

WHITEPAPER

Developing a HACCP Plan

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QUICK SUMMARY

This whitepaper will cover the specific methodology employed when developing a HACCP plan. This includes the 12 tasks in HACCP and the seven principles as defined in the Hazard Analysis and Critical Control Point (HACCP) system and guidelines for its application, which was adopted during the twenty-second session of the Codex Alimentarius Commission in 1997 and included as Annex to the Recommended International Code of Practice - General Principles of Food Hygiene.

A previous draft of the Hazard Analysis and Critical Control (HACCP) system and guidelines for its application was included as Appendix II to ALINORM 97/13 and was adopted by the twentieth session of the Codex Alimentarius Commission in 1993.

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INTRODUCTION

HACCP is the most widely used risk based tool for developing food safety management programs. Its principles require the user to identify potential hazards relating to a specific product or process, to determine the risk of these hazards impacting on consumers and where critical to put in place monitoring and control procedures. Developing an effective HACCP plan requires a clear understanding of the principles and specific steps involved in a HACCP study. This whitepaper covers in detail these requirements and illustrates how users can build a plan capable of identifying and controlling food safety hazards relevant to their products and processes. The methodology covered in this whitepaper is based on the Codex Alimentarius Commission guidelines which is cited in most food safety standards. We have used the core document developed by Codex to ensure alignment with legal and commercial requirements. We have developed this content in appropriate areas and use the Safefood 360 food safety management platform to illustrate how the requirements are met.

1 HISTORY AND BACKGROUND OF THE HACCP SYSTEM

1.1 History of HACCP

HACCP is the most important food safety tool employed across the global food industry. Due to its systematic and preventive approach it has gained widespread acceptance from governmental agencies, global food standards (GFSI) and codes of practice.

The HACCP concept has its origins in the 1960's when the Pillsbury Company under the direction of the United States Army and the United States National Aeronautics and Space Administration (NASA) developed a system to ensure the production of safe food for the United States space programme. NASA needed to ensure that food produced and supplied to astronauts would not endanger their health during missions, putting the program at risk. Needless to say, if astronauts were to become ill from food poisoning the option of pulling in to the nearest hospital was not an option. NASA's demand for 100% safe food was unrealistic. Pillsbury therefore developed an approach which stated that while the food could not be guaranteed as safe, the process and conditions under which it was made could be assured, and thus maximising the safety of the products. HACCP emphasized control of the process as opposed to final product inspection and testing. Pillsbury presented the HACCP concept publicly at a conference for food protection in 1971. These principles were introduced into regulations for low-acid canned food in 1974 by the United States Food and Drug Administration (FDA). In the early 1980's, the HACCP approach was adopted by other major food companies and in the 1990's found its way into global legislation. In recent years it has become the most commonly cited methodology for risk based food safety systems in global standards including the GFSI.

1.2 The CODEX Alimentarius General Principles of Food Hygiene

The Codex Alimentarius Commission have adopted *Guidelines for the application of the Hazard Analysis Critical Control Point (HACCP) system*. The commission was also informed that the draft revised General Principles of Food Hygiene would incorporate the HACCP approach. The Codex General Principles of Food Hygiene sets out the requirements for good food hygiene and includes the principles for HACCP Ref: *General Principles of Food Hygiene* [CAC/RCP 1-1969, Rev 3 (1997)]. These controls are internationally recognized and underpin the need for food safety for human consumption and international trade.

1.3 Advantages of HACCP

HACCP has a number of advantages for the management of food safety.

- It focuses on those critical points in food processing and handling required for safe food production
- Science based and systematic allowing for the specific identification of food safety hazards
- Requires the implementation of measures to control these hazards where significant

- Employs the principle of risk assessment allowing prevention to be based on the control program rather than inspection and testing
- Better use of resources
- Standardization of hazard management allowing for easier auditing and inspection by second and third parties

In theory, the HACCP system can be applied across all stages of the food supply chain. It is designed to supplement and work alongside other management systems of control for quality and GMP. Global food safety standards such as those under the GFSI require these systems to be integrated with HACCP to form a total food safety system.

1.4 Application of HACCP

HACCP is not intended to control all hazards that may impact on a specific stage of the food supply chain. Rather it is intended to build on the existing best practices employed in these sectors and focus on specific hazards and steps where significant hazards need special control. For this reason, HACCP assumes a certain level of good agricultural practices (GAP) or good manufacturing practices (GMP) are already in place.

In terms of its successful application, HACCP like all risk management systems, requires sufficient commitment from all stakeholders including management. The application of the specific principles also require a team possessing the various skills needed to produce safe food including microbiology, public health, food technology, environmental health, chemistry, engineering, etc.

1.5 HACCP and Food Safety Standards

Food industries, retailers and regulatory agencies have all adopted the principles of HACCP and the requirement for food businesses to install it in their operation. For example, the Global Food Safety Initiative (GFSI) requires all schemes benchmarked against its guidance document to have HACCP as part of the scheme. Large food retailers like Tesco, Woolworths and M&S have developed their own set of technical standards which include HACCP as a core requirement. In recent years changes in the global legal framework, e.g. FSMA, have led to a dramatic increase in the need for developed and developing nations to install HACCP to conduct trade.

2 THE CODEX GUIDELINES FOR THE APPLICATION OF THE HACCP SYSTEM

2.1 The HACCP System

The purpose of the HACCP system is the identification of specific food safety hazards which can potentially cause illness, injury or death if consumed and to put in place controls for these. The focus of the controls is on preventing these hazards either entering the system or their elimination or reduction to an acceptable level.

2.2 Definitions

The following are definitions of key words and terms employed in the HACCP system.

<i>Control (verb):</i>	To take all necessary actions to ensure and maintain compliance with criteria established in the HACCP plan.
<i>Control (noun):</i>	To state wherein correct procedures are being followed and criteria are being met.
<i>Control measure:</i>	Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.
<i>Corrective action:</i>	Any action to be taken when the results of monitoring at the CCP indicate a loss of control.
<i>Critical Control Point (CCP):</i>	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.
<i>Critical limit:</i>	A criterion which separates acceptability from unacceptability.
<i>Deviation:</i>	Failure to meet a critical limit.
<i>Flow diagram:</i>	A systematic representation of the sequence of steps or operations used in the production or manufacture of a particular food item.
<i>HACCP:</i>	A system which identifies, evaluates, and controls hazards which are significant for food safety.
<i>HACCP plan:</i>	A document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety in the segment of the food chain under consideration.
<i>Hazard:</i>	A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.
<i>Hazard analysis:</i>	The process of collecting and evaluating information on hazards, and conditions leading to their presence, to decide which are significant for food safety and therefore should be addressed in the HACCP plan.
<i>Monitor:</i>	The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.
<i>Step:</i>	A point, procedure, operation or stage in the food chain including raw materials, from primary production to final consumption.
<i>Validation:</i>	Obtaining evidence that the elements of the HACCP plan are effective.
<i>Verification:</i>	The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan.

2.3 Principles of the HACCP System

The HACCP system consists of the seven principles. Each principle is designed to develop the level of understanding of hazards, their identification and implementation of controls. The principles are defined by CODEX as follows:

Principle 1: Conduct a hazard analysis

Identify the potential hazard(s) associated with food production at all stages, from primary production, processing, manufacture and distribution until the point of consumption. Assess the likelihood of occurrence of the hazard(s) and identify the measures for their control.

Principle 2: Determine the Critical Control Points (CCPs)

Determine the points, procedures or operational steps that can be controlled to eliminate the hazard(s) or minimize its (their) likelihood of occurrence. A "step" means any stage in food production and/or manufacture including the receipt and/or production of raw materials, harvesting, transport, formulation, processing, storage, etc.

Principle 3: Establish critical limit(s)

Establish critical limit(s) which must be met to ensure the CCP is under control.

Principle 4: Establish a system to monitor control of the CCP

Establish a system to monitor control of the CCP by scheduled testing or observations.

Principle 5: Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.

Principle 6: Establish procedures for verification to confirm that the HACCP system is working effectively.

Principle 7: Establish documentation concerning all procedures and records appropriate to these principles and their application.

HACCP requires management commitment. Without commitment, it is not possible to conduct the required activities to develop the final HACCP plan. Another key requirement underpinning the principles of HACCP is data and its quality. To effectively apply the principles, the HACCP team must collect, compile and use data from a variety of sources. Activities such as hazard identification, analysis, risk assessment and validation all require quality data.

HACCP is not designed to replace existing standards of good practice or legislation in a food sector. As a system it sits on top of these to separate the critical aspects of a specific process or operation and identify the relevant CCP's where applicable. HACCP while an essential tool for the management of food safety, does require a flexible approach, taking into account the nature of the process, product and operation under study.

2.4 Application of HACCP Principles

Codex goes on to define how these principles are practically applied using a logical sequence of steps. By following each step in sequence, users can develop a HACCP plan which is based on their actual food product/process and which is effective in controlling the specific hazards identified in the hazard analysis.

The following summarises each step:

Step 1: Assemble HACCP team

The first step is to put together a team of individuals with the necessary skills, knowledge and experience to develop an effective HACCP plan. By its nature this team will be multidisciplinary and ideally will be made up of team members working directly on the site. Where required, expertise may be obtained from other external sources. In all cases, the internal HACCP team will retain ultimate responsibility for the HACCP system. One of the initial tasks of the HACCP team is to clearly define the scope of the HACCP plan including the product/process to be assessed, segments of the food chain to be included and the general classes of hazards to be included.

