HACCP** is not to replace this traditional approach to food safety inspection and quality assurance but rather to add a preventive quality assurance dimension. Companies implementing **HACCP** will be able to provide greater levels of confidence to the consumers and to minimize the risks of economic losses arising from condemnation, confiscation and or destruction of contaminated food supplies.

It has been shown that the benefits to be derived from the implementation of HACCP far exceed the cost of implementation over time. While the cost of implementing HACCP depends on the general sanitary and hygienic conditions prevailing at the facility prior to initiating the system, it does not *necessarily* require expensive equipment, etc.: what is required in the main is the establishment of critical control points and their effective monitoring.

Implementation of aHACCPsystem is also required under the basic food safety regulations of many importing countries[[1]](#footnote-1), and the World Trade Organization agreement on sanitary and phytosanitary measures (WTO-SPS) requires compliance with at the least the minimum levels of food safety measures which meet internationally acceptable standards of food safety which can only realistically be attained by implementing a HACCP system.

## 3] Staff

The development and implementation of, and supervision of compliance with, the HACCP system should be undertaken by a dedicated team of individuals (the “HACCP team”) consisting of staff (or externally hired experts) who have specific knowledge and expertise appropriate to the product and process. HACCP of necessity, however, must involve the entire staff of a given facility and all staff should be aware of and be able to undertake their responsibilities within the HACCP plan.

# Part C | The HACCP Principles and Guidelines

## 1] Overview

HACCP is a systematic approach to the identification, evaluation and control of food safety hazards, based on 7 principles. These principles outline how to establish, implement and maintain a HACCP Plan for an operation or facility (following the application of various preliminary steps – the full process is set out in Part D).

**Principle 1: Conduct a hazard analysis**

**Principle 2: Determine the critical control points (CCPs)**

**Principle 3: Establish critical limits**

**Principle 4: Establish monitoring procedures**

**Principle 5: Establish corrective actions**

**Principle 6: Establish verification procedures**

**Principle 7: Establish record-keeping and documentation procedures**

## 2] The 7 HACCP Principles

### Principle 1: Conduct a hazard analysis

The application of this principle involves listing the steps in the process and identifying where significant hazards are likely to occur. The HACCP team will focus on hazards that can be prevented, eliminated or controlled by the HACCP plan. A justification for including or excluding the hazard is reported and possible control measures are identified.

### Principle 2: Determine the critical control points (CCPs)

A critical control point (CCP) is a point, step or procedure at which control can be applied and a food safety hazard can be prevented, eliminated or reduced to acceptable levels. A critical control point may control more that one food safety hazard or in some cases more than one CCP is needed to control a single hazard. The number of CCP's needed depends on the processing steps and the control needed to assure food safety.

### Principle 3: Establish critical limits

A critical limit (CL) is the 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. The critical limit is usually a measure such as time, temperature, water activity (Aw), pH, weight, or some other measure that is based on scientific literature and/or regulatory standards.

### Principle 4: Establish monitoring procedures

The HACCP team will describe monitoring procedures for the measurement of the critical limit at each critical control point. Monitoring procedures should describe how the measurement will be taken, when the measurement is taken, who is responsible for the measurement and how frequently the measurement is taken during production.

### Principle 5: Establish corrective actions

Corrective actions are the procedures that are followed when a deviation in a critical limit occurs. The HACCP team will identify the steps that will be taken to prevent potentially hazardous food from entering the food chain and the steps that are needed to correct the process. This usually includes identification of the problems and the steps taken to assure that the problem will not occur again.

### Principle 6: Establish verification procedures

Those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan. The HACCP team may identify activities such as auditing of CCP's, record review, prior shipment review, instrument calibration and product testing as part of the verification activities.

### Principle 7: Establish record-keeping and documentation procedures

A key component of the HACCP plan is recording information that can be used to prove that the food was produced safely. The records also need to include information about the HACCP plan. Record should include information on the HACCP Team, product description, flow diagrams, the hazard analysis, the CCP's identified, Critical Limits, Monitoring System, Corrective Actions, Recordkeeping Procedures, and Verification Procedures.

# Part D | Developing a HACCP Plan

The format of HACCP plans will vary. In many cases the plans will be product and process specific. However, some plans may use a unit operations approach. Generic HACCP plans can serve as useful guides in the development of process and product HACCP plans; however, it is essential that the unique conditions within each facility be considered during the development of all components of the HACCP plan. Model forms for completing a HACCP Plan and Hazard Analysis are provided in the **Froms** section of these Guidelines, but use of these forms are not mandatory.

