HACCP

A Toolkit for Implementation

2nd Edition

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RSC Publishing

Leatherhead Food Research

HACCP:

a Toolkit for Implementation

This edition first published 2010 by
Leatherhead Publishing, a division of
Leatherhead Food International Ltd
Randalls Road, Leatherhead, Surrey KT22 7RY, UK
URL: http://www.leatherheadfood.com

and

Royal Society of Chemistry
Thomas Graham House, Science Park, Milton Road,
Cambridge, CB4 0WF, UK
URL: http://www.rsc.org
Regstered Charity No. 207890

ISBN: 978-1-905224-97-5

A catalogue record of this book is available from the British Library

Typeset by Alison Turner and Jackie Apps
Printed and bound by Henry Ling, Dorchester

FOREWORD

HACCP: A Toolkit for Implementation is the second edition of this book; the first was published in A4 format and contained a series of forms and record sheets at the end of the book, which were intended to be photocopied for use to assist the progress of a HACCP study.

This new edition of the book is in a more convenient A5 format, and contains more case studies and background information. An online link is included to the same series of HACCP forms as before which can be printed as required so that the book remains the starting point and an invaluable tool for any company developing or checking a HACCP plan. This link is: www.leatherheadfood.com/haccpbook-support-documents

The book gives an outline of the HACCP principles and guidance for completing a HACCP study. It is designed as a quick introduction to HACCP and as a guide for a less experienced HACCP team to use as a reference as they progress through their study.

CONTENTS

1. INTRODUCTION

1.1 What is HACCP?

Hazard Analysis and Critical Control Point (HACCP) is a systematic method to identify, evaluate and control food safety hazards. HACCP was developed in the early 1960s to help deliver safe food for United States (US) astronauts. In space, food poisoning is not an option; *Salmonella* or *Staphylococcus aureus* are potential killers in that environment! At the same time, the US Army was also investigating systems for producing safe food for its troops, following a food poisoning incident with *Staph. aureus*. The National Aeronautical and Space Administration (NASA) appointed the Pillsbury Company to develop a zero tolerance food safety system, which became HACCP. An engineering principle called Failure Mode and Effects Analysis (FMEA) was used as the basis of the system of hazard analysis and control.

HACCP was first used in the meat industry in the US, before being adopted by other sectors of the food industry. Different HACCP systems began to be developed for different industries. In the late 1960s, the Codex Alimentarius Commission (CAC), a food standards body jointly funded by the World Health Organisation (WHO) and the Food and Agriculture Organisation (FAO) of the United Nations (UN), developed a standard for HACCP that is still used around the world today. This standard has been through a number of revisions, the most recent in 2003 (see Further Reading).

HACCP as a system provides a means of identifying and assessing potential hazards in food production and establishing preventive control procedures for those hazards. The emphasis on prevention of hazards reduces reliance on traditional inspection and end-product testing. A properly applied HACCP system is now internationally recognised as an effective means of ensuring food safety.

The HACCP concept can be applied to new or existing products and processes, and throughout the food chain from primary production to

consumption. It is compatible with existing standards for quality management systems such as the International Organisation for Standardisation (ISO) 9000-2000 series; HACCP procedures can be fully integrated into an ISO 9000-2000 quality system. Figure 1.1 illustrates the integration of HACCP within a quality management framework, with HACCP at the centre, Pre-requisite programmes (PRPs) next, and quality management as the outer 'skin'. An explanation of PRPs is given in Chapter 2. The new ISO 22000 food safety standard formally integrates HACCP within the structure of a quality management system.

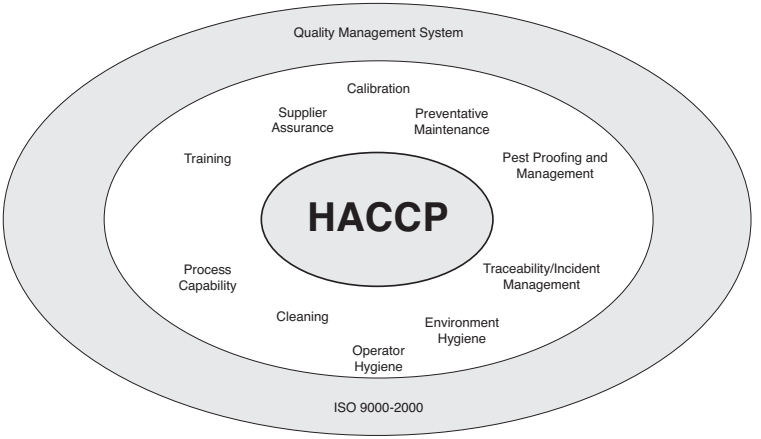


Fig. 1.1. Relationship between HACCP, Prerequisites and Quality Management (Adapted from Mortimore and Wallace, 1998)

The British Retail Consortium (BRC) published a standard for food producers for Own Brand goods being sold into the UK retail market in 1998. This has been revised and expanded with each new edition, now called the Global Standard for Food Safety, reflecting the global nature of the food supply chain. A revised version is produced every 3 years; the latest, Issue 5, was published in 2008 (see Further Reading). HACCP has played an increasing role in the standard, with the latest issue requiring a thorough review of company HACCP systems, including significant time spent in the factory inspecting the process. The BRC standard is used by companies supplying directly to retailers ('own label' products), and by other companies as a benchmark for their suppliers.

The application of HACCP at all stages of the food supply chain is being actively encouraged, and increasingly is required worldwide. For example, the CAC advises that "the application of HACCP systems can aid inspection by regulatory authorities and promote international trade by increasing confidence in food safety".

Although not intended for primary producers, many are using HACCP or a simplified version, to ensure safety of the supply chain, particularly if supplying to retailers or large companies.

There is also a strong customer demand for HACCP around the world. In many countries, there is a legal requirement for all food business operators to have some form of hazard analysis based on HACCP, as a means of ensuring food safety.

1.2 Legislation

In the European Community (EC), a risk analysis approach based on HACCP has been a legal requirement for member states since 1993 for all food processing sites. More recently, new hygiene legislation, EC Regulation 852/2004 on the hygiene of foodstuffs, has been implemented throughout the EC, requiring all seven Principles of HACCP to be implemented to an appropriate level, dependent upon the complexity of the food business. This means that HACCP, in one form or another, is now required by all businesses producing food for sale to the general public. Other legislation, EC Regulation 853/2004 and EC Regulation 854/2004, lay down specific hygiene rules for food of animal origin, and specific rules for the organisation of official controls on products of animal origin intended for human consumption respectively. In the United Kingdom (UK), the EC Regulation is enforced by the Food Hygiene (England) Regulations 2006.

Other legislation upon which HACCP impinges includes EC Regulation 178/2002, the General Food Law, which prescribes safe food, traceability and recall procedures, and the rapid alert system for highlighting potentially harmful foods and ingredients entering EU trade. Also Directive 2007/68/EC amending the labelling Directive 2000/13/EC concerning allergens, since allergens have been recognised as an increasing food safety risk within the food industry. Companies should seek advice with respect to labelling, and the use of processing aids, since the regulatory position is constantly changing with respect to allergens, including which allergens are on the list of those that should be included on product labelling.

EC Regulation 2073/2005 on Microbiological Criteria is used in conjunction with the hygiene legislation to ensure the safety of processed products for consumer sale - for example, ready meals and critical ingredients - for example, meat and dairy products.

EC Regulation 2073/2005 states that in the case of microbiological monitoring indicating unacceptable results 'the Food Business Operator shall take measures to find the cause of the unsatisfactory results in order to prevent the recurrence of the unacceptable microbiological contamination. Those measures may include modifications to the HACCP-based procedures or other food hygiene control measures in place.'