Step 2: Describe product

In order to identify all the factors which can impact on the safety of the product under study, the HACCP team must first clearly describe the product including composition, physical/chemical structure (including A_w , pH, etc.), packaging, durability and storage conditions and method of distribution.

Step 3: Identify intended use

The intended use of the product is important since the same hazard may impact on different groups or populations. For this reason the intended use should define specific and vulnerable groups who may use the product. The team will also need to include how the product will be used, e.g. ready to eat (RTE) or requires further preparation by the consumer.

Step 4: Construct flow diagram

A flow diagram is a graphical representation of the process steps involved in making the food product and is developed by the HACCP team. It should be comprehensive and cover all the steps in the processes and the defined scope of the HACCP study.

Step 5: On-site verification of flow diagram

Following the development of the flow diagram, the HACCP team should confirm the actual processing operation against it. Amendments should be made where required prior to formal verification and sign off by the HACCP team.

Step 6: List all potential hazards associated with each step, conduct a hazard analysis, and consider any measures to control identified hazards (see Principle 1)

Principle 1 is introduced at this step in HACCP. It requires the HACCP step to list all hazards that may be reasonably expected to occur at each step covered in the scope of the HACCP study. This may include primary production, processing, manufacture, and distribution until the point of consumption. Next, the HACCP team should conduct a hazard analysis to identify which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food. In conducting the hazard analysis, wherever possible the following should be included:

- the likely occurrence of hazards and severity of their adverse health effects
- the qualitative and/or quantitative evaluation of the presence of hazards
- survival or multiplication of microorganisms of concern
- production or persistence in foods of toxins, chemicals or physical agents; and conditions leading to the above.

Point one above also introduced the application of risk assessment as the key method of identifying significant hazards. Finally, the HACCP team must consider what control measures, if any, exist which can be applied for each hazard. More than one control measure may be required to control a specific hazard(s) and more than one hazard may be controlled by a specified control measure.

Step 7: Determine Critical Control Points (see Principle 2)

The main tool for identifying CCP's is the Codex decision tree. It can in many cases assist the user in the process of separating out steps which are critical to food safety but it is not always logical or relevant to all processes. Users must make a judgement on this when considering its use. It may need to be modified to ensure effective CCP identification. The decision tree can sometimes lead to the need to modify the step in the process where control is necessary for safety but no control measure exists.

Step 8: Establish critical limits for each CCP (see Principle 3)

Clear and specific limits must be set where a CCP has been identified. In some cases more than one critical limit may be required. Ideally the critical limit should be measurable and typically can cover criteria such as temperature, time, moisture level, pH, A_w , available chlorine, and sensory parameters such as visual appearance and texture.

Step 9: Establish a monitoring system for each CCP (see Principle 4)

Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits. The monitoring procedures must be able to detect loss of control at the CCP. It should facilitate adjustment of the process prior to loss of control. All records and documents associated with monitoring CCPs must be signed by the person(s) doing the monitoring and by a responsible reviewing official(s) of the company.

Step 10: Establish corrective actions (see Principle 5)

For each CCP there must be clearly defined actions in the event of any deviations from critical limits. Actions must be capable of bringing the CCP back under control and address the disposition of any suspect products. Records must be kept.

Step 11: Establish verification procedures (see Principle 6)

Verification is essential to ensure that the plan you have developed is being fully complied with. This can include auditing methods, procedures and tests, review of the HACCP system and its records, review of deviations and product dispositions.

Validation should also be considered where you confirm the efficacy of all elements of the HACCP plan.

Step 12: Establish documentation and record keeping (see Principle 7)

HACCP records should be maintained of the entire HACCP system. In addition, HACCP procedures should be documented and approved consistent with the size and complexity of the operation. Documentation includes hazard analysis, CCP determination and Critical limit determination. Record examples include CCP monitoring activities, deviations and associated corrective actions and any modifications to the HACCP system.

3 ASSEMBLE THE HACCP TEAM - STEP 1

3.1 The HACCP Team

The HACCP team should be appointed following public declaration of commitment by senior management. Once received, the team should be assembled based on a review of the knowledge, skills and experience required. Therefore the team will be multidisciplinary and may be made up of internal and external members especially where the internal team is small. Ensure the team includes personnel who are directly involved in daily processing activities and who know the process well. Ideally the team should have between two and six members. Additional members can be temporarily co-opted as required. Key criteria to be considered when determining the team composition include:

- Knowledge of hazard identification and HACCP techniques
- Knowledge of possible critical control points
- Knowledge of local engineering
- Knowledge of local operations
- Knowledge of food science, microbiology and technology

The team members and their specific roles in the HACCP team should be documented.

Figure: Sample HACCP Team

HACCP Team		
Team Members	Name	Function
	Kristine Dougherty	Food Safety / Technology
	Patrick Song	Operations
	Alex May	Maintenance
	Malcolm Wagner	Team Leader
		Add Line
Expert Assistance	The HACCP study was support by external experts including Food Focus (HACCP Principles) and Microtech Laboratories (Microbiology).	

Scope

One of the first tasks of the HACCP team should be to identify the scope of the HACCP plan. This should include the limit of the study to a specific product and process, type(s) of hazards to be included (e.g. biological, chemical, physical) and the part of the food chain to be studied.

Fig: Example of HACCP scope

Study Details	
Product / Process	Cooked Meat
Scope	The HACCP plan covers cooked meat products produced by the company at its premises. Specifically it covers fully cooked, not shelf stable meat product. The product is boneless and vacuum packed for shipment to the customer. The HACCP study scope starts at the sourcing and receiving of raw materials and ingredients through processing and packing and finished at distribution and information provision to the consumer. The study also address all major hazard categories including chemical, physical and biological.
Notes	The HACCP plan has been developed based on the principles of CODEX and in compliance with global food standards.

HACCP Team Leader

All HACCP teams should have a designated HACCP team leader whose role is to:

- Appoint the HACCP team with the required composition
- Coordinate and manage the team's work
- Take responsibility for the implementation and maintenance of the HACCP system
- Ensure the principles and steps are followed
- Chair HACCP team meetings
- Represent the team before management
- Provide management with budgets and project plans relating to HACCP

3.2 Training Requirements

Training requirements for HACCP team varies depending on the team member and the requirements of specific customers and standards. It is essential that the team leader receives full training in the Codex General Principles of Food Hygiene and the guidelines for the application of the HACCP system to ensure that the team will work together with a common focus and use the same approach and terminology. Other team members should also receive training commensurate with their role and responsibilities.

Figure: Sample HACCP Training Program

The screenshot shows a web-based form for a HACCP Training Programme. The interface has a blue header with the company name 'Celtic Pure Ltd' and navigation tabs: Dashboard, HACCP, Management, PRP Control, Monitoring, and Utilities. The 'HACCP' tab is active, and the 'Training Programme (2)' section is selected. The form fields are as follows:

- Name:** HACCP Training Workshop
- Description:** Instruct learners in the origins and reasons for having a Food Safety Management System.
- Trainer:** A dropdown menu showing 'Trainer' and 'George Howlett' with an 'Add Line' button below it.
- Location:** Celtic Pure Ltd
- Duration:** 8 Hours
- Risk:** High (with a warning icon) and Justification: Intolerable risk - specific action required
- Learning Objectives:**
 1. Describe the origins and reasons for having an effective Food Safety Management System (FSMS).
 2. Understand and interpret the requirements of the HACCP.
 3. Understand the principles of HACCP.
 4. Identify the main hazards associated with food, water and beverages.
 5. Develop a practical HACCP system including plan, controls and records.
 6. Impart the knowledge to learners so that they can develop, document and implement a HACCP system.
- Content:**
 1. Origins and Principles of Food Safety Management.
 2. Current Legal and commercial reasons for HACCP.

3.3 Resources

HACCP requires resources. Management must allocate the necessary resources for the HACCP study including:

- Time for team meetings and administration
- Costs of initial training
- Necessary documents
- Access to analytical laboratories

- Access to information sources to answer questions raised by the team (e.g. universities, public and private research authorities, government and public authorities, scientific and technical literature, databases)

HACCP team meetings shall be held regularly over the implementation phase and thereafter to ensure it is maintained. Meetings should be conducted under a clearly defined agenda. A timeline for the completion of the HACCP set up should be decided at the initial meeting(s) and adhered to by the team. Progress should be reviewed. The following is an example of a HACCP team meeting record.