A separate HACCP plan should be developed for each location where fish and fishery products are processed and for each kind of fish and fishery product processed at that location. You may group products together in a single HACCP plan if the food safety hazards and controls are the same for all products in the group.

In the development of a HACCP plan, there are **12 recommended steps** (as approved by the Codex Committee for Food Hygiene). These consist of five preliminary tasks that need to be accomplished before the application of the HACCP principles to a specific product and process. The five preliminary tasks are given in Figure 1. The steps are to be implemented sequentially.

Figure 1 Preliminary Tasks in the Development of the HACCP Plan

## 1] Preliminary steps

### Step 1: Assemble the HACCP team

The first task in developing a HACCP plan is to assemble a HACCP team consisting of individuals who have specific knowledge and expertise appropriate to the product and process. It is the team's responsibility to develop the HACCP plan. The team should be multi-disciplinary and include both management and individuals from areas such as engineering, production, sanitation, quality assurance and food microbiology (depending on the specific requirements of the food processing operation).

The team should also include local personnel who are involved in the operation as they are more familiar with the variability and limitations of the operation. In addition, this fosters a sense of ownership among those who must implement the plan.

Experts should be hired to assist if the required expertise is not available in the staff. However, **a plan which is developed totally by outside sources may be erroneous, incomplete, and lacking in support at the local level**.

### Step 2: Describe the product

A description of the product subject to the HACCP plan is to be provided.

**Describe the food:** Identify the market name or Latin name (species) of the fishery component(s) of the product.*Examples:*

* *Tuna (Thunnus albacares)*
* *Shrimp (Penaeus spp.)*
* *Queen Conch (Strombus gigas)*

**Fully describe the finished product food.** *Examples:*

* *Individually quick frozen, cooked, peeled shrimp*
* *Fresh grouper fillets*
* *Raw shrimp, in-shell*
* *Conch fritters*

**Describe the packaging type**. *Examples:*

* *Vacuum-packaged plastic bag*
* *Aluminum can*
* *Bulk, in wax-coated paperboard box*
* *Plastic container with snap lid*

**Describe the method of distribution and storage.** Identify how the product is distributed and stored after distribution.*Examples:*

* *Stored and distributed frozen*
* *Distributed on ice and then stored under refrigeration or on ice*

Other items that might be included in the description are: its composition and structure and any ingredients; storage; and shelf life. The description of the product should include a description of the traceability procedures applied.

### Step 3: Describe the intended use and consumers

**Describe the normal expected use of the food.** *Examples:*

* *To be eaten with or without further cooking*
* *To be eaten raw or lightly cooked*
* *To be further processed into a heat and serve product*

**Identify the intended consumer or user of the product.** The intended consumers may be the general public or a particular segment of the population (e.g., infants, immune-compromised individuals, etc.).The intended user may also be another processor that will further process the product.*Examples:*

* *By the general public*
* *By the general public, including some distribution to hospitals and nursing homes*
* *By another processing facility*

### Step 4: Develop a flow diagram

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. Receiving and storage steps for each of the ingredients, including non-fishery ingredients, should be included.

The flow diagram need not be as complex as engineering drawings. A block type flow diagram is sufficiently descriptive (see Appendix 1 | Model Process Flow for Frozen Conch). Also, a simple schematic of the facility is often useful in understanding and evaluating product and process flow.

### Step 5: Verify the flow diagram

The HACCP team should perform an on-site review of the operation to verify the accuracy and completeness of the flow diagram. Modifications should be made to the flow diagram as necessary and documented.

## 2] Applying the HACCP Principles

After these five preliminary tasks have been completed, the seven principles of HACCP are applied.

### Conduct a hazard analysis (Principle 1)

The HACCP team conducts a hazard analysis and identifies appropriate control measures. The purpose of the hazard analysis is to develop a list of (reasonably foreseeable) hazards which are of such significance that they are reasonably likely to cause illness or injury if not effectively controlled.

A thorough hazard analysis is the key to preparing an effective HACCP plan. If the hazard analysis is not done correctly and the hazards warranting control within the HACCP system are not identified, the plan will not be effective regardless of how well it is followed.