Again it states 'A food management preventative approach such as employing good hygiene practices and a system based on HACCP principles must be in place. Food testing against the appropriate criteria should be undertaken, if appropriate, when validating and verifying HACCP.'

Some businesses may find it difficult to interpret the legislation for their circumstances, for example, small scale caterers. Several guidance documents are available, published under the auspices of the recommendation for 'National or Community Guides' under EC Regulation 852/2004. There are 'Safer Food Better Business' and 'CookSafe', produced by Food Standards Agency England and Wales, and Scotland, respectively (see Further Reading).

Within the UK, EC Regulation Nos. 852/2004 and 853/2004 are implemented through the Food Hygiene Regulations 2006.

2. PREPARATION FOR THE IMPLEMENTATION OF HACCP

2.1 Stages in the HACCP Process

Typically a HACCP study is divided into four stages, as illustrated in Figure 2.1.

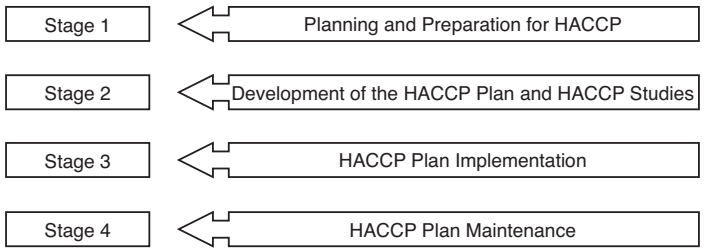


Fig. 2.1. Key stages of HACCP. (Adapted from Mortimore and Wallace, 2001)

Essentially, the bulk of the HACCP process is completed after stage two, with stage three concerned with running the process, and stage four, verification. We will be concerned with Stage 1 in this chapter.

2.2 Stage 1: Preparation and Planning

Good preparation is vital for an effective HACCP study. There are four stages that should be carried out before the HACCP study proper is started; these are shown in Figure 2.2.

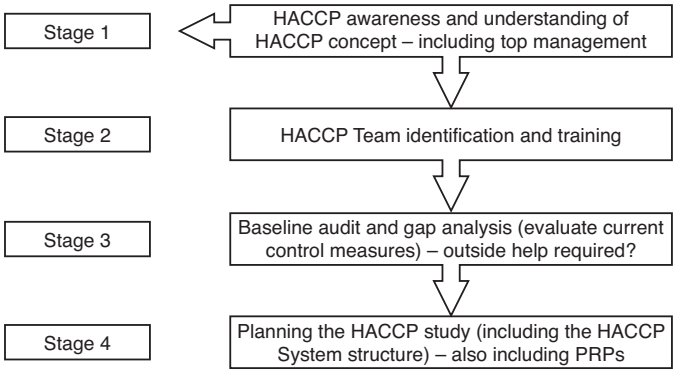


Fig. 2.2. Stage 1: Preparation and Planning for HACCP. (Adapted from Mortimore and Wallace, 2001)

2.3 HACCP Awareness and Basic Training

There may need to be a basic HACCP awareness session to explain what it is, why it is needed and how it works, before the study can start.

Basic training needs must be addressed before the study can start. Management commitment is essential to ensure that the team has enough time to carry out the HACCP study, and that additional monitoring, calibration or control equipment is provided if required. Management commitment means that there is an understanding of the benefits of HACCP, both financial and operational, and the degree of continuing commitment required. HACCP does not end with the completion of a study and production of a HACCP manual, which sits on the shelf gathering dust. HACCP is a continuing, living system, which must be appraised on a regular and scheduled basis.

HACCP Pitfall:
Management commitment is vital; unfortunately it is another area where poor adherence causes knock-on effects through the application of HACCP

2.4 Teams

An effective HACCP plan is best carried out as a multidisciplinary team exercise to ensure that the appropriate product-specific expertise is available. The team should include members familiar with all aspects of the production process as well as specialists with expertise in particular areas such as microbiology or engineering. If expert advice is not available on-site, it may be obtained from external sources.

Well-designed teams comprise between four and six experienced personnel; any more and the team becomes too large and unwieldy. The leader must understand HACCP and its implementation. Core disciplines include production or operations, quality assurance or technical, engineering, and microbiology, with one person acting as the team leader.

Question:
We are a small company of only 4 people, how do we make up a team?
Answer:
You can draft in outside expertise. For example, an EHO may be able to help, or a consultant, or someone from an industry association

Often some parts of the study will require additional specialist knowledge, for example, supplier assurance, purchasing, research and development, distribution, hygiene or cleaning. An essential requirement is the ability to evaluate risk and make safe judgements.

2.5 Resource Assessment - Baseline Audit

A gap analysis should be carried out before the HACCP analysis is performed, asking some of the questions below:

- Have staff been adequately trained, both in general food hygiene practices, and more specifically in HACCP?
- Has the HACCP team leader received HACCP training?

- Has the HACCP team received training at the right level?
- Is there management commitment to HACCP?
- Is there a requirement for a form of quality manual or other procedure control, which will make the implementation of HACCP easier?
- How is the HACCP study going to be structured; in stages, or looking at the whole process at once?

The HACCP team should be trained to Level 2 (Foundation) as a basic requirement, with the Team Leader trained to Level 3 (Intermediate). Preferably the whole team should be trained to Level 3.

HACCP Pitfall:
Failure to train and keep training up to date is a common problem.

2.6 Pre-requisite Programmes (PRPs)

Before a HACCP system is set up it is essential that another set of basic procedures is in place to ensure that good workplace practices are in operation. Codex says "Prior to the application of HACCP to any sector of the food chain, that sector should have in place PRPs such as Good Hygienic Practices (GHPs) according to the Codex General Principles of Food Hygiene, the appropriate Codex Codes of Practice, and appropriate food safety requirements".

The term PRPs was first described by the WHO, and refers to all those hygienic practices and operational controls, including staff training, which help to ensure that food is produced in the most hygienic manner possible. PRPs include much of what is often referred to as Good Manufacturing Practice (GMP).

PRPs include factors for control of raw materials, operational control, personal hygiene and training, sanitation and maintenance practices, control of food, packaging and sanitary waste, design of buildings and equipment, control of pests, traceability and recall procedures. Companies that do not take PRPs into account before they set up HACCP systems will find that they have too many Critical Control Points (CCPs) and, because of the dilution of effort, poor control of their HACCP. PRPs control risks that cannot have effective real time monitoring procedures, or those repetitive

hazards that occur at different locations in the factory. PRPs can be considered as those routines and policies that continue even when the food process stops. Figure 2.3 shows typical PRPs for HACCP. Figure 1.1 illustrated this in a slightly different way.

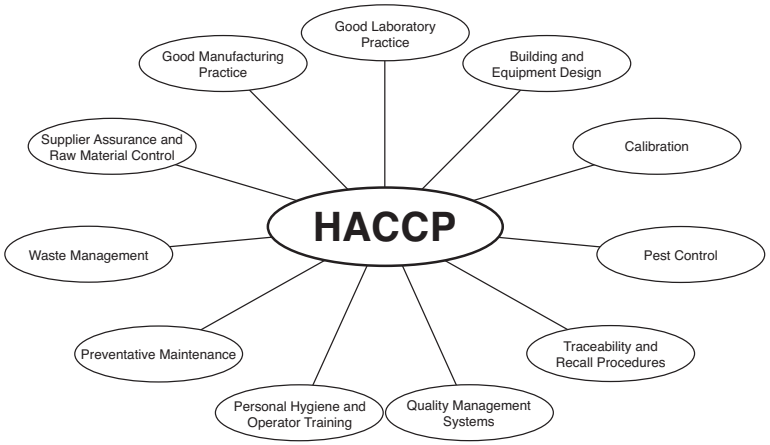


Fig. 2.3. Typical Prerequisite Programmes for HACCP (Adapted from Mortimore and Wallace, 2001)

It is important to make sure that the location of the factory does not compromise food safety or spoilage considerations. The design, layout and general construction should minimise build up of dirt and waste debris, and should be adequately proofed against the ingress and settling of pests. There should be adequate toilets and hand washing facilities for the size of the operation. Equipment must be easy to clean, and it should be maintained and calibrated regularly, to ensure hygienic and accurate operations. Food factories need an adequate supply of clean water for washing, and for direct heating or cooling, if used. It is critical to make sure that waste water flow across the factory does not compromise food safety. Control and maintenance of facilities is very important, for example, control of air temperature, chill stores, freezers, adequate lighting and ventilation.