FIGURE: HACCP TEAM REVIEW MEETING

HACCP Review (6)				Management Review								
<div> COMPLETED <div>Actions</div> </div>												
No.	Date	Name	Reason for Review	HACCP Bottled								
6	10/10/2013	HACCP Review (6)	Process Step Change									
HACCP Review Details												
Date	10/10/2013											
Reason for Review	Process Step Change											
Meeting Chaired By	Claire Braiden											
Minutes Taken By	Claire Braiden											
HACCP Plan	Bottled Water (1)											
Notes	Amendment to Daily HACCP Record											
Documents Required	<div>Procedure / Record</div> <div> Daily Hacop Record </div>											
In Attendance	<table border="1"> <thead> <tr> <th>Employee</th> <th>Position</th> </tr> </thead> <tbody> <tr> <td>Brian Walsh</td> <td>Asst. Technical/Quality Manager</td> </tr> <tr> <td>Timothy Oliver</td> <td>Operations Manager</td> </tr> <tr> <td>Padraig Mc Eneaney</td> <td>Managing Director</td> </tr> </tbody> </table>			Employee	Position	Brian Walsh	Asst. Technical/Quality Manager	Timothy Oliver	Operations Manager	Padraig Mc Eneaney	Managing Director	Apologies
Employee	Position											
Brian Walsh	Asst. Technical/Quality Manager											
Timothy Oliver	Operations Manager											
Padraig Mc Eneaney	Managing Director											
Signed: Claire Braiden, 10/10/2013 13:31												
HACCP Review Report												
Executive Summary												
Agenda Items & Report												
Item	Reviewed											
HACCP Principles Used	No											
HACCP Team (Membership & Competency)	No											
External Expertise (Membership & Competency)	No											
Product Description	No											
Intended Use	No											
Flow Diagrams & Verification	No											
Hazard Analysis & Risk Assessment	No											
Control Measure Assessment	No											
CCP Determination	No											
Critical Limits	No											
Monitoring Procedures	No											
Records	Yes											
Critical Limits	No											
Corrective Actions	No											
CCP Monitor Training	No											

4 DESCRIBE PRODUCT AND IDENTIFY INTENDED USE - STEPS 2 AND 3

4.1 Product Description

The HACCP team should fully describe each product including all ingredients, processing methods, and packaging materials used in the formulation of the product. This will assist in the identification of all possible hazards associated with the product. It should include:

- Product name (common name) or group of product names (the grouping of like products is acceptable as long as all hazards are addressed)
- Important end-product characteristics: properties or characteristics of the food under review that are required to ensure its safety (e.g. A_w , pH/preservatives)
- How the product is to be used (i.e. ready-to-eat/further processing required, heated prior to consumption)
- Type of package, including packaging material and packaging conditions (e.g. modified atmosphere)
- Shelf-life, including storage temperature and humidity if applicable
- Where the product will be sold (e.g. retail, institutions, further processing)
- Labelling instructions (e.g. handling and usage instructions)
- Special distribution control (e.g. shipping conditions)

The HACCP team can use the following questions below to help in the development of the product description.

Formulation of product	<ul style="list-style-type: none"> • What raw materials or ingredients are used? • Are microorganisms of concern likely to be present in or on these materials, and if so what are they? • If food additives or preservatives are used, are they used at acceptable levels, and at those levels do they accomplish their technical objective? • Will the pH of the product prevent microbial growth or inactivate particular pathogens? • Will the A_w of the product prevent microbial growth? • What is the oxidation/reduction potential (Eh) of the product?
Processing and preparation check-list	<ul style="list-style-type: none"> • Can a contaminant reach the product during preparation, processing or storage? • Will microorganisms or toxic substances of concern be inactivated during cooking, reheating or other processing? • Could any microorganisms or toxins of concern contaminate food after it has been heated? • Would more severe processing be acceptable or desirable? • Is the processing based on scientific data? How does the package or container affect survival and/or growth of microorganisms? • How much time is taken for each step of processing, preparation, storage and display? • What are the conditions of distribution?

Figure: Sample Product Description

Product Data	
Ingredients, Composition & Recipe	Raw meat, water, salt, dextrose, sugar, phosphates, nitrites, acids & spices.
Origin of Ingredients	Raw meat is sourced locally. Other ingredients are sourced from a variety of countries including domestic.
Physical & Chemical Properties	Low pH.
Treatment & Processing	Curing, cooking and cooling.
Packaging System	Vacuum Packaged.
Storage & Distribution Conditions	Maximum temperatures: Storage: 5oC ; Distribution: 5oC.
Shelf life	60 days from the date of packing at stated storage conditions.
Instructions for Use	Keep refrigerated at maximum 5oC. Consume with 3 days of purchase.
Potential Misuse	Use beyond shelf life. Temperature abuse after purchasing and prior to consumption.
Intended Use & Target Consumers	Fully cooked, not shelf stable, ready to eat product. Intended for consumption by the general population. purchased or reheated before consumption. It will be sold at retail service/self service or food service. No specifically as product consumers.

Product Ingredients and Incoming Materials

The HACCP team should list the hazard(s) also associated with ingredients and incoming materials.

Figure: Sample Ingredient Hazards

Hazards	Hazard	Notes
	Acanthamoeba spp., Naegleria fowleri and other amoebae	Notes
	Egg substitutes, e.g., Egg Beaters	Notes
	Add Line	
Risk	<div>  Medium </div> <div>Justification</div>	
	Undesirable risk - evaluation required, specific actions may be required	

4.2 Identification of Intended Use

This is the normal use by end-users or consumers. This can include specifying where the product will be sold, target consumer group(s), and sensitive portion of the population (i.e. elderly, immune-suppressed, pregnant women and infants).

Figure: Intended Use & Target Consumers



5 CONSTRUCT FLOW DIAGRAM AND ON-SITE CONFIRMATION OF FLOW DIAGRAM - TASKS 4 AND 5

5.1 Flow Diagram [Step 4]

A picture paints a thousand words. In order for the HACCP team to correctly identify all hazards at each step, it must first identify all steps. This is best done by the team developing a flow chart which shows each step in sequence and the relationship between each step. The team can then focus on each step in sequence and list the relevant hazards. Information which can be included in the flow diagram includes:

- All ingredients and packaging used
- Sequence of all process operations (including raw material addition)
- Time/temperature including delays
- Flow conditions for liquids and solids
- Product recycle/rework loops
- Equipment design features

Figure: Sample Flow Diagram



5.2 Plant Schematic

A plant schematic should be developed to show various flows other than product. It can also be used to show rooms, locations, personnel flow, waste flow etc. It can aid in the identification of any areas of potential cross-contamination.

Figure: Plant Schematics



5.3 On-site Confirmation of Flow Diagram and Plant Schematic (Step 5)

Once the process flow diagram and plant schematic have been drafted, they must be confirmed by an on-site inspection for accuracy and completeness. This will ensure that all the major process operations have been identified. All members of the HACCP team should be involved in the flow diagram confirmation. Adjustments should be made to the flow diagram, as necessary based on the actual operations observed.

Figure: Verification of Flow Diagram

Verified By	User	Status	Date Verified
	Tim Oliver	Verified	29/10/2013
	Brian Walsh	Verified	29/10/2013
	Padraig McEneaney	Verified	29/10/2013
	Claire Braiden	Verified	29/10/2013

6 LIST ALL POTENTIAL HAZARDS ASSOCIATED WITH EACH STEP, CONDUCT A HAZARD ANALYSIS AND CONSIDER ANY MEASURES TO CONTROL IDENTIFIED HAZARDS - STEP 6 / PRINCIPLE 1

6.1 Hazard Analysis

Hazard analysis is the first HACCP principle and requires the team to identify all potential hazards that may exist. Hazard identification is critical for developing an effective HACCP plan. It requires technical expertise and scientific background including food science and HACCP.

The Codex defines a hazard as "A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect" which are of such a nature that their elimination or reduction to acceptable levels is essential to the production of safe food. Hazards will vary depending upon sources of ingredients, formulations, processing equipment, processing and preparation methods, duration of processes and storage conditions. When conducting hazard analysis all biological, chemical and physical hazards should be considered. In addition the analysis can separate out other hazard categories such as allergens and radiological.

6.2 Potential Hazards

There are three main categories of hazards - biological, chemical and physical.

Biological hazards

Foodborne biological hazards include microbiological organisms such as bacteria, viruses, fungi and parasites. These organisms are commonly associated with humans and with raw products entering the food establishment. Many of these microorganisms occur naturally in the environment where foods are grown. Most are killed or inactivated by cooking, and numbers can be minimized by adequate control of handling and storage practices (hygiene, temperature and time).

Examples of Biological Hazards	
Bacteria [spore-forming]	Bacteria [non-spore-forming]
<i>Clostridium botulinum</i>	<i>Brucella abortis</i>
<i>Clostridium perfringens</i>	<i>Brucella suis</i>
<i>Bacillus cereus</i>	<i>Campylobacter</i> spp.
	<i>Pathogenic Escherichia coli</i> [E.coli 0157:1-17, EHEC, EIEC, ETEC, EPEC]
	<i>Listeria monocytogenes</i>
	<i>Salmonella</i> spp. [<i>S. typhimurium</i> , <i>S. enteritidis</i>]
	<i>Shigella</i> [<i>S. dysenteriae</i>]
	<i>Staphylococcus aureus</i>
	<i>Streptococcus pyogenes</i>
	<i>Vibrio cholerae</i>
	<i>Vibrio parahaemolyticus</i>
	<i>Vibrio vulnificus</i>
	<i>Yersinia enterocolitica</i>

The majority of reported foodborne disease outbreaks and cases are caused by pathogenic bacteria. A certain level of these microorganisms can be expected with some raw foods. Improper storage or handling of these foods can contribute to a significant increase in the level of these microorganisms. Cooked foods often provide fertile media for rapid growth of microorganisms if they are not properly handled and stored.

Examples of Biological Hazards [continued]	
Viruses Hepatitis A and E Norwalk virus group Rotavirus	Protozoa and parasites <i>Cryptosporidium parvum</i> <i>Diphyllbothrium latum</i> <i>Entamoeba histolytica</i> <i>Giardia lamblia</i> <i>Ascaris lumbricoides</i> <i>Taenia solium</i> <i>Taenia saginata</i> <i>Trichinella spiralis</i>

Viruses can be foodborne/water-borne or transmitted to food by human, animal or other contact. Unlike bacteria, viruses are unable to reproduce outside a living cell. They cannot therefore replicate in food, and can only be carried by it.