Biological, chemical, and physical hazards can affect the safety of fishery products. Some food safety hazards are associated with the product (e.g., the species of fish, the way in which the fish is raised or caught, and the region of the world from which the fish originates). These hazards are introduced outside the processing plant environment before, during, or after harvest. These are referred to as species-related hazards. Other food safety hazards are associated with the way in which the product is processed (e.g., the type of packaging, the manufacturing steps, and the kind of storage). These hazards are introduced within the processing plant environment, and are referred to as process-related hazards.

For guidance on potential food safety hazards that are species related and process related, see [**Fish and Fishery Products Hazards and Controls Guidance, Chapter 3**](http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM252383.pdf) (US Food and Drug Administration, 2011).

The process of conducting a hazard analysis involves two stages.

**(1) Hazard identification**

The first step requires the HACCP team to review the ingredients used in the product, the activities conducted at each step in the process and the equipment used, the final product and its method of storage and distribution and the intended use and consumers of the product. Based on this review, the team develops a list of potential biological, chemical or physical hazards that may be introduced, increased, or controlled at each step in the production process. See Appendix 2 | Examples of Questions to be Considered When Conducting a Hazard Analysis.

**(2) Hazard evaluation**

After the list of potential hazards is assembled, the process moves to the second step – hazard evaluation. Here, the HACCP team decides which potential hazards must be addressed in the HACCP plan. During this stage, each potential hazard is evaluated based on the severity of the potential hazard and its likely occurrence.

Severity is the seriousness of the consequences of exposure to the hazard. Considerations of severity (e.g. magnitude and duration of illness or injury) can be helpful in understanding the public health impact of the hazard. Consideration of the likely occurrence is usually based upon a combination of experience, epidemiological data and information in the technical literature. When conducting the hazard evaluation, it is helpful to consider the likelihood of exposure and severity of the potential consequences if the hazard is not properly controlled.

During the evaluation of each potential hazard, the food, its method of preparation, transportation, storage and persons likely to consume the product should be considered to determine how each of these factors may influence the likely occurrence and severity of the hazard being controlled. The team must consider the influence of likely procedures for food preparation and storage and whether the intended consumers are susceptible to a potential hazard.

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.

See Appendix 3 | Examples of How the Stages of Hazard Analysis are used to Identify and Evaluate Hazards for further guidance.

A summary of the HACCP team workings and the rationale developed during the hazard analysis should be kept for future reference. This information will be useful during future reviews and updates of the hazard analysis and the HACCP plan.

Upon completion of the hazard analysis, the hazards associated with each step in the production of the food should be listed along with any measure(s) that are used to control the hazard(s). More than one control measure may be required for a specific hazard. On the other hand, more than one hazard may be addressed by a specific control measure.

The hazard analysis summary could be presented in several different ways.

### Determine critical control points (CCPs) (Principle 2)

Complete and accurate identification of CCPs is fundamental to controlling food safety hazards. The information developed during the hazard analysis is essential for the HACCP team in identifying which steps in the process are CCPs. One strategy to facilitate the identification of each CCP is the use of a CCP decision tree, although this is not mandatory. (See Appendix 4 | Example of a CCP Decision Tree).

Critical control points are located at any step where hazards can be either prevented, eliminated or reduced to acceptable levels. Examples of CCPs may include: thermal processing, chilling, testing ingredients for chemical residues, product formulation control, and testing product for metal contaminants. CCPs must be carefully developed and documented. In addition, they must be used only for purposes of product safety. For example, a specified heat process, at a given time and temperature designed to destroy a specific microbiological pathogen, could be a CCP. Likewise, refrigeration of a precooked food to prevent hazardous microorganisms from multiplying, or the adjustment of a food to a pH necessary to prevent toxin formation could also be CCPs. Different facilities preparing similar food items can differ in the hazards identified and the steps which are CCPs. This can be due to differences in each facility's layout, equipment, selection of ingredients, processes employed, etc.

### Establish critical limits (Principle 3)

A critical limit 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. A critical limit is used to distinguish between safe and unsafe operating conditions at a CCP. Critical limits should not be confused with operational limits which are established for reasons other than food safety.

Each CCP will have one or more control measures to assure that the identified hazards are prevented, eliminated or reduced to acceptable levels. Each control measure has one or more associated critical limits. Critical limits may be based upon factors such as: temperature, time, physical dimensions, humidity, moisture level, water activity (aw), pH, titratable acidity, salt concentration, available chlorine, viscosity, preservatives, or sensory information such as aroma and visual appearance. Critical limits must be scientifically based. For each CCP, there is at least one criterion for food safety that is to be met.