HACCP Pitfalls:
It is very common to find HACCP fails at the point of operational PRPs, not necessarily failures at CCPs. This is why it is vital to get PRPs in place before starting the HACCP study, and to review them regularly.

Operational controls are also important, for example, control of cross contamination for physical, microbiological and chemical hazards; time and temperature within processes; control of raw materials; hygienic control of packaging and document control.

Good storage facilities are required, both for raw materials and finished products. If finished products are chilled, then control of the chill chain from processing, through storage, transportation and delivery to the customer is critical.

2.6.1 Control of PRPs

PRPs are controlled by a rigorous internal audit procedure; the BRC has noted the importance of auditing of PRPs by raising internal audits to a 'Fundamental Requirement'; i.e. one that must be in place and followed correctly to ensure adherence to good practices. Further details on auditing procedures are contained within Section 3 of this book, Running the HACCP system.

Table 2.I provides a summary of PRPs, their areas of control and examples of some typical procedures; this list is not exhaustive. It may not be necessary to prepare a list especially for the HACCP study; it may already exist in the contents page or introductory section of the Quality manual. A blank copy of this table has been included in Appendix 1 and online at www.leatherheadfood.com/haccpbook-support-documents to be photocopied and completed as required.

TABLE 2.I
Example of a summary of PRPs

Programme	Area of control	Procedures	Manager/Department responsible
Personal Hygiene and Training Policy	Wearing, maintenance and cleaning of over clothing; provision and use of hand washing facilities	Training SOP Training register (Reference to internal documents)	Training Manager/ HR Manager
Raw Material Control			
Supplier Assurance			
Waste Control			
Traceability and recall			
Internal Audit Policy			
Transport register			
Security	Access to the site and production areas	Site security policy Visitor policy Contractor policy Visitor and contractor signing in logs	Buildings and Security Officer
Operation of the clean room	Prevention of cross contamination	Cleaning SOPs for clean room	Cleaning Supervisor
Preventative maintenance	Condition of equipment; prevention of machine failure	Equipment register Purchase policy Maintenance policy Maintenance log	Engineering Manager Purchasing Manager
Cleaning and Sanitation	Frequency and method of cleaning	Cleaning policy Cleaning register Cleaning log	Cleaning Supervisor
Pest control	Management of pest control provisions	Pest control policy Pest control log Pest control subcontractor contract	Food Safety Manager Pest Control Contractor

2.7 Scope of Study

The scope should be determined before the HACCP study is started. First, the starting point of the study must be considered as to whether it begins at raw material intake, or before or after that point in the process. It needs to be decided which hazards are to be examined – all hazards, or just biological, chemical and/or physical. Alternatively, the study can just examine one particular hazard, as a result of new evidence, for example, *Escherichia coli* O157:H7.

HACCP Pitfall:
Attempting to do too much at once. A common problem is to try and address the whole HACCP study as one; break down the HACCP study into stages. Do you have a quality management system? Is it time to introduce one, as many parts of HACCP have quality management elements, and the implementation of one will help in the implementation of HACCP.

Table 2.II provides a summary of what a typical document summarising the scope of the HACCP study and its team members could list; a blank copy of this form is included in Appendix 1.

TABLE 2.II
Summary HACCP team and scope of study

HACCP of Line/process/product/other: Production of fresh pasta - Penne - line B

Start Date: 10th September 2009

Target implementation date: 31st March 2010

Scope of the study: Buying of ingredients, through mixing, extrusion, pasteurisation and cooling upon storage.

Team Members: (The examples given here are not exhaustive and many HACCP studies will require non-core team members).

Core Team	**Name**	**Job Title/role**
Team leader	J. Penne	Technical Manager
Secretary	T. Spiralli	QA Manager
	B. Cereus	Co. Microbiologist
	J. Fusilli	Production Supervisor

Other Team members

Name	**Job title**	**Area of expertise**
A. Lira	Purchasing Manager	Raw material suppliers

Once the start point and hazards have been determined, the HACCP system needs to be structured in one of three basic ways; as a linear, modular or generic based plan.

A linear approach is where HACCP is applied to each individual product that the company produces. Unless the company only produces a few products, this will lead to a large number of HACCP plans that will become difficult to manage. The plan starts with raw materials, and works through to the finished product. This approach is suited to small businesses or those producing relatively few products. This was common in many food businesses starting out in HACCP; they have usually evolved into the systems described below, or combinations of these, with linear elements.

A modular approach is often used where there are multiple paths for components of the finished product through the factory. For example, there may be three or four mixing and blending processes for raw ingredients, several main processes involving cooking or kill steps, and three or four

different ways to assemble and pack the finished product. If a linear approach was used there would be a large number of individual HACCP plans. By using the modular method, each sub-process becomes a mini HACCP plan; each is linked to any relevant module before or after it to make the finished product. The danger with this approach is that transfer stages between modules can be missed.

Finally, generic plans tend to be used where the same basic operations are carried out on the same type of ingredients at more than one site. Franchised restaurants often use this approach. Generic plans can themselves be modular or linear. Generic plans can be the first attempt at HACCP plans within a company; as experience grows, more individual plans will develop from the generic example. See Figures 2.4, 2.5 and 2.6 for examples.

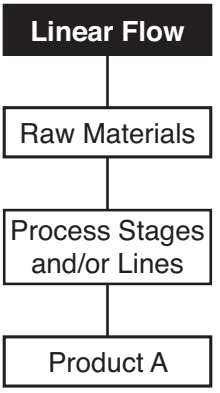


Fig. 2.4. Linear HACCP Plan ((Adapted from Mortimore and Wallace, 2001)

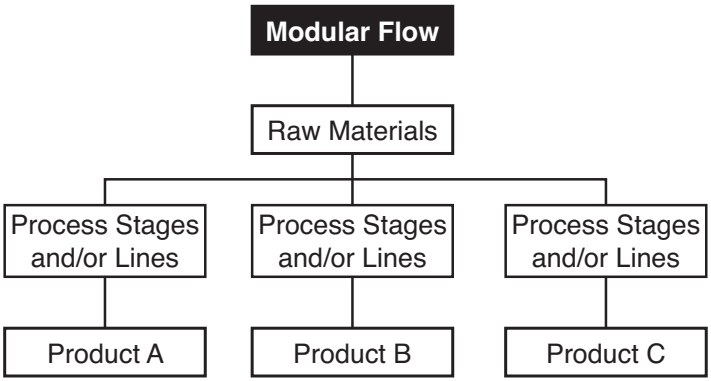


Fig. 2.5. Modular HACCP Plan (Adapted from Mortimore and Wallace, 2001)