Parasites are most often animal host-specific and can include humans in their life cycles. Parasitic infections are commonly associated with undercooked meat products or contaminated ready-to-eat food. Parasites in products that are intended to be eaten raw, marinated or partially cooked can be killed by effective freezing techniques.

Fungi include moulds and yeasts. Fungi can be beneficial, as they can be used in the production of certain foods (e.g. cheese). However, some fungi produce toxic substances (mycotoxins) which are toxic for humans and animals.

Figure: Sample Hazard Identification for Biological Hazard

Hazard Details

Process Steps

Hazard Category

Nature

Details / Source

Hazards

Cooking

Biological

Survival

Potential survival of pathogens.

Hazard	Description	
Listeria Monocytogenes (Bacteria)	This is a Gram-positive bacterium, motile by means of flagella. Some studies suggest that 1-10% of humans may be intestinal carriers of L. monocytogenes.	X
Escherichia coli O157:H7 (Bacteria)	Currently, there are four recognized classes of enterovirulent E. coli (collectively referred to as the EEC group) that cause gastroenteritis in humans. Among these is the enterohemorrhagic (EHEC) strain designated E. coli O157:H7.	X
Clostridium Botulinum (Bacteria)	Clostridium botulinum is an anaerobic, Gram-positive, spore-forming rod that produces a potent neurotoxin. More detailed description - relevant to the specific process / product	X
Bacillus cereus and other Bacillus spp. (Bacteria)	Bacillus cereus is a Gram-positive, facultatively aerobic sporeformer whose cells are large rods and whose spores do not swell the sporangium.	X
Staphylococcus Aureus (Bacteria)	S. aureus is a spherical bacterium (coccus) which on microscopic examination appears in pairs, short chains, or bunched, grape-like clusters. These organisms are Gram-positive.	X

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Chemical hazards

Chemical contaminants in food may be naturally occurring or may be added during the processing of food. Harmful chemicals at high levels have been associated with acute cases of foodborne illnesses and can be responsible for chronic illness at lower levels.

Examples of Chemical Hazards	
Naturally occurring chemicals Allergens Mycotoxins (e.g. aflatoxin) Scombrototoxin (histamine) Ciguatoxin Mushroom toxins Shellfish toxins · Paralytic shellfish poisoning (PSP) · Diarrhoeic shellfish poisoning (DSP) · Neurotoxic shellfish poisoning (NSP) · Amnesic shellfish poisoning (ASP) · Pyrrolizidine alkaloids · Phytohaemagglutinin	Added chemicals Polychlorinated biphenyls (PCBs) Agricultural chemicals · Pesticides · Fertilizers · Antibiotics · Growth hormones Prohibited substances · Direct · Indirect Toxic elements and compounds · Lead · Zinc · Cadmium · Mercury · Arsenic · Cyanide Food additives Vitamins and minerals Contaminants · Lubricants · Cleaners · Sanitizers · Coatings · Paints · Refrigerants · Water or steam treatment chemicals · Pest control chemicals
From packaging materials Plasticizers Vinyl chloride Printing/coding inks Adhesives Lead Tin	

Physical hazards

Illness and injury can result from hard foreign objects in food. These physical hazards can result from contamination and/or poor practices at many points in the food chain from harvest to consumer, including those within the food establishment. Examples include wood, plastic and metal.

Material	Injury potential	Sources
Glass	Cuts, bleeding; may require surgery to find or remove	Bottles, jars, light fixtures, utensils, gauge covers, etc.
Wood	Cuts, infection, choking; may require surgery to remove	Field sources, pallets, boxes, building materials
Stones	Choking, broken teeth	Fields, buildings
Metal	Cuts, infection; may require surgery to remove	Machinery, fields, wire, employees
Insulation	Choking; long-term if asbestos	Building materials
Bone	Choking	Improper processing
Plastic	Choking, cuts, infection; may require surgery to remove	Packaging, pallets, equipment
Personal effects	Choking, cuts, broken teeth; may require surgery to remove	Employees

6.3 Sources of Information for Hazard Analysis

The information required concerning potential hazards associated with a specific food can be obtained from a variety of sources including the following.

- Reference texts
- Websites
- Food Safety Standards
- Codes of Practice
- Legislation
- Company complaint files
- Scientific research and review papers
- Epidemiological data on foodborne illness or disease

6.4 How to Conduct a Hazard Analysis

After listing all the hazards (biological, chemical or physical) that may be reasonably expected at each step from primary production, processing, manufacturing and distribution until the point of consumption, the HACCP team should assess the potential significance or risk of each hazard by considering its likelihood of occurrence and severity. The estimate of the risk of a hazard occurring is based upon a combination of experience, epidemiological data and information in the technical literature. Severity is the degree of seriousness of the consequences of a hazard if the hazard is not controlled. There may be differences of opinion even among experts as to the risk of a hazard.

Figure: Sample Risk Assessment for Biological Hazard

Risk Assessment	
Risk	High
Probability	Intolerable risk - specific action required 4 - High Probability - Could occur 2 or 3 times a year
Severity	4 - Severe symptoms, hospitalisation, some deaths
Report	Medium Risk - A variety of pathogens may be present in the raw meat. Proper finished internal core temperature based on time/temperature schedule to reduce risk of pathogen survival.

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Hazards addressed under the HACCP system must be of such a nature that their prevention, elimination or reduction to acceptable levels is essential to the production of safe foods. Hazards of a low probability of occurrence and a low severity should not be addressed under the HACCP system but may be addressed through the good manufacturing practices (GMPs) contained in the Codex General Principles of Food Hygiene. Five areas of review can assist the team in identifying all potential hazards and understanding their nature.

1. Review incoming material	<p>For example, a ready-to-eat product must not contain pathogens in amounts that may harm the consumer. On the other hand, if the end-product is not a ready-to-eat product, some microorganisms may be acceptable in the end-product if a further operation (e.g. cooking at home) will eliminate or reduce them to an acceptable level. To facilitate the identification of potential hazards, answer the following questions for each incoming material:</p> <ul style="list-style-type: none"> • Could pathogenic microorganisms, toxins, chemicals or physical objects possibly be present on/in this material? • Are any returned or reworked products used as ingredients? If yes, is there a hazard linked to that practice? • Are preservatives or additives used in the formulation to kill microorganisms or inhibit their growth or to extend shelf-life? • Are any ingredients hazardous if used in excessive amounts? (for example, nitrites could be a chemical hazard if used excessively) • Could any ingredients, if used in amounts lower than recommended or if omitted altogether, result in a hazard because of microbial vegetative or sporulated cell outgrowth? • Does the amount and type of acid ingredients and the resulting pH of the final product affect growth or survival of microorganisms? • Do the moisture content and the water activity (A_w) of the final product affect microbial growth? Do they affect the survival of pathogens (parasites, bacteria, fungi)? • Should adequate refrigeration be maintained for products during transit or in holding?
2. Evaluate processing operations for hazards	<p>The objective of this activity is to identify all realistic potential hazards related to each processing operation, the product flow and the employee traffic pattern. This can be accomplished by reviewing the process flow diagram and the plant schematic and modifying them as follows:</p> <ul style="list-style-type: none"> • Assign a number to each processing step on the process flow diagram from receiving to shipping • Examine each step on the process flow diagram and determine if a hazard [biological, chemical or physical] exists for that operation • Review the plant schematic and employee traffic pattern in the same manner • To help in determining if a hazard exists, the following questions should be answered for each processing step: • Could contaminants reach the product during this processing operation? (consider personnel hygiene, contaminated equipment or material, cross-contamination from raw materials, leaking valves or plates, dead ends [niches], splashing, etc.) • Could any microorganisms of concern multiply during this processing operation to the point where they constitute a hazard? (consider temperature, time)

3. Observe actual operating practices	<p>The HACCP team must be very familiar with every detail of the operation under investigation. Any identified hazard must be recorded on the appropriate forms. The HACCP team shall:</p> <ul style="list-style-type: none"> • Observe the operation long enough to be confident that it comprises the usual process or practices • Observe the employees (e.g. could raw or contaminated product cross-contaminate workers' hands, gloves or equipment used for finished or post-process product?) • Observe hygienic practices and note the hazards • Analyse if there is a kill step [process which destroys all microorganisms] during the process (if so, attention should be focused on potential cross-contamination after this processing operation)
4. Take measurements	<p>It may be necessary to take measurements of important processing parameters to confirm actual operating conditions. Before measuring, make sure all devices are accurate and correctly calibrated. The following are examples of some of the measurements that may be done, depending on the product or process type:</p> <ul style="list-style-type: none"> • Measure product temperatures, considering heat processing and cooling or chilling operations: take measurements at the coldest point of the product when heat processing is evaluated and at the warmest point of the product when cooling or chilling is evaluated (frequently at the centre of the largest piece) • Measure time/temperature for cooking, pasteurizing, canning cooling (rates), storing, thawing, reconstituting, etc. • Measure the dimension of the containers used to hold foods being cooled and the depth of the food mass • Measure pressure, headspace, venting procedure, adequacy of container closure, initial temperatures and any other factors critical to the successful delivery of a scheduled process • Measure the pH of the product during processing and also of the finished product, measuring pH at room temperature whenever possible • Measure A_w of the product, running duplicate samples whenever possible (because of variations) and remembering to make corrections for ambient temperatures, as necessary • Sample collections, inoculated-pack studies and microbial challenge studies could be necessary when information on hazards is not otherwise available, for new products or for assessing expected shelf-life.
5. Analyse the measurements	<p>A qualified individual (with proper scientific background) must analyse the measurements to interpret correctly the data collected. For example:</p> <ul style="list-style-type: none"> • Plot time/temperature measurements using a computer or on graph paper • Interpret controlled data versus optimal growth temperatures of microorganisms and temperature ranges at which they can multiply • Estimate and evaluate probable cooling rates; interpret cooling rates and compare the measured temperatures with temperature ranges within which bacteria of concern multiply rapidly versus temperature at which growth begins, slows and ceases [see reference material]; determine whether covers are used on containers to cool down foods (which may delay cooling but may also prevent contamination); if containers are stacked against each other in a manner affecting cooling or heating time/evaluate the impact • Compare A_w and pH values to ranges at which pathogens multiply or are eliminated • Evaluate the shelf stability of the product

6.5 Control Measures

After the hazard analysis is completed, the team must then consider what control measures, if any, exist which can be applied for the control of each hazard. Control measures are any actions and activities that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level. More than one measure may be required to control a specific hazard and more than one haz-

and may be controlled by a specified measure.