### Establish monitoring procedures (Principle 4)

Monitoring is 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.

Monitoring serves three main purposes. First, monitoring is essential to food safety management in that it facilitates tracking of the operation. If monitoring indicates that there is a trend towards loss of control, then action can be taken to bring the process back into control before a deviation from a critical limit occurs. Second, monitoring is used to determine when there is loss of control and a deviation occurs at a CCP, i.e., exceeding or not meeting a critical limit. When a deviation occurs, an appropriate corrective action must be taken. Third, it provides written documentation for use in verification.

Assignment of the responsibility for monitoring is an important consideration for each CCP. Specific assignments will depend on the number of CCPs and control measures and the complexity of monitoring. Personnel who monitor CCPs are often associated with production (e.g., line supervisors, selected line workers and maintenance personnel) and, as required, quality control personnel. Those individuals must be trained in the monitoring technique for which they are responsible and must accurately report the results of monitoring. In addition, employees should be trained in procedures to follow when there is a trend towards loss of control so that adjustments can be made in a timely manner to assure that the process remains under control. The person responsible for monitoring must also immediately report a process or product that does not meet critical limits.

All records and documents associated with CCP monitoring should be dated and signed or initialled by the person doing the monitoring. Monitoring equipment must be carefully calibrated for accuracy.

Ideally, monitoring should be continuous. When it is not possible to monitor a CCP on a continuous basis, it is necessary to establish a monitoring frequency and procedure (e.g. a sampling system) that will be reliable enough to indicate that the CCP is under control. Most monitoring procedures need to be rapid because they relate to on-line, "real-time" processes and there will not be time for lengthy analytical testing. Examples of monitoring activities include: visual observations and measurement of temperature, time, pH, and moisture level.

### Establish corrective actions (Principle 5)

The HACCP system for food safety management is designed to identify health hazards and to establish strategies to prevent, eliminate or reduce their occurrence. Where there is a deviation from established critical limits, corrective actions are necessary.

Corrective actions should include the following elements: (a) determine and correct the cause of non-compliance; (b) determine the disposition of non-compliant product and (c) record the corrective actions that have been taken. Specific corrective actions should be developed in advance for each CCP and included in the HACCP plan. As a minimum, the HACCP plan should specify what is done when a deviation occurs, who is responsible for implementing the corrective actions and that a record 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.

### Establish verification procedures (Principle 6)

Verification is defined as those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan. Verification processes should be identified during the development and implementation of the HACCP plans and maintenance of the HACCP system. An example of a verification schedule is given in Figure 2.

Figure 2 Example of a Company Established HACCP Verification Schedule

|  |  |  |  |
| --- | --- | --- | --- |
| Activity | **Frequency** | **Responsibility** | **Reviewer** |
| Verification Activities Scheduling | Yearly or Upon HACCP System Change | HACCP Coordinator | Plant Manager |
| Initial Validation of HACCP Plan | Prior to and During Initial Implementation of Plan | Independent Expert(s)(a) | HACCP Team |
| Subsequent validation of HACCP Plan | When Critical Limits Changed, Significant Changes in Process, Equipment Changed, After System Failure, etc. | Independent Expert(s)(a) | HACCP Team |
| Verification of CCP Monitoring as Described in the Plan (e.g., monitoring of patty cooking temperature) | According to HACCP Plan (e.g., once per shift) | According to HACCP Plan (e.g., Line Supervisor) | According to HACCP Plan (e.g., Quality Control) |
| Review of Monitoring, Corrective Action Records to Show Compliance with the Plan | Monthly | Quality Assurance | HACCP Team |
| Comprehensive HACCP System Verification | Yearly | Independent Expert(s)(a) | Plant Manager |
| (a) Done by others than the team writing and implementing the plan. May require additional technical expertise as well as laboratory and plant test studies. | | | |

An important aspect of verification is evaluating whether the facility's HACCP system is functioning according to the HACCP plan. An effective HACCP system requires little end-product testing, since sufficient validated safeguards are built in early in the process. Therefore, rather than relying on end-product testing, firms should rely on frequent reviews of their HACCP plan, verification that the HACCP plan is being correctly followed and review of CCP monitoring and corrective action records.

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

Examples of verification activities are included in Appendix 5 | Examples of Verification Activities.