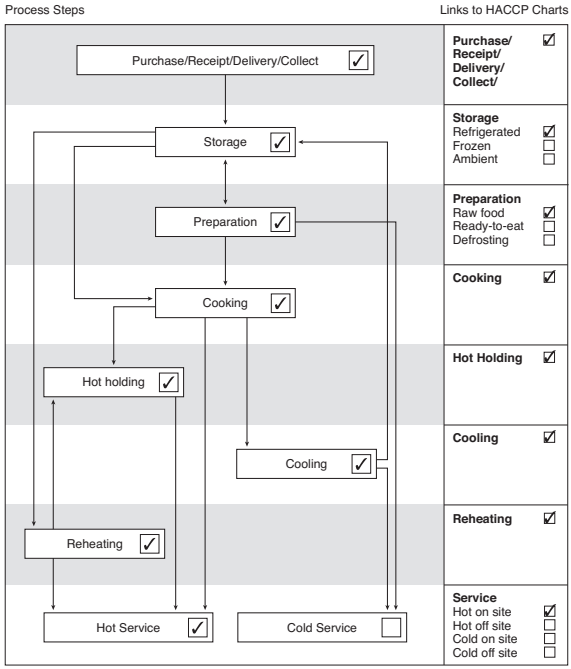


Fig. 2.6. Generic HACCP Plan (Adapted from CookSafe, FSA Scotland, 2004)

2.8 Summary

Good preparation is vital to ensure that the HACCP study is concise and to the point. Lack of attention to detail at this stage can lead to an unwieldy HACCP plan that is difficult to use.

3. HACCP PRINCIPLES

3.1 Introduction

HACCP is a logical process that needs to be followed step by step in order for it to work properly. The HACCP system is made up of seven principles as described by Codex:

Principle 1	Conduct a hazard analysis
Principle 2	Determine the CCPs
Principle 3	Establish critical limit(s)
Principle 4	Establish a system to monitor control of the CCP
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

3.2 Codex Logic Sequence

It is recommended by CAC that the practical application of HACCP principles should be carried out breaking the seven principles down further, into bite-sized chunks. They describe a twelve-stage logic sequence; Figure 3.1 illustrates this sequence.

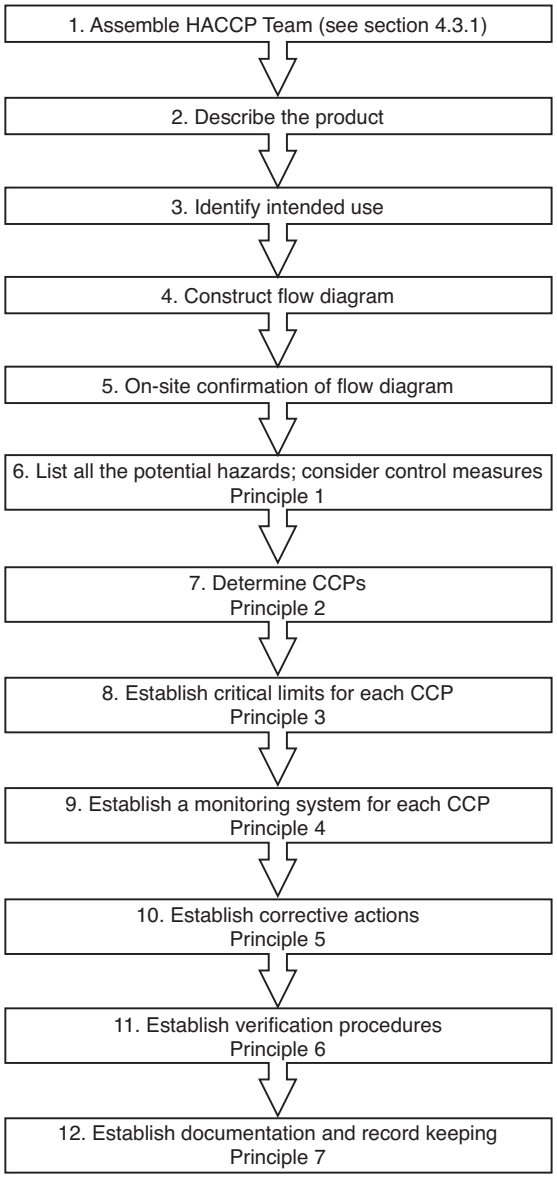


Fig. 3.1. Flow diagram illustrating the twelve-stage Codex Logic Sequence (Adapted from Codex, 2003)

The remainder of this book will examine the seven HACCP principles, and look at how these work together with Codex's twelve stages to lead to the successful implementation of a HACCP plan.

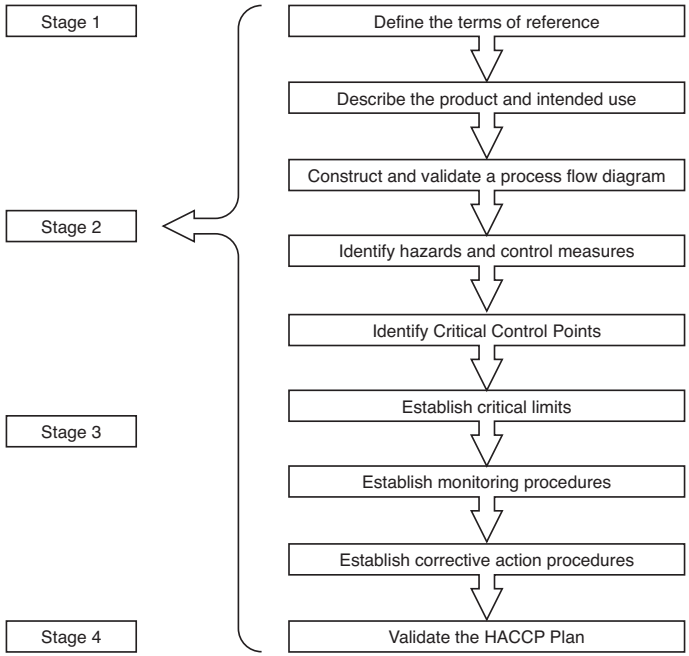


Fig. 3.2. Stage 2 HACCP Studies and Plan Development (Adapted from Mortimore and Wallace, 2001)

Figure 3.2 demonstrates the sequence of events that lead up to implementation of HACCP; it excludes verification.

4. PRINCIPLE 1 – CONDUCT A HAZARD ANALYSIS,

4.1 Introduction

The first principle requires the most preparatory work of all the principles to ensure that the hazard analysis is full and effective. There are six distinct stages for this principle; it is essential that the first five are carried out carefully and thoroughly; otherwise the hazard analysis may fail because of incomplete preparation.

The scope of the study must be decided and recorded, before any of this work is carried out. This is done by defining the extent of the production process to be considered and the categories of hazard to be addressed – biological, chemical and/or physical.

Hazard analysis is the process of analysing the likely hazards that could occur in a manufacturing process, collecting information about those hazards and their severity to the customer, assessing the likelihood of their occurrence, and then determining if they therefore need to be controlled within HACCP, or within other more general programmes, such as PRPs.

4.2 Information Gathering

The management system of the company will have gathered information about customer complaints, system failures, raw material and supplier faults. All such systems should be fully updated before starting the hazard analysis.

Use your records!
All companies have a wealth of data that is rarely used to its full extent. Recall and customer complaints, goods-in rejections, all tell you something about the consistency of raw material and finished products.

4.3 Building the HACCP Plan

As mentioned in Chapter 3, Codex recommends using the logic sequence to build the HACCP plan, stage by stage.

4.3.1 Stage 1 – Assemble the HACCP team

As discussed in section 2.4, an effective HACCP study is best carried out as a multidisciplinary team exercise to ensure that the appropriate product-specific expertise is available.

The team should include members from across the production process including specialists in particular areas such as food safety or microbiology, engineering, production or operations, quality assurance or technical, and possibly hygiene.