Figure: Sample Control Measures

Preventive Measures	Measure	Notes
	Heat treatment	Cooking
	Standard Operating Procedure	Cooking

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Controlling hazards

Biological hazards can be controlled by limiting, removing or altering the growth kinetics microorganisms need to survive, grow and reproduce. They can be destroyed, eliminated or controlled by thermal processing (heating or cooking), freezing or drying. Food growers or processors should have three objectives for their HACCP programmes with regard to biological hazards:

- To eliminate or significantly reduce the hazard
- To prevent or minimize microbial growth and toxin production
- To control contamination

CONTROLLING BIOLOGICAL HAZARDS		
Control measures for bacteria	<ul style="list-style-type: none"> • Temperature/time control (proper control of refrigeration and storage time, for example, minimizes the proliferation of microorganisms) • Heating and cooking (thermal processing) for an adequate time and at an adequate temperature to eliminate microorganisms or reduce them to acceptable levels • Cooling and freezing • Fermentation and/or pH control (for example, lactic acid-producing bacteria in yoghurt inhibit the growth of other microorganisms that do not tolerate the acidic conditions and competition) • Addition of salt or other preservatives, which at acceptable levels may inhibit growth of microorganisms • Drying, which may use enough heat to kill microorganisms or may remove enough water from the food to prevent certain microorganisms from growing even when drying is conducted at lower temperatures • Packaging conditions (vacuum packaging, for example, can be used to inhibit microorganisms that require air to grow) • Source control, i.e. control of the presence and level of microorganisms by obtaining ingredients from suppliers who can demonstrate adequate controls over the ingredients [e.g. suppliers that follow an HACCP programme] • Cleaning and sanitizing, which can eliminate or reduce the levels of microbiological contamination • Personal and hygienic practices, which can reduce the levels of microbiological contamination 	
Control measures for viruses	<ul style="list-style-type: none"> • Thermal processing - heating or cooking methods such as steaming, frying or baking - which may destroy many but not all viruses (the type of virus determines the appropriate controls) • Personal hygienic practices, including the exclusion of workers affected by certain viral diseases, e.g. hepatitis 	
Control measures for parasites (worms and protozoa)	<ul style="list-style-type: none"> • Dietary control (infection from <i>Vitellina</i> in pork, for example, has decreased as a result of better control of the pigs' diet and environment) - a method not always practical, however, for all species of animals used for food (the diet and environment of wild fish, for example, cannot be controlled) • Heating, drying or freezing • Salting or brining • Visual examination, which can be used in some foods to detect parasites [e.g. a procedure called "candling" can be used for certain fish] • Good personal hygiene practices by food handlers, proper disposal of human faeces and proper sewage treatment 	

CONTROLLING CHEMICAL HAZARDS

Control measures for chemical hazards	<ul style="list-style-type: none"> • Source control, i.e. specifications for raw materials and ingredients and vendor certification that harmful chemicals or levels are not present • Processing control, i.e. formulation control and the proper use and control of food additives and their levels • Proper segregation of non-food chemicals during storage and handling • Control of incidental contamination from chemicals [e.g. greases, lubricants, water and steam treatment chemicals, paints] • Labelling control, i.e. ascertaining that the finished product is accurately labelled with ingredients and known allergens
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CONTROLLING PHYSICAL HAZARDS

Control measures for physical hazards	<ul style="list-style-type: none"> • Source control, i.e. specifications for raw materials and ingredients and vendor certification that unacceptable physical hazards or levels are not present • Processing control, e.g. use of magnets, metal detectors, sifter screens, de-stoners, clarifiers, air tumblers • Environmental control, i.e. ensuring that good manufacturing practices are followed and that no physical contamination occurs to the food through the building, facilities, work surfaces or equipment
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6.6 Hazard Assessment

The information gathered from the hazard analysis can be used to determine:

- The severity of the hazard(s)
- Risks associated with hazards identified at various stages of the operation
- The points, steps or procedures at which control can be applied and a food safety hazard can be prevented, eliminated or reduced to an acceptable level, i.e. critical control points (CCPs)

Severity

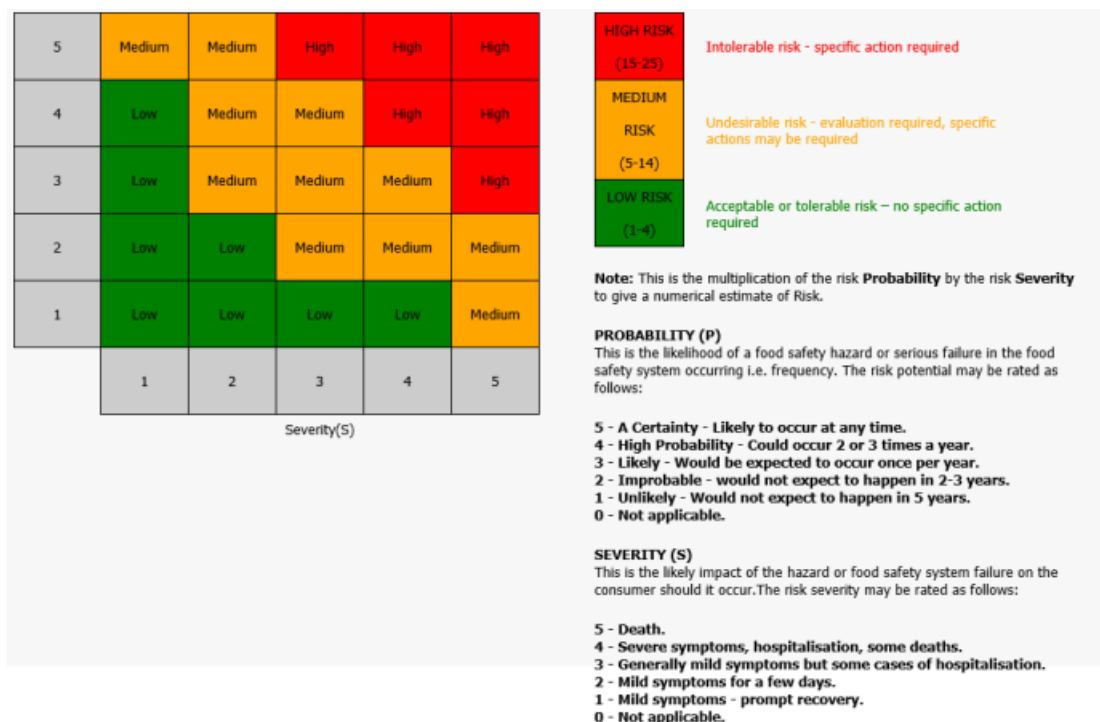
Severity is the magnitude of a hazard or the degree of consequences that can result when a hazard exists. Disease-causing hazards can be categorized according to their severity. One system uses the categories of:

- **High** (Intolerable Risk) - examples include illnesses caused by *Clostridium botulinum*, *Salmonella typhi*, *Listeria monocytogenes*, *Escherichia coli* 0157:H7, *Vibrio cholerae*, *Vibrio vulnificus*, paralytic shellfish poisoning, amnesic shellfish poisoning
- **Medium** (Undesirable Risk) - examples include illnesses caused by *Brucella* spp., *Campylobacter* spp., *Salmonella* spp., *Shigella* spp., *Streptococcus* type A, *Yersinia enterocolitica*, hepatitis A virus, mycotoxins, ciguatera toxin
- **Low** (Acceptable or Tolerable Risk) - examples include illnesses caused by *Bacillus* spp., *Clostridium perfringens*, *Staphylococcus aureus*, Norwalk virus, most parasites, histamine-like substances and most heavy metals that cause mild acute illnesses

Risk of hazard

Risk is a function of the probability of an adverse effect and the magnitude of that effect, consequential to a hazard(s) in food. Degrees of risk can be categorized as high (H), medium (M), low (L) and negligible (N).

Figure: Sample Risk Assessment Model



7 DETERMINE CRITICAL CONTROL POINTS - STEP 7/PRINCIPLE 2

7.1 Critical Control Points

The determination of critical control points (Step 7) is the second principle of HACCP. The Codex guidelines define a critical control point (CCP) as "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".

If a hazard has been identified at a step where control is necessary for safety/and if no control measure exists at that step or at any other, then the product or process should be modified at that step, or at an earlier or later stage, to include a control measure.