In addition, a periodic comprehensive verification of the HACCP system should be conducted by an unbiased, independent authority. Such authorities can be internal or external to the food operation. This should include a technical evaluation of the hazard analysis and each element of the HACCP plan as well as on-site review of all flow diagrams and appropriate records from operation of the plan. A comprehensive verification is independent of other verification procedures and must be performed to ensure that the HACCP plan is resulting in the control of the hazards. If the results of the comprehensive verification identify deficiencies, the HACCP team modifies the HACCP plan as necessary.

### Establish record-keeping and documentation procedures (Principle 7)

Generally, the records maintained for the HACCP System should include the following:

1. A summary of the hazard analysis, including the rationale for determining hazards and control measures.
2. The HACCP Plan

* Listing of the HACCP team and assigned responsibilities.
* Description of the food, its distribution, intended use, and consumer.
* 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\*
  + Corrective actions\*
  + Verification procedures and schedule\*
  + Record-keeping procedures\*

\* A brief summary of position responsible for performing the activity and the procedures and frequency should be provided

1. Support documentation such as validation records.
2. Records that are generated during the operation of the plan.

Examples of HACCP records are given in Appendix 6 | Examples of HACCP Records.

# Part E | Implementation and Maintenance of the HACCP Plan

The successful implementation of a HACCP plan is facilitated by commitment from top management. The next step is to establish a plan that describes the individuals responsible for developing, implementing and maintaining the HACCP system. Initially, the HACCP coordinator and team are selected and trained as necessary. The team is then responsible for developing the initial plan and coordinating its implementation. Product teams can be appointed to develop HACCP plans for specific products. An important aspect in developing these teams is to assure that they have appropriate training. The workers who will be responsible for monitoring need to be adequately trained. Upon completion of the HACCP plan, operator procedures, forms and procedures for monitoring and corrective action are developed. Often it is a good idea to develop a timeline for the activities involved in the initial implementation of the HACCP plan. Implementation of the HACCP system involves the continual application of the monitoring, record-keeping, corrective action procedures and other activities as described in the HACCP plan.

Maintaining an effective HACCP system depends largely on regularly scheduled verification activities. The HACCP plan should be updated and revised as needed. An important aspect of maintaining the HACCP system is to assure that all individuals involved are properly trained so they understand their role and can effectively fulfil their responsibilities.

# Forms

This section contains a blank model Hazard Analysis Critical Control Point (HACCP) Plan Form and a blank model Hazard Analysis Worksheet.

Note that these are two-page forms, with the second page to be used if your process has more critical control points or more processing steps than can be listed on one page.









# Appendices

## Appendix 1 | Model Process Flow for Frozen Conch

## Appendix 2 | Examples of Questions to be Considered When Conducting a Hazard Analysis

The hazard analysis consists of asking a series of questions which are appropriate to the process under consideration. The purpose of the questions is to assist in identifying potential hazards.