The team should ideally have a maximum of six members. Larger teams are difficult to manage and can be far less productive. Team members should be trained in HACCP methods. Other staff can be called into meetings as and when required, for example, hygiene personnel (if not in the main team),

Don't forget the scribe!
Someone has to keep track of discussions, deadlines and the dates for meetings. An independent scribe/secretary is vital.

suppliers, purchasing managers, research and development personnel, and logistics or distribution personnel. The team should also be free to call in experience from outside the company if required. Team members must have appropriate product-specific expertise, and be familiar with the lines being studied. They should understand any specific issues related to the product, such as ingredient sensitivity, any recipe or control factors, the details of the process, the desired packaging, and the target consumer. Records of all team meetings should be kept. An example of this is given below, in Table 4.I, and a blank template is included in Appendix 1 which can be downloaded as required.

What about small companies? A small company can have a small team or draft in expertise from outside; an EHO, consultant, or help from a trade body.

TABLE 4.I
HACCP team meeting notes

Present: Core team and Purchasing (A. Lira)

Issue	Decision or Action	Details of action	Who is responsible?	Planned completion date
Purchase of liquid egg	Action	Arrange audit of supplier	A. Lira	12/09
Accuracy of flow chart	Decision	Flow chart matches process		

A good HACCP team is united, motivated and inspired about the project. It is the team leader's job to ensure that this is the case throughout the study and that senior management receive and respond to regular progress reports. The team leader requires sound project management skills and must be able to set realistic deadlines.

For the HACCP team leader, team management skills are as important as experience in HACCP; a lack of unity and focus is very disruptive to getting the job done.

The team leader also needs understanding and control of the budget for carrying out the study, and the ability to communicate and liaise with management. Costs include training, if required, firstly for the team, and then for the rest of the workforce. Administrative support is essential, and it is vital to ensure that staff are released for both the meetings and other work required for the study, so that deadlines are met. Further costs may include purchase of additional control and monitoring equipment. Other work may need to be carried out, for example, process capability, or laboratory experiments, to ensure that the process will work. Finally ongoing investment in training and equipment is required to make sure that the HACCP plan stays live and relevant.

The task needs to be broken down into manageable stages, or it could seem unwieldy, and lose focus. Realistic deadlines should be developed, and management commitment is crucial at all stages. The progress record sheet given in Appendix 1 can be used to help monitor the progress of the study.

Training for the team:
Teams need training in HACCP; a member of the team should understand food safety and hazards, particularly microbial. Invest in training, either in-house or with a specialist provider.

A team that represents the different areas of the workforce is more likely to get commitment from all areas. A good team also shares the workload and should be better at spotting problems and designing solutions. A broad team demonstrates commitment to the workforce.

Management commitment is vital!

PRP review should occur before HACCP starts, but a Quality Management System (QMS) should have review steps for all these.

4.3.1.1 Team summary

The team:

- Plans the study
- Completes the study and generates documentation
- Ensures verification **
- Communicates and trains
- Reviews deviations from CCPs **
- Reviews the HACCP plan in response to change **
- Schedules and conducts internal audits **

*** In companies where there is more than one line these practices may be already part of the QMS, and the relevant schedules will be extended to include the new HACCP study.*

4.3.2 Stage 2 – Describe the product

It is important to have a complete understanding of the product, which should be described in detail. The description should include information such as composition/recipe, physical and chemical structure (including water activity (a_w), pH, and preservatives), processing conditions (heat treatment, freezing, smoking and extruding), type of packaging, shelf-life, storage and distribution conditions, and instructions for use.

Table 4.II is an example of what a typical 'product description and intended use form' should contain; which can be used for both this and the next stage. A blank form is included in Appendix 1.

Recipe details should include any control factors such as sugar or salt content, and any sensitive ingredients that require care in processing. Processing factors include the type of heat treatment i.e. pasteurisation, higher temperature cooking or sterilisation; type of process, such as freezing, blending, extruding or smoking. Other factors include a_w, pH, and

preservatives (organic acids, nitrites). Packaging conditions include type of packaging such as whether modified atmospheres are used; and if so, the composition. Label instructions should also be discussed in detail, particularly if the product contains allergens, or there are possible allergen contamination issues. Special attention should therefore be given to allergy advice on the label. The team must make sure that it keeps up to date with current legislation in this regard.

TABLE 4.II
Product description and intended use form

Name of product	Fresh Tagliatelle Pasta Verde
Description	A fresh pasta, nest shaped, made with durum wheat, liquid pasteurised egg and salt, coloured with spinach
Packaging	Packaged into 500 g metallised film pillow packs, packaged under a 50:50 CO_2/N_2 gas mix
Conditions of storage	Chill max 5 ˚C
Shelf life	21 days from date of packing
Instructions on the label	Keep chilled below 5 ˚C Allergy advice: this product contains gluten and eggs.
Consumer group	This product is intended for healthy adults
Recommendation of further processing required before consumption	Cook in boiling water for 5 minutes

4.3.3 Stage 3 – Identify intended use

The intended use should be based on the expected uses of the product by the end-user or consumer, for example, is a cooking process required, or is chilled storage required after opening? If that is the case, particular attention needs to be given to the information provided on the label, making sure that it is clear, including unambiguous instructions for further processing. For

example, cooking, or storage instructions after opening. It is also important to identify the consumer target groups.

Vulnerable groups of the population, such as children, the elderly, or those in hospital, may need to be considered specifically, as they may be particularly susceptible to certain micro-organisms. They also need to evaluate the potential for abuse, and who could abuse the product, and what would be the effects of such abuse.

What type of abuse could cause problems with the pasta product? Answer (a) storage temperatures above 8 °C could allow contaminating* L. monocytogenes *to grow more rapidly, shortening the shelf-life. Spoilage organisms could also grow, shortening the stability shelf-life. Answer (b) undercooking could allow survival of contaminating microorganisms.

4.3.4 Stage 4 – Construct a flow diagram

The flow diagram should be constructed by the HACCP team; it should contain sufficient technical data for the study to progress. It should be a simple, yet accurate representation of all steps in the production process from raw materials to the end product.

Figure 4.1 is an example of a simple flow diagram. It should contain enough technical information for the study to be undertaken. Ideally, it should be in a simple linear format, from top to bottom of the page. One convention is to have ingredients running across the top, from the first to the last, and process steps either on the left hand side, or in the middle of the page. Try to avoid lines that cross over as it makes the flow diagram messy and difficult to read.

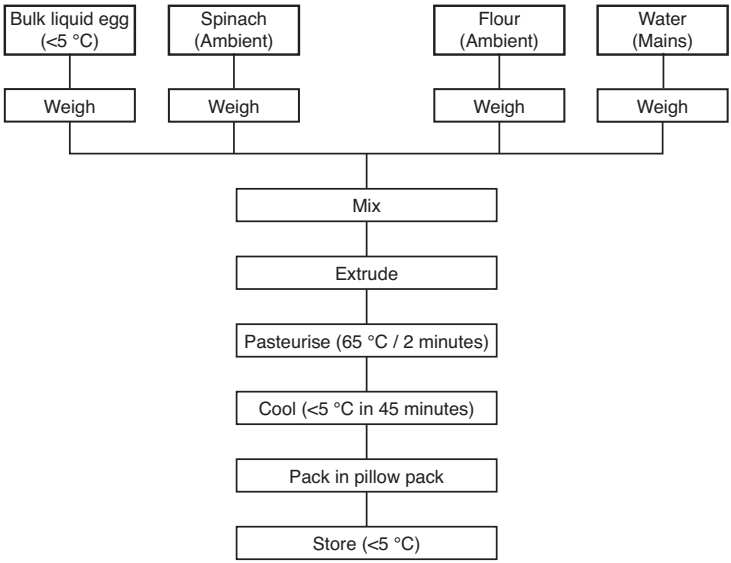


Fig. 4.1. Flow diagram for the manufacture of fresh pasta

Only actual operational steps should be included, not transfer stages, unless they have an operational process associated with them. If the plan is modular then there will be a number of flow diagrams making up the composite whole. It is important to ensure that the various modules add up, and that no hazards are missed in the linking between modules. A master flow diagram with module numbers and no other detail helps to clarify the whole process. Time and temperature, other process details, and position of CCPs should be included on the flow diagram. It is usual to start with raw materials, and work down to the finished product. Some teams find it helpful to number the process steps.