The determination of a CCP in the HACCP system can be facilitated by the application of a decision tree such as that included in the Codex *Hazard Analysis and Critical Control Point (HACCP) system and guidelines for its application* (see Figure) which indicates a logical reasoning approach. The application of the decision tree should be flexible according to the type of operation (production, slaughter, processing, storage, distribution or other). The decision tree proposed by Codex may not

be applicable to all situations.

Figure: CCP Decision Tree

CCP Determination

CCP Decision Tree

No.	Question	Answer
1	Do preventive control measures exist?	Yes
	Is control at this step necessary for safety?	-
2	Is the step specifically designed to eliminate or reduce the likely occurrence of the hazard to an acceptable level?	Yes
3	Could contamination occur or increase to unacceptable levels?	-
4	Will a subsequent step eliminate or reduce the hazard to an acceptable level?	-

Result

CCP

Decision Report

This step is specifically designed to reduce the levels of pathogenic bacterial to a safe level. There is no further processing step to control the hazards. Failure to reach a minimum core temperature and time profile is likely to result in adverse health effects.

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The decision tree asks a series of questions which when answered in order will drive you to the next logical question in the sequence until you arrive at a decision as to whether the step is a CCP or not a CCP. There are four questions in the sequence as follow:

Question 1: Do control measure(s) exist?

Question 1 should be interpreted as asking whether or not the operator could use a control measure at this operation or anywhere else in the food establishment to control the identified hazard. Control measures could include, for example, temperature control, visual examination or use of a metal detector.

If the response to Question 1 is "yes", under Question 1, then proceed to Question 2 in the decision tree. If the response is "no", i.e. a control measure does not exist, indicate how the identified hazard will be controlled before or after the manufacturing process (outside the control of the operator). For example, salmonella in raw poultry is controlled by the end-user. Alternatively, modify the operation, process or product so that a control measure exists, and then proceed to the next identified hazard in the process.

Question 2: Is the step specifically designed to eliminate or reduce the likely occurrence of the identified hazard to an acceptable level?

Examples of procedures or operations in a food process that are designed specifically to identify hazards include:

- The retorting operation in a canning plant
- Pasteurization
- Chlorination of cooling water
- The addition of a metal detector to a process line
- A particular sanitation procedure performed by the operator to clean contact surfaces without which the line would be stopped and the product would be contaminated

Acceptable and unacceptable levels need to be defined within the overall objectives in identifying the CCPs of the HACCP plan. If the process or operation is specifically designed to eliminate or reduce the likely occurrence of the hazard to an acceptable level, answer "yes" under Question 2. Such a step automatically becomes a CCP. If the step is not specifically designed, answer "no" and proceed to the next question. Note that Question 2 applies to processing operations only. For in-

coming materials as delivered, write "no" and proceed to Question 3.

Question 3: Could contamination with the identified hazard occur in excess of acceptable levels or increase to unacceptable levels?

In other words, is it likely that the hazard could have an impact on the safety of the product?

Question 3 refers to both probability (likelihood) and seriousness. The response is a judgement call involving risk assessment which must be based on all of the information that has been gathered. If data suggest that contamination with the identified hazard may increase to an unacceptable level and result in an unacceptable health hazard, answer "yes" and proceed to the next question in the decision tree. If the contamination is not known to represent a substantial threat to human health or is not likely to occur, answer "no" (not a CCP) and proceed to the next identified hazard in the process.

Question 4: Will a subsequent step eliminate the identified hazard or reduce likely occurrence to an acceptable level?

This question is designed to identify those hazards that are known to represent a human health threat or that could increase to an unacceptable level, and that will be controlled by a subsequent process operation. If no subsequent operation is scheduled in the process to control this identified hazard, answer "no". This particular process step becomes a CCP and should be identified as such. If there is a subsequent operation or operations later in the process that will eliminate the identified hazard or reduce it to an acceptable level, answer "yes". This step is not a CCP. However, you will need to identify the subsequent step(s) that control(s) the hazard, thus proceeding to the next identified hazard.

7.2 Identification of CCP's

CCP's should be uniquely numbered to ensure they are clearly identified within the process or operation. Numbering and identification systems can vary from operation to operation.

7.3 Parameters Attached to CCP's

Once the CCPs have been established, the next step is to document the parameters that will be monitored and controlled. HACCP Principles 3 to 7 will lead to the development of the establishment's HACCP plan. This HACCP plan will provide the written guidelines that will be followed in the establishment.

8 ESTABLISH CRITICAL LIMITS FOR EACH CRITICAL CONTROL POINT - STEP 8/PRINCIPLE 3

8.1 Critical Limits

At each critical control point (CCP)/critical limits are established and specified. Critical limits are defined as criteria that separate acceptability from unacceptability. A critical limit represents the boundaries that are used to judge whether an operation is producing safe products. Critical limits may be set for factors such as temperature, time (minimum time exposure), physical product di-

mensions, water activity, moisture level, etc. These parameters, if maintained within boundaries, will confirm the safety of the product.

The critical limits should meet requirements of government regulations and/or company standards and/or be supported by other scientific data. In some cases, food control regulatory authorities provide information on which to establish the critical limits based on known food hazards and the results of risk analysis (e.g. the time/temperature requirements for thermal processes such as pasteurization, cooking, retorting; maximum number and size of physical contaminants, chemical residues). It is essential that the person(s) responsible for establishing critical limits have a knowledge of the process and of the legal and commercial standards required for the product. Sources of information on critical limits include:

- Scientific publications/research data
- Regulatory requirements and guidelines
- Experts (e.g. thermal process authorities, consultants, food scientists, microbiologists, equipment manufacturers, sanitarians, academics)
- Experimental studies (e.g. in-house experiments, contract laboratory studies)

If the information needed to establish critical limits is not available, a conservative value should be selected or regulatory limits used. Rationale and reference materials used should be recorded. The materials should become part of the support documentation of the HACCP plan. Once the critical limits are established, they should be documented. The following are examples of CCP that may be in food processes.

Hazard	CCP	Critical limit
Bacterial pathogens (non-sporulating)	Pasteurization	72°C for at least 15 seconds
Metal fragments	Metal detector	Metal fragments larger than 0.5 mm
Bacterial pathogens	Drying oven	$A_w < 0.85$ for controlling growth in dried food products
Excessive nitrite	Curing room/brining	Maximum 200 ppm sodium nitrite in finished product
Bacterial pathogens	Acidification step	Maximum pH of 4.6 to control <i>Escherichia coli</i> and <i>Campylobacter</i>
Food allergens	Labelling	Label that is legible and contains a listing of correct ingredients
Histamine	Receiving	Maximum of 25 ppm histamine levels in evaluation of tuna for histamine

9 ESTABLISH A MONITORING SYSTEM FOR EACH CRITICAL CONTROL POINT - STEP 9 / PRINCIPLE 4

9.1 Monitoring

The Codex *Hazard Analysis and Critical Control Point (HACCP) system and guidelines for its application* defines monitoring as "the act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control". Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits. The monitoring procedures must be able to detect loss of control at the CCP. Therefore, it is important to specify fully how, when and by whom monitoring is to be performed. The purposes of monitoring include the following:

- To measure the performance level of the system's operation at the CCP (trend analysis)
- To determine when the performance level of the system results in a loss of control at the CCP, e.g. when there is deviation from a critical limit (see Step 10)
- To establish records that reflect the performance level of the system's operation at the CCP to comply with the HACCP plan

There are many ways to monitor the critical limits of a CCP. Monitoring can be done on a continuous (100 percent) or batch basis. The monitoring system may take time to achieve a result from the monitoring procedure. Most monitoring procedures will need to be rapid, as they relate to on-line processes which in general do not leave time for lengthy analytical testing. For this reason physical and chemical measurements or visual observations, which may be done rapidly, are often preferred to microbiological testing. Examples of some physical and chemical measurements taken to monitor critical limits are temperature, time, pH, moisture level and water activity (A_w). It is essential that all monitoring equipment be properly calibrated for accuracy.

Monitoring procedures performed during the operation should result in written documentation which will serve as an accurate record of the operating conditions. Monitoring records provide information on conditions during the operation and allow for action to be taken in the event of a loss of control or for a process adjustment to be made if there is a trend towards a loss of control. Accurate monitoring procedures and associated records provide information to the operator and allow for decisions to be made on the acceptability of the lot at a particular stage in the process. 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 (see Step 10).

The worst scenario is that in which monitoring procedures indicate that any one of the critical limits is exceeded, which indicates loss of control of a CCP. This lack of control is considered to be a deviation resulting in the production of a hazardous or unsafe product. The situation requires immediate identification and control of the affected product and corrective action.

Responsibility for monitoring should be clearly defined, and individuals must be adequately trained in the monitoring procedures for the CCP for which they are responsible. They must also fully understand the purpose and importance of monitoring. The individual should have ready access to the monitoring activity, must be unbiased in monitoring and must accurately report the monitoring activity.