1. Ingredients
   1. Does the food contain any sensitive ingredients that may present microbiological hazards (e.g., Salmonella, Staphylococcus aureus); chemical hazards (e.g., aflatoxin, antibiotic or pesticide residues); or physical hazards (stones, glass, metal)?
   2. Are potable water, ice and steam used in formulating or in handling the food?
   3. What are the sources (e.g., geographical region, specific supplier)
2. Intrinsic Factors - Physical characteristics and composition (e.g., pH, type of acidulants, fermentable carbohydrate, water activity, preservatives) of the food during and after processing.
   1. What hazards may result if the food composition is not controlled?
   2. Does the food permit survival or multiplication of pathogens and/or toxin formation in the food during processing?
   3. Will the food permit survival or multiplication of pathogens and/or toxin formation during subsequent steps in the food chain?
   4. Are there other similar products in the market place? What has been the safety record for these products? What hazards have been associated with the products?
3. Procedures used for processing
   1. Does the process include a controllable processing step that destroys pathogens? If so, which pathogens? Consider both vegetative cells and spores.
   2. If the product is subject to recontamination between processing (e.g., cooking, pasteurizing) and packaging which biological, chemical or physical hazards are likely to occur?
4. Microbial content of the food
   1. What is the normal microbial content of the food?
   2. Does the microbial population change during the normal time the food is stored prior to consumption?
   3. Does the subsequent change in microbial population alter the safety of the food?
   4. Do the answers to the above questions indicate a high likelihood of certain biological hazards?
5. Facility design
   1. Does the layout of the facility provide an adequate separation of raw materials from ready-to-eat (RTE) foods if this is important to food safety? If not, what hazards should be considered as possible contaminants of the RTE products?
   2. Is positive air pressure maintained in product packaging areas? Is this essential for product safety?
   3. Is the traffic pattern for people and moving equipment a significant source of contamination?
6. Equipment design and use
   1. Will the equipment provide the time-temperature control that is necessary for safe food?
   2. Is the equipment properly sized for the volume of food that will be processed?
   3. Can the equipment be sufficiently controlled so that the variation in performance will be within the tolerances required to produce a safe food?
   4. Is the equipment reliable or is it prone to frequent breakdowns?
   5. Is the equipment designed so that it can be easily cleaned and sanitized?
   6. Is there a chance for product contamination with hazardous substances; e.g., glass?
   7. What product safety devices are used to enhance consumer safety?
      * metal detectors
      * magnets
      * sifters
      * filters
      * screens
      * thermometers
      * bone removal devices
      * dud detectors
   8. To what degree will normal equipment wear affect the likely occurrence of a physical hazard (e.g., metal) in the product?
   9. Are allergen protocols needed in using equipment for different products?
7. Packaging
   1. Does the method of packaging affect the multiplication of microbial pathogens and/or the formation of toxins?
   2. Is the package clearly labeled "Keep Refrigerated" if this is required for safety?
   3. Does the package include instructions for the safe handling and preparation of the food by the end user?
   4. Is the packaging material resistant to damage thereby preventing the entrance of microbial contamination?
   5. Are tamper-evident packaging features used?
   6. Is each package and case legibly and accurately coded?
   7. Does each package contain the proper label?
   8. Are potential allergens in the ingredients included in the list of ingredients on the label?
8. Sanitation
   1. Can sanitation have an impact upon the safety of the food that is being processed?
   2. Can the facility and equipment be easily cleaned and sanitized to permit the safe handling of food?
   3. Is it possible to provide sanitary conditions consistently and adequately to assure safe foods?
9. Employee health, hygiene and education
   1. Can employee health or personal hygiene practices impact upon the safety of the food being processed?
   2. Do the employees understand the process and the factors they must control to assure the preparation of safe foods?
   3. Will the employees inform management of a problem which could impact upon safety of food?
10. Conditions of storage between packaging and the end user
    1. What is the likelihood that the food will be improperly stored at the wrong temperature?
    2. Would an error in improper storage lead to a microbiologically unsafe food?
11. Intended use
    1. Will the food be heated by the consumer?
    2. Will there likely be leftovers?
12. Intended consumer
    1. Is the food intended for the general public?
    2. Is the food intended for consumption by a population with increased susceptibility to illness (e.g., infants, the aged, the infirmed, immunocompromised individuals)?
    3. Is the food to be used for institutional feeding or the home?

Source: US Food and Drug Administration (1997). **HACCP Principles & Application Guidelines**.

## Appendix 3 | Examples of How the Stages of Hazard Analysis are used to Identify and Evaluate Hazards

|  |  |  |  |
| --- | --- | --- | --- |
| **Hazard Analysis Stage** | | Frozen cooked beef patties produced in a manufacturing plant | Commercial frozen pre-cooked, boned chicken for further processing |
| **Stage 1 Hazard  Identification**  Determine potential  hazards associated with product | | Enteric pathogens (i.e., E. coli O157:H7 and Salmonella) | Staphylococcus aureus in finished product. |
| **Stage 2 Hazard Evaluation** | Assess severity of health consequences if potential hazard is not properly controlled. | Certain strains of S. aureus produce an enterotoxin which can cause a moderate foodborne illness. | Certain strains of S. aureus produce an enterotoxin which can cause a moderate foodborne illness. |
| Determine likelihood of occurrence of potential hazard if not properly controlled. | E. coli O157:H7 is of very low probability and salmonellae is of moderate probability in raw meat. | Product may be contaminated with S. aureus due to human handling during boning of cooked chicken. Enterotoxin capable of causing illness will only occur as S. aureus multiplies to about 1,000,000/g. Operating procedures during boning and subsequent freezing prevent growth of S. aureus, thus the potential for enterotoxin formation is very low. |
| Using information above, determine if this potential hazard is to be addressed in the HACCP plan. | The HACCP team decides that enteric pathogens are hazards for this product.  **Hazards must be addressed in the plan.** | The HACCP team determines that the potential for enterotoxin formation is very low. However, it is still desirable to keep the initial number of S. aureus organisms low. Employee practices that minimize contamination, rapid carbon dioxide freezing and handling instructions have been adequate to control this potential hazard.  **Potential hazard does not need to be addressed in plan.** |