Messy flow diagrams are the bane of a successful HACCP plan. Simple is good!

It may also be useful to produce a second diagram which includes details of the factory and equipment layout, features of equipment design, time/temperature data, cleaning and hygiene procedures. This can highlight any potential contamination risks from the physical location of a process step in relation to another. Note that this is also a requirement of Issue 5 of the British Retail Consortium (BRC) Global Standard for Food Safety.

Some other examples of flow diagrams are given in Chapter 13.

4.3.5 Stage 5 – On-site verification of the flow diagram

It is essential that the flow diagram matches the process that is actually carried out. To do this, the HACCP team must observe the operation at all stages of manufacture, from start up to shut down, across shift patterns, by 'walking the line'. It is critical to observe production during all production shifts, including weekend and night shifts. The diagram must be accurate because much of the hazard analysis is based on hazards generated or removed during the production process. It is vital that both the process and diagram match at all times. If they do not, an assessment should be made of a non-existent or out-of-date process.

> ***Remember the night shift! A common mistake is to assume that the HACCP plan relates to all production shifts.***

4.3.6 Stage 6 – List all potential hazards associated with each step, conduct a hazard analysis, and consider any measures to control identified hazards

The HACCP team should list all hazards that may reasonably be expected to occur at each step in the production process. The team should then conduct a hazard analysis to identify which hazards must be eliminated or reduced in order to produce safe food. Existing control measures for each hazard should be recorded and evaluated. Some hazards may require more than one control measure, or control at more than one place to ensure control of the hazard.

4.3.6.1 Hazards

Key questions to ask at this stage are:

1. What are the hazards?
2. Can they be quantified?
3. What are the control measures?
4. What is the risk of these hazards occurring?
5. What is the severity of the hazards, and what are the likely consequences to health if the hazard is realised?

Codex says that the HACCP team should "list all hazards that may reasonably be expected to occur at each step in the production process". In practice, if the team has not considered PRPs, then there may be too many minor hazards cropping up within the hazard analysis process that will dilute the effectiveness.

Hazards from PRPs or within HACCP?

One way of looking at this is to determine if the hazard can occur only if production is operating, or if it could occur at any time.

If the former, it is more likely to be controlled as a CCP, if the latter, within the PRPs.

If hazards are noted as being controlled within the PRP system, then there still needs to be a means of capturing any changes as a result of a HACCP review. Table 4.III is a simple form that can help to log any changes noted as a result of a HACCP review resulting in changes to controls at PRPs.

Table 4.III
Logging Improvements - Hazards and PRPs

Process Step/Area	Hazard/Issue	Control Measure	Currently in Place? Yes/No/Unknown

The hazard analysis should identify those hazards that need to be eliminated or reduced to an acceptable level to be able to produce safe food. When non-critical hazards are identified during the process, then effective control by the relevant PRP should be confirmed, and the results recorded.

Some teams find it useful to brainstorm to get the list of hazards and then eliminate the unrealistic ones before deciding at which step of the production process the remaining ones could occur.

Codex says a hazard is a "biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect". It could also be described as something that is a danger to health.

Hazards can be divided into three types:

- Biological
- Chemical
- Physical

On occasions when products are, or could be, apparently allergen-free, or free from a particular allergen, allergens can be considered as a separate hazard category. The BRC Global Standard for Food Safety Issue 5 requires food businesses to recognise allergens as a fourth hazard category, elevating them out of biological hazards.

Hazards can occur as part of the process, but they can also be associated with raw materials. It is a good idea to separate out the analysis of process hazards from raw material hazards. Raw material hazards may be controlled within the process, as with microbiological hazards such as *Salmonella* and *E. coli* O157:H7 in raw meat.

However, in some cases, they are controlled at the raw material intake stage as with many chemical hazards and some physical hazards such as bones within meat and fish. In practice, this means that they can be

controlled by the goods-in procedures of supplier assurance, and certificates of conformance.

A consideration of the significance of the hazard at this stage helps with preparation of the next stage - determination of CCPs, since there is no point in taking non-significant hazards through to the CCP stage. Table 4.IV shows an example of a hazard analysis form; a blank template of this is included in Appendix 1. No attempt at CCP determination should be carried out at this stage.

Significance of hazards:

This is arguably the most important aspect of hazard analysis, since this determines which hazards are carried through to the next stage, determination of CCP. Sufficient time should be invested in this stage. Judgement and experience are vital. Do NOT include spoilage organisms in the HACCP plan.

Some organisms could be safety risks; for example, yeasts in a soft drink could cause a glass bottle to explode.

A full description of biological hazards is outside the scope of this book. Appendix 2 gives a brief summary of some of the most important microbial hazards, their source, the illness caused, and any special characteristics associated with it. In this section we will examine the background to hazard analysis for pathogenic micro-organisms. The first point to stress is that spoilage organisms – yeasts, spoilage bacteria, and non-mycotoxin producing moulds – should not be considered during this process.

Various types of risk assessment models are available to help in determining the significance of the hazard; an example is given below in Table 4.III. Other more complex models are available.

TABLE 4.III
Risk Ranking Scheme

Probability/Severity	Unlikely	Occasionally	Probable	Common
Low	1	1	2	2
Medium	1	2	3	3
High	2	3	3	4
Very High	2	3	4	4

An in-house determination of the categories will have to be carried out; what constitutes low, medium, high, and unlikely, through to common. Remember that this relates to the likelihood of the hazard occurring if the process fails, not if it is carried out correctly. Note that public perception of the risk of hazards is often at variance with the scientific viewpoint, illustrated in Figure 4.2.

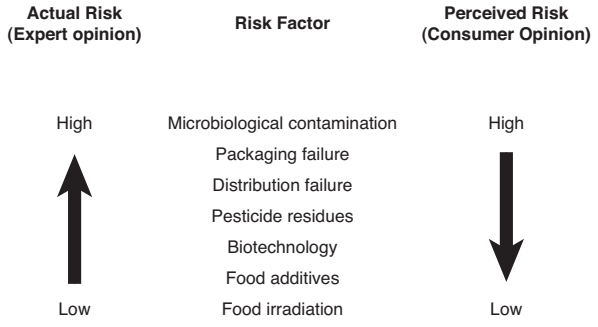


Fig. 4.2. Perception of the Risk of Certain Hazards

TABLE 4.IV
Hazard analysis chart

Process step	Hazard	Source/Cause	Significant hazard?	Control measure(s)	Comments
Purchase of liquid egg	Presence of *Salmonella*	Fault in pasteurisation at supplier end	Yes	Use approved supplier Obtain certificate of conformance	
Extrusion	Pasta – wrong shape	Incorrect plate used	No		The shape of pasta is a quality issue
Pasteurisation	Survival of vegetative pathogens due to inadequate pasteurisation	Temperature too low and / or process time too short	Yes	Set correct process time / temperature	
Cooling	Growth of spore forming pathogens e.g. *Bacillus cereus*	Cooling too slow	Yes	Blast chiller	
Storing at <5 °C	Growth of *Listeria monocytogenes*	Improper chiller temperature	Yes	Correct temperature control	
Incorrect gas mixture	Growth of aerobic microbes including yeasts and moulds	Poor control of gas flushing, or leaky seal	No		Growth of spoilage organisms is a quality and shelf life stability issue

Pathogens are the focus of HACCP and the following are examples of some important questions that should be asked when considering them:

- Is the pathogen a faecal organism, one from the environment, or is it able to produce spores or other resistant forms?
- Can the pathogen grow in the food under the conditions of production and storage, or does it merely need to contaminate food to cause a problem?
- Can the organism produce toxins in food or in the body; if in food, how heat stable are the toxins, and at what dose do they cause problems?
- Are particular consumer groups more susceptible to the effects of the pathogen than others (infants, children, the elderly, pregnant women)?