9.2 Design of a Monitoring System

The control measures discussed at Step 6 are intended to control a hazard or hazards at each CCP. The monitoring procedures will determine if the control measures are being implemented and ensure that critical limits are not exceeded. The monitoring specifications for each CCP should be documented:

Figure: Example of CCP Monitoring Details

CCP Monitoring Details							
CCP Name		Cooking					
Monitoring	Critical Limit	How	Responsible	Frequency	Corrective Action	Record	Verification
Temperature / Time Monitoring	Ham should have a minimum internal temperature of 148°F; Recommend using 155°F or higher.	Continuous chart recorder per each batch. Temperature probe measurements at the core of ham located in the 'cold' part of the oven.	Cooking Operator	Continuous	Divert to rework, completely reprocess through the entire cooking cycle, or reject and condemn product.	Cooking Potentially Hazardous Foods	Daily review of records before shipping product by Quality Manager. Weekly calibration of temperature recording devices.
Temperature / Time Monitoring	Ham should have a minimum internal temperature of 148°F; Recommend using 155°F or higher.	Continuous chart recorder per each batch. Temperature probe measurements at the core of ham located in the 'cold' part of the oven.	Cooking Operator	Continuous	Divert to rework, completely reprocess through the entire cooking cycle, or reject and condemn product.	CCP1 Monitoring	Daily review of records before shipping product by Quality Manager. Weekly calibration of temperature recording devices.

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What will be monitored?

Monitoring may mean measuring a characteristic of the product or of the process to determine compliance with a critical limit. Examples include:

- Measurement of the time and temperature of a thermal process
- Measurement of cold-storage temperatures
- Measurement of pH
- Measurement of A_w

Monitoring may also mean observing whether a control measure at a CCP is being implemented. Examples include:

- Visual examination of sealed cans
- Verification of vendor's certificates of analysis

It is also important to remember at this stage that monitoring procedures may determine if operating limits are being adhered to rather than the critical limits, so that the operator has time to make any necessary process adjustment.

How will critical limits and preventive measures be monitored?

Deviation from a critical limit should be detected in as short a time as possible to allow corrective action to limit the amount of adversely affected product. To ensure accurate knowledge of conditions during the process, the monitoring procedures should provide rapid (real-time) results and should not involve lengthy analytical procedures. Microbiological testing is rarely effective for monitoring CCPs for this reason, and also because large sample-sizes would be needed to find microorganisms at levels that may cause illness. Instead, physical and chemical measurements (e.g. pH, A_w , time, temperature) are preferred, as they can be done rapidly and can often be related to

the microbiological control of the process.

Effective monitoring depends upon the proper selection and calibration of the measuring equipment. The equipment used for monitoring CCPs will vary depending on the attribute being monitored. Examples of monitoring equipment include:

- Thermometers
- Clocks
- Scales
- pH-meters
- Water activity meters
- Chemical analytical equipment

Equipment should undergo periodic calibration or standardization as necessary to ensure accuracy. However, the variability of the equipment should be considered in setting the critical limits. Operators should be trained in proper use of the monitoring equipment and should be provided with a clear description of how the monitoring should be carried out. The details should be relevant to the type of monitoring performed; for example, it would be important to specify that temperature measurements for a heating process should be made at the coldest point of the process, while temperature measurements for a cooling process should be made at the warmest part.

Monitoring frequency

Monitoring can be continuous or non-continuous. Where possible, continuous monitoring is preferred; it is possible for many types of physical or chemical methods. Examples of continuous monitoring include:

- Measuring the time and temperature of a pasteurization or retorting process
- Checking each package of frozen, mechanically chopped spinach with a metal detector
- Monitoring the container closures on glass jars by passing them under a dud detector

For continuous monitoring to be effective, it is necessary to review the monitoring results periodically and take action when appropriate. The length of time between checks is important as it is directly related to the amount of product involved when there is a deviation from a critical limit.

Where non-continuous monitoring is the chosen system, the frequency of monitoring should be determined from historical knowledge of the product and process. When problems are detected the frequency of monitoring may need to be increased until the cause of the problem is corrected. The following questions will help to determine the correct frequency:

- How much does the process normally vary?
- How close is the operating limit to the critical limit?
- How much product is the processor prepared to risk if there is deviation from the critical limit?

Who will monitor?

In developing the HACCP plan consideration should be given to assigning responsibility for monitoring. Individuals assigned to monitor CCPs may include:

- Line personnel
- Equipment operators
- Supervisors
- Maintenance personnel
- Quality assurance personnel

Once assigned, the individual responsible for monitoring a CCP must:

- Be adequately trained in the CCP monitoring techniques
- Fully understand the importance of CCP monitoring
- Have ready access (be close) to the monitoring activity
- Accurately report each monitoring activity
- Have the authority to take appropriate action as defined in the HACCP plan
- Immediately report critical limit deviation

It is important that the responsible individual report all unusual occurrences and deviations from critical limits immediately to make sure that process adjustments and corrective actions are made in a timely manner. This person should record and sign all monitoring results and occurrences associated with monitoring CCPs. Records and documents associated with monitoring CCPs should also be signed by one or more responsible reviewing officials of the company.

10 ESTABLISH CORRECTIVE ACTIONS - STEP 10/PRINCIPLE 5

10.1 Establishing Corrective Actions

The Codex *Hazard Analysis and Critical Control Point (HACCP) system and guidelines for its application* defines corrective action as "any action to be taken when the results of monitoring at the CCP indicate a loss of control". Loss of control is considered as a deviation from a critical limit for a CCP. Deviation procedures are a predetermined and documented set of actions to be implemented when a deviation occurs. All deviations must be controlled by taking action(s) to control the non-compliant product and to correct the cause of non-compliance. Product control includes proper identification, control and disposition of the affected product. The control and disposition of the affected product and the corrective action(s) taken must be recorded and filed.

10.2 Deviation

The Codex guidelines for the application of the HACCP system define deviation as "failure to meet a critical limit". Procedures should be in place to identify, isolate and evaluate products when critical limits are exceeded. The food business should control deviations as follows.

Identification of deviation

The producer should have a system in place to identify deviations when they occur.

Isolation of affected product

The producer should have effective procedures in place to isolate, mark clearly and control all product produced during the deviation period.

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

Evaluation of affected product

Product evaluation should be conducted by a qualified person. For example, thermal process deviations would be evaluated by a competent process authority or reference centre. The evaluation of affected product should be adequate to detect potential hazards, i.e. it should be ensured that sampling is adequate to identify the extent of the problem, that the tests are appropriate, that the judgement is based on sound science and that the product is not released until the evaluation has determined that no potential hazard exists.

10.3 Corrective Action Procedures

Since the main reason for implementing HACCP is to prevent problems from occurring, corrective action should be taken to prevent deviation at a CCP. Corrective action should be taken following any deviation to ensure the safety of the product and to prevent recurrence of the deviation. Corrective action procedures are necessary to determine the cause of the problem, take action to prevent recurrence and follow up with monitoring and reassessment to ensure that the action taken is effective. If the corrective action does not address the root cause of the deviation, the deviation could reoccur. The food company's corrective action programme should include the following:

- Investigation to determine the cause of the deviation
- Effective measures to prevent recurrence of the deviation
- Verification of the effectiveness of the corrective action taken

10.4 Deviation and Corrective Action Records

Records should be available to demonstrate the control of products affected by the deviation and the corrective action taken. Adequate records permit verification that the producer has deviations under control and has taken effective corrective action. The following information should be recorded in the deviation and corrective action records.

Deviation

- Product/code
- Date produced/held/released
- Reason for the hold
- Amount of product held
- Results of evaluation: amount analysed, analysis report, number and nature of defects
- Signature of personnel responsible for hold and evaluation
- Disposition of held product (if appropriate)
- Signed authorization for disposition

Corrective action

- Cause of deviation identified
- Corrective action taken to correct deficiency
- Follow-up/assessment of effectiveness of corrective action
- Date
- Signature of person responsible

11 ESTABLISH VERIFICATION PROCEDURES - STEP 11 / PRINCIPLE 6

11.1 Verification

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". Verification and auditing methods, procedures and tests, including random sampling and analysis, can be used to determine if the HACCP system is working correctly.

11.2 Description of Verification Activities

Each HACCP plan should include verification procedures for individual CCPs. HACCP plans are expected to evolve and to improve with experience and new information. Periodic verification helps improve the plan by exposing and strengthening weaknesses in the system and eliminating unnecessary or ineffective control measures. Verification activities include:

- HACCP plan validation
- HACCP system audits
- Equipment calibration
- Targeted sample collection and testing

Developing a HACCP Plan

CCP Monitoring Details							
CCP Name		Cooking					
Monitoring	Critical Limit	How	Responsible	Frequency	Corrective Action	Record	Verification
Temperature / Time Monitoring	Ham should have a minimum internal temperature of 148°F; Recommend using 155°F or higher.	Continuous chart recorder per each batch. Temperature probe measurements at the core of ham located in the 'cold' part of the oven.	Cooking Operator	Continuous	Divert to rework, completely reprocess through the entire cooking cycle, or reject and condemn product.	Cooking Potentially Hazardous Foods	Daily review of records before shipping product by Quality Manager. Weekly calibration of temperature recording devices.
Temperature / Time Monitoring	Ham should have a minimum internal temperature of 148°F; Recommend using 155°F or higher.	Continuous chart recorder per each batch. Temperature probe measurements at the core of ham located in the 'cold' part of the oven.	Cooking Operator	Continuous	Divert to rework, completely reprocess through the entire cooking cycle, or reject and condemn product.	CCP1 Monitoring	Daily review of records before shipping product by Quality Manager. Weekly calibration of temperature recording devices.

Signed: Safefood 360 Support User, 03/03/13 05:32

Edit

Figure: Example of CCP Monitoring Details indicating Verification

HACCP Plan Validation

The final output of the HACCP study is the HACCP plan. It summarizes all the elements of the HACCP study. The following is an example.