**NB: For illustrative purposes only. The potential hazards identified may not be the only hazards associated with the products listed. The responses may be different for different establishments.**

## Appendix 4 | Example of a CCP Decision Tree

**Q3**

**Critical Control Point**

No

**Is control measure at this step essential, in combination with other control measures, but out of control does not automatically implicate there is an immediate food safety risk?**

Is the step specifically designed to eliminate or reduce the likely occurrence of a hazard to an acceptable level?

No

Yes

No

No

Yes

**Q1**

Yes

Stop\*

Is the step specifically designed and essential to eliminate or reduce the likely occurrence of a hazard to an acceptable level by it self?

Not a CCP

Is control at this step necessary for safety?

Modify steps in the process or product

Do preventative control measure(s) exist for the identified hazard (including control measures upstream)?

**Q2**

Operational measures

**Critical Control Point**

No

Yes

Will a subsequent step eliminate identified hazard(s) or reduce likely occurrence to acceptable levels?

Operational measures

**Q4**

Stop\*

Yes

No

Not a CCP

Could contamination occur, with identified hazard(s) in excess of acceptable level(s), or could this increase to unacceptable levels?

## Appendix 5 | Examples of Verification Activities

1. Verification procedures may include:
   1. Establishment of appropriate verification schedules.
   2. Review of the HACCP plan for completeness.
   3. Confirmation of the accuracy of the flow diagram.
   4. Review of the HACCP system to determine if the facility is operating according to the HACCP plan.
   5. Review of CCP monitoring records.
   6. Review of records for deviations and corrective actions.
   7. Validation of critical limits to confirm that they are adequate to control significant hazards.
   8. Validation of HACCP plan, including on-site review.
   9. Review of modifications of the HACCP plan.
   10. Sampling and testing to verify CCPs.
2. Verification should be conducted:
   1. Routinely, or on an unannounced basis, to assure CCPs are under control.
   2. When there are emerging concerns about the safety of the product.
   3. When foods have been implicated as a vehicle of foodborne disease.
   4. To confirm that changes have been implemented correctly after a HACCP plan has been modified.
   5. To assess whether a HACCP plan should be modified due to a change in the process, equipment, ingredients, etc.
3. Verification reports may include information on the presence and adequacy of.
   1. The HACCP plan and the person(s) responsible for administering and updating the HACCP plan.
   2. The records associated with CCP monitoring.
   3. Direct recording of monitoring data of the CCP while in operation.
   4. Certification that monitoring equipment is properly calibrated and in working order.
   5. Corrective actions for deviations.
   6. Sampling and testing methods used to verify that CCPs are under control.
   7. Modifications to the HACCP plan.
   8. Training and knowledge of individuals responsible for monitoring CCPs.
   9. Validation activities.

Source: US Food and Drug Administration (1997). **HACCP Principles & Application Guidelines**.

## Appendix 6 | Examples of HACCP Records

1. Ingredients for which critical limits have been established.
   1. Supplier certification records documenting compliance of an ingredient with a critical limit.
   2. Processor audit records verifying supplier compliance.
   3. Storage records (e.g., time, temperature) for when ingredient storage is a CCP.
2. Processing, storage and distribution records
   1. Information that establishes the efficacy of a CCP to maintain product safety.
   2. Data establishing the safe shelf life of the product; if age of product can affect safety.
   3. Records indicating compliance with critical limits when packaging materials, labelling or sealing specifications are necessary for food safety.
   4. Monitoring records.
   5. Verification records.
3. Deviation and corrective action records.
4. Employee training records that are pertinent to CCPs and the HACCP plan.
5. Documentation of the adequacy of the HACCP plan from a knowledgeable HACCP expert.

1. These food safety regulations are the Canadian Food Safety Enhancement Programme (CFSEP); the US Food Safety Modernization Act (FSMA) and the European Union (EU) Council Directives 93/43/EEC governing Hygiene of Food Stuffs and 94/356/EC Regulations governing “Own Checks”. The implementation of the HACCP System is now mandatory with these laws. [↑](#footnote-ref-1)