- Is a particular organism or a group of similar organisms being considered?
- Does the organism naturally contaminate the raw material, or is it a frequent/infrequent contaminant?
- If present, can it survive under process and storage conditions, or does it decline and die out?
- Under what circumstances can it grow, and is there much strain variation?

Note that some organisms can survive all but the most aggressive thermal process; some can grow, albeit slowly, at refrigeration temperatures; some have a very low infectious dose; most do not require oxygen to grow, although there are very few strict anaerobes. Across the spectrum of organisms that are considered in this process, the way in which different organisms react to the product's control factors of pH, a_w, and preservatives vary enormously.

It is important to be specific in identifying the hazard; start with the hazard and then state the cause e.g. contamination with the particular pathogen of concern due to poor hygiene or poor temperature control, or survival of *Salmonella* due to inadequate time/temperature control at a particular CCP.

The team may need external help in conducting a hazard analysis. This help could include consultants, industry bodies, specialists within other parts of the organisation, previous experience and records, raw ingredient suppliers, examples of recalls from the media, technical books and journals, and computer models.

4.3.6.2 Biological hazards

Codex describes control measures as "any action or activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level".

Typical control measures include:

- Adequate cooking – pasteurisation, cooking, sterilising
- Rapid cooling to <8 °C, preferably 5 °C or below
- Hot holding above 63 °C
- Adjustment of pH/organic acid content
- Adjustment of a_w

- Use of chemical preservatives such as nitrite, sulphite, sorbate, nisin
- Packaging and modified gas atmospheres

PRPs will also help here by ensuring that the overall plant contamination level does not increase, leading to a microbial overload of the process.

It may be necessary to conduct shelf life or challenge studies to determine control measures. If these are carried out they must include sensible parameters, for example, typical domestic storage temperatures (5 °C), the legal upper chill storage temperature (8 °C), and mild abuse temperatures (12 °C). In addition to the proper intended use, it is important at this stage to consider the potential for abuse by consumers.

A decision tree for the process of determining if a certain pathogen is likely to be a hazard in the finished product is given in Figure 4.3, developed by Notermans and Mead.

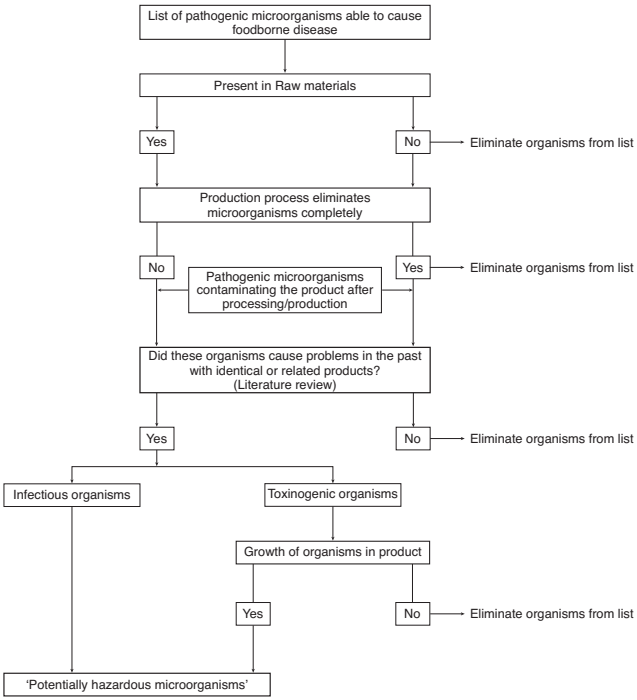


Fig. 4.3. Decision Tree for Risk Assessment of Pathogens. (Adapted from Notermans and Mead, 1996)

Remember, it is the risk of the hazard occurring if the process fails, not if it is maintained, that we must consider. If a producer makes cooked meat pies that are intended for reheating by the consumer, the likelihood of *Salmonella* surviving, and potentially causing food poisoning in a meat pie that has not had a full heat process is very high.

Use your brain!

Brainstorming is a useful technique for hazard analysis; it needs practice to make it work. The key points are:
(a) use a scribe - you can't catch all ideas on paper if you are thinking of them as well!
(b) All ideas are valid, at least initially; write them all down, sift later.
(c) Think outside the box!

4.3.6.3 Chemical hazards

Chemical hazards can occur in the raw materials, in the process, and from packaging materials.

Some examples of contaminants are heavy metals, arsenic, dioxins, polychlorinated biphenyls (PCBs), pesticides, hormones and antibiotic residues. Some foods contain natural toxins that may be harmful at certain levels; control is by careful selection of raw ingredients, processing to remove some or all of the toxin, or limiting the proportion in the food. Legumes in particular have a range of toxins that may need to be considered. In some cases, poor handling causes or exacerbates the problem. Histamine is a toxin produced by the breakdown of the amino acid histidine in certain types of fish (mackerel and tuna); rapid cooling after capture and maintenance of the chill chain minimises the risk of histidine production to harmful levels.

Process contaminants include refrigerants, lubricants, pest control agents, and cleaning chemicals.

Packaging contaminants include plasticisers, printing inks, and adhesives. All of these hazards should be controlled within PRPs such as Good Agricultural Practices (GAP), GHP, and Good Storage Practices (GSP).

4.3.6.4 Physical hazards

Again, physical hazards can occur in the raw materials or the process. They include natural materials such as bone, tendons, or skin from animals, and stalks, stems and other fibrous material from plants. Alternatively, they can come from raw material or process contaminants such as metal, glass, hard plastic and wood.

Control is dependent upon the type of physical hazard. For metal detection and removal, magnetised sieves and grids can be used. Glass is more difficult to control, and usually involves a policy decision to minimise the use or occurrence of glass within the factory. Diligence is essential in this case to make sure that employees understand the importance of adhering to the policy. Glass registers, audits, breakage procedures and records are components of this policy. X-ray detection can be used for non-metal physical contaminants, but this is expensive.

Adequate maintenance of machinery, knife policy and adherence to metal policies are some of the control measures. Other measures include separation by air, floatation, filters, vibration, vision systems, colour sorting and human inspection and sorting.

4.4 Summary

Food-specific knowledge is required to undertake a hazard analysis. Always be alert for new information on hazards, or new hazards. Build review procedures into HACCP so that they are automatically carried out if hazard knowledge changes, or the production process changes. Expect the unexpected, and imagine the worst that could happen!

5. PRINCIPLE 2 – DETERMINE CCPS

5.1 Introduction

This stage is probably the one most fraught with problems for many people, and it is the CCP decision tree that causes most anxiety. Codex is quite clear that the determination of CCPs may be helped by using a decision tree, such as the example shown in Figure 5.1. This provides a logical, structured approach to decision making; however, it is not the only way to determine CCPs, and the use of the decision tree should be flexible; it may not work in all situations.

It is also very important that the team is trained in how to use the decision tree. In many cases, common sense will tell you that a certain stage is a CCP; pasteurisation will be one of the CCPs in the production of milk for human consumption. Documentation of the decision-making process is vital to ensure that the reasoning behind a decision is recorded.

Note:
If a significant hazard has been identified, but there are no control measures, then the process must be modified to include a control measure.