Figure: Example HACCP Summary Plan

CCP	Hazard	Monitoring	Critical Limit	How	Frequency	Respon...	Corrective Action	Record	Verification
#1 Cooking	Biological: Survival (Listeria Monocytogenes, Escherichia coli O157:H7, Clostridium Botulinum, Bacillus cereus and other Bacillus spp., Clostridium Perfringens, Staphylococcus Aureus, Vibrio cholerae Serogroup O1)	Temperature / Time Monitoring	Ham should have a minimum internal temperature of 148°F. Recommend using 155°F or higher.	Continuous chart recorder per each batch. Temperature probe measurements at the core of ham located in the 'cold' part of the oven.	Continuous	Cooking Operator	Divert to rework, completely reprocess through the entire cooking cycle, or reject and condemn product.	Cooking Potentially Hazardous Foods	Daily review of records before shipping product by Quality Manager. Weekly calibration of temperature recording devices.
#2 Cooling	Biological: Survival (Clostridium Botulinum, Clostridium Perfringens)	Temperature / Time Control	Chilling to begin within 90 minutes or less from the time the cooling cycle is completed. All product must be chilled from 120°F to 55°F in no more than 6 hours. Product must reach 40°F internal temperature within 12 hours.	Core probe and chart recorder	Per Batch	Packing Operator	Repeat heat process or reject product.	Cooling Potentially Hazardous Foods	Daily review of records before shipping product by Supervisor. Monthly calibration of temperature recording devices. Weekly internal temperature checks to verify time/temperature parameters are reaching desired internal temperature.
#3 Metal Detection	Physical: Contamination (Metal)	Checking of Detection unit	2.0 mm Ferrous; 2.5mm Non-Ferrous; 6.0mm Stainless Steel	Check wands / Test Packs	Hourly	Packing Operator	Reject product from last clear check, re-metal detect product and discard product if required.	Metal Detection Record	Verification of records daily by Supervisor. Calibration of the unit annually.

HACCP Plan Validation

Validation is the act of assessing whether the HACCP plan for the particular product and process adequately identifies and controls all significant food safety hazards or reduces them to an acceptable level. HACCP plan validation should include:

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

Fig: CCP Validation of Cooked Meat Product

Supporting Documents	
CCP Validation	CCP validation is based on technical guidance document for the corrective cooking temp/time for meats.
Supporting Documents	<div>Title</div> <div>Cooked Meats Temperature / Time Guidance</div>

HACCP system audits

As part of verification, audits are performed to compare the actual practices and procedures of the HACCP system with those written in the HACCP plan. Audits are systematic and independent examinations involving on-site observations, interviews and review of records to determine whether the procedures and activities stated in the HACCP plan are implemented in the HACCP system. These examinations are usually performed by one or more independent persons who are not involved in implementation of the HACCP system. Audits may be performed for individual CCPs and/or for the overall plan.

Figure: HACCP Audit Checklist and Report

Details												
Date	27/12/11											
Start Date / Time	27/12/11 12:43											
Finish Date / Time	27/12/11 12:43											
Auditor	<div>Auditor</div> <div>Auditmate Ltd.</div>											
In Attendance	<table border="1"> <thead> <tr> <th>Employee</th> <th>Opening Meeting</th> <th>Audit</th> </tr> </thead> <tbody> <tr> <td>Alex May</td> <td>Yes</td> <td>Yes</td> </tr> <tr> <td>Allan Marsh</td> <td>Yes</td> <td>Yes</td> </tr> </tbody> </table>	Employee	Opening Meeting	Audit	Alex May	Yes	Yes	Allan Marsh	Yes	Yes		
Employee	Opening Meeting	Audit										
Alex May	Yes	Yes										
Allan Marsh	Yes	Yes										
Procedure / Record	.											

Audit Record				
Checklist	Requirement	Conforms?	Category	Report
	Is the company's Food Safety Plan based on a HACCP system? Is it systematic, comprehensive, thorough, fully implemented and maintained?	Yes		
	Is it systematic, comprehensive, thorough, fully implemented and maintained?	Yes		
	Is Codex Alimentarius HACCP principles used?	Yes		
	Is reference made to relevant legislation, codes of practice or guidelines?	Yes		
	Is the HACCP plan developed and managed by a multi-disciplinary food safety team that includes those responsible for Quality Technical, Production Operations, Engineering and other relevant functions?	Yes		
	Have team members specific knowledge of HACCP and relevant knowledge of product, process and associated hazards?	Yes		
	Is there a HACCP food safety team leader designated and qualified?	Yes		
	Are records maintained to demonstrate the HACCP food safety team has the required knowledge and understanding of HACCP?	Yes		
	Where external expertise is used, does the day-to-day management of the food safety system remain the responsibility of the company?	Yes		
	Do senior management demonstrate commitment and support for the HACCP food safety team?	Yes		

Calibration

Calibration involves checking instruments or equipment against a standard to ensure accuracy. Calibration should be documented and the records should be available for review during verification. Calibration of appropriate equipment and instruments used in the development and implementation of the HACCP plan should be carried out during monitoring and/or verification.

Figure: Calibration Record for pH Meter

Calibration (311)

COMPLETED

Actions

No.	Date	Item	Group	Location	Serial Number	Recorded By
311	31/10/13	Jenway pH Meter	Inspection / Testing Equipment	Laboratory	728539J80	Javika Solanki

Calibration Record

Date: 31/10/13

Item: Jenway pH Meter

Type: Check

Calibrator: Dipak Patel

Certificate Number

Procedure

Point	4	7	10
Reading	3.9	6.9	9.9

Signed: Javika Solanki, 04/11/13 03:44

Edit

Result

Report

Result: Fail

Generate Corrective Action

Nonconformances

Details of nonconformance / issue	Risk
Calibration results are out of range. Equipment needs to be isolated.	High

View

12 ESTABLISH DOCUMENTATION AND RECORD KEEPING - ACTION 12/PRINCIPLE 7

12.1 Documentation and Record Keeping

Records should be maintained for all aspects of the HACCP system including monitoring, the deviations and the corrective actions (including disposition of product) that occurred at the identified CCP. Records may be in any form, e.g. processing chart, written record, computerized record. The importance of records to the HACCP system cannot be overemphasized. It is imperative that the company maintains complete, current, properly filed and accurate records. Four types of records should be kept as part of the HACCP programme:

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

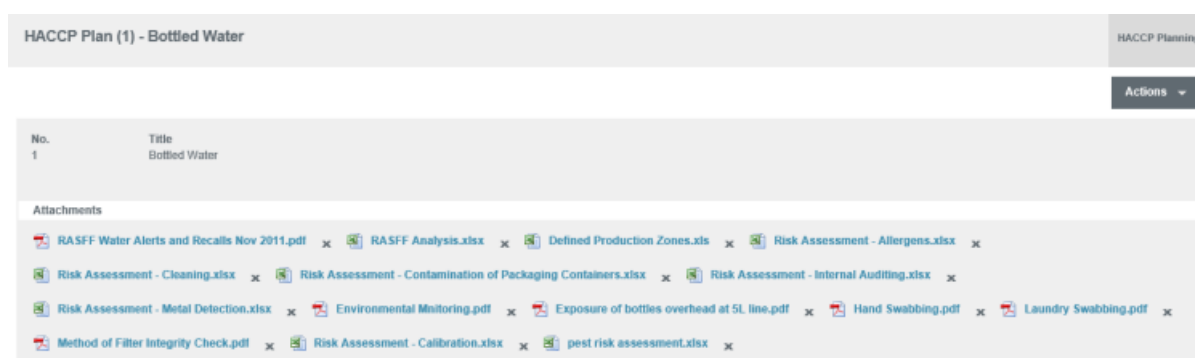
12.2 Supporting Documents

Supporting documents are those documents, data and information used to support the development of the HACCP plan. This can include:

- 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

These documents should be retained on file for the attention of auditors.

Figure: Attached HACCP Supporting Documents



12.3 Records Generated by the HACCP System

HACCP system records are kept to demonstrate adherence of the HACCP system with the HACCP plan. These records are used to demonstrate control at CCPs in the food process. The records generated by the HACCP system include all activities and documentation required by the plan, as follows.

- Monitoring records for all CCPs
- Deviation and corrective action records
- Verification/validation records
- Training records

Reference

Hazard Analysis and Critical Control Point (HACCP) system and guidelines for its application [Annex to CAC/RCP 1-1969, Rev. 3 (1997)]

Safefood 360° Food Safety Management Software



Product Benefits

- Easily record and manage all elements of your food safety system including HACCP and CCP monitoring, PRP's, management systems and documents
- Eliminate paper using the 30 integrated modules that come as standard
- Access and work with your system from any location at anytime
- Stay up to date and fully compliant with software that updates automatically in line with changes to global food standards
- Improve compliance and audit outcomes through the action driven features of the software
- Accelerate compliance with all of the international food safety standards including the BRC, SQF, IFS & FSSC 22000.
- Spend less time managing your food safety system and more on value adding activities

Product Features

- Dashboards & KPI's
- 100's of reports as standard
- Notifications
- Multi-site management & oversight
- Real-time legal and alert updates to dashboard
- Roles & security
- Actions management
- Safe and secure web based solution
- No internal IT support or data back-up required
- Unlimited Users
- 24/7 world class customer support
- Covers in complete detail the requirements of the SQF, BRC, IFS, FSSC 22000, retailer standards and legislation
- FDA 21 CFR Part 11 –Technical Compliance
- Automatic audit log
- One click data export



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