5.2 Critical Control Points

What is control? Control means to regulate; it should not be confused with checking, testing or verifying. For example, rapid fermentation for a yoghurt or cheese is the control factor, not measuring the pH after 4 hours. That is a

monitoring procedure that does not affect the safety of the product. It indicates that the process is under control.

It is vital that the number of CCPs is realistic for the process under study; too many and the plan becomes unwieldy and cumbersome, but all those necessary to ensure the safety of the product must be included. It is also important that the study does not confuse safety and quality. HACCP is only concerned with food safety.

Codex says that a CCP is "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". This therefore means that total eradication of the hazard is not always necessary if the reduction renders the product safe for human or animal consumption.

5.3 Prevention, Elimination or Reduction?

Prevention indicates that the hazard is latent, that it has not yet occurred. An example might be a process where the product is processed at 95 °C for 30 seconds; most pathogens are destroyed, but most pathogenic spores will survive. Spores will germinate and grow if cooling is too slow; rapid cooling prevents the hazard from occurring. Alternatively, the hazard may be there at a low level, and in this case prevention means keeping it down to a safe level. One example of this is *L. monocytogenes*, which may be present in salads but is kept at a safe level by adequate chilling.

Another example would be rapid chilling of fresh pasta or a ready meal product after a heating process; this prevents the outgrowth of heat-shocked *Bacillus cereus* spores and potential toxin production.

Elimination indicates that the hazard is already there, and needs to be completely removed; an example would be a vegetative pathogen such as *Salmonella* in meat. Elimination is by a heat process, for example adequate cooking.

In the third case, the hazard is there, and cannot be completely removed, but this is not necessary for the production of safe food. An example would be metal detection and removal, which works to the detection limit of the process. Another example would be a mycotoxin or other chemical contaminant. There will be a maximum tolerance limit which must be met. Monitoring measures for the material must be in place, so that material exceeding the maximum tolerance level is not used for human consumption.

There will be a number of significant hazards that have been identified from the hazard analysis stage; these will now need further evaluation to

determine where in the process the CCPs are located. Starting with the raw material intake stage each process stage must be examined in turn, assessing the hazards.

5.4 The Decision Tree

The decision tree is shown in Figure 5.1. Answers are filled in on the Process Step Decision Tree Record Sheet, as shown in Tables 5.I and 5.II.Templates of both of these forms are included in Appendix 1.

5.4.1 How to use the decision tree

It is critical to use the experience of the team to determine if a process step is a CCP. Sometimes, experienced teams can make assessments without using the decision tree. The decision tree should always be used if the team cannot decide if a raw or process stage is a CCP, or if there is general disagreement.

5.4.1.1 Question 1. Do control preventative measure(s) exist?

The decision tree starts by asking a simple question; assuming there are hazards in the process at this step (otherwise we would not be undertaking a CCP analysis), do control measures exist for the hazards that have been identified? If the answer is yes, move to Question 2, otherwise, go to Question 1a.

5.4.1.2 Question 1a. Is control at this step necessary for safety?

If the answer to Question 1a is yes, this means that there is no control at this step for the significant hazard that has been identified. The product or process must be modified to include a control measure. Codex recognises that in some cases, more than one stage is required to control a hazard.

If the answer is no, possibly because control is exerted further down the process, then pass to the next process step or hazard.

For the majority of the time, control measures have already been identified as part of the hazard analysis stage; the purpose here is to make sure that there are control measures for all significant hazards.

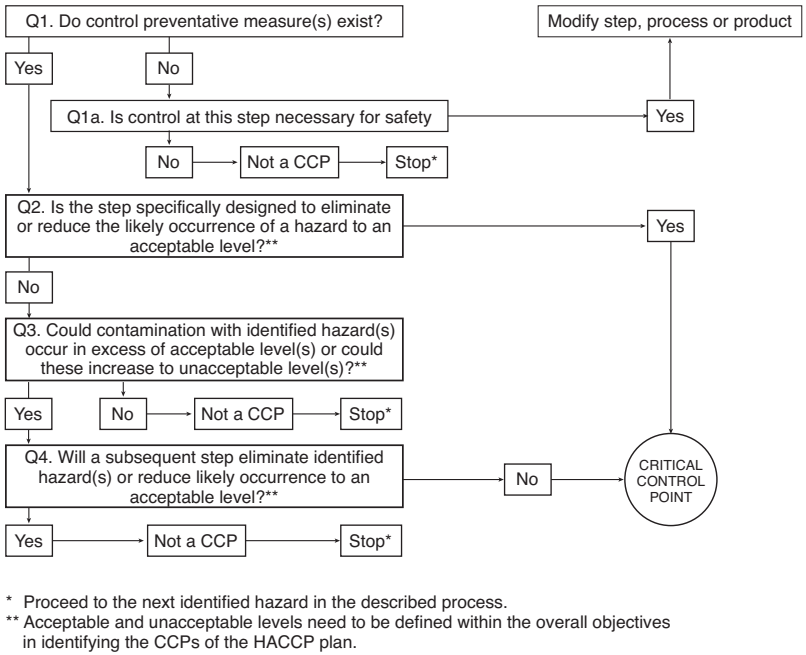


Fig. 5.1. Process step decision tree (Adapted from Codex, 2003)

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

The purpose of this question is to determine whether the step under consideration directly controls the identified hazard. Always ask the question for the process step, not the control measure. It can be useful to substitute the actual name of the hazard and the process step for the words hazard and process step; this can often help to clarify whether the step is a CCP or not. Some process steps are fairly obviously CCPs, for example,

pasteurisation of a ready meal, whereas some preparatory steps (chopping, portioning) are probably not.

> ***Tip:***
>
> ***Remember to ask the question of the step and the hazard, adding the actual step and hazard at the appropriate place.***
>
> ***You must carry out the significance estimation first, or minor hazards will be seen as CCPs.***

If the answer is yes, then this step is a CCP, and there is no need to progress further with questions for this process step or hazard. Return to Question 1 for the next hazard at this step, or move on to the following process step. If the answer is no, continue to Question 3.

5.4.1.4 Question 3. Could contamination with identified hazard(s) occur in excess of acceptable level(s) or could this increase to unacceptable level(s)?

Again, put the name of the hazard and step in the question. Question 3 is really asking if the product could become contaminated with chemical, physical or biological hazards, or if growth of a pathogen could occur if controls fail at this point.

If the answer is no, move on to the next step or hazard (control is not necessary here). If yes, go to Question 4.

5.4.1.5 Question 4. Will a subsequent step or action eliminate or reduce

the hazard to an acceptable level?

This question follows on from Question 3 in that if we identify a contamination risk there we then need to see if a subsequent step can bring it under control. If the answer here is yes, and a subsequent step will control the hazard, then move to the next step or hazard as this is not a CCP. If the answer is no, then this step is a CCP, and we must make sure that adequate controls are put into place for the hazard at this process step.

Comment:
Sometimes a company feels a certain hazard must be controlled as a CCP, but it is clear that either:

1. The hazard cannot be controlled
2. Sensible critical limits cannot be ascribed to the CCP
3. Adequate real-time monitoring is not possible

A decision must then be made to change the process to accommodate this, or live with the hazard. Was it really a CCP? It is more than likely that a hygiene or cross-contamination related hazard will be controlled by prerequisite programmes. For example, personnel hygiene, PPE, facility design, operational flow and training.

5.4.2 Two simple demonstrations of the decision tree

Figures 5.2 and 5.3 detail two simple demonstrations of the decision tree, and Tables 5.I and 5.II show the records that accompany them. The first demonstration (Figure 5.2) makes use of part of the pasta production flow diagram found in Figure 4.1, while the latter (Figure 5.3) is a hypothetical process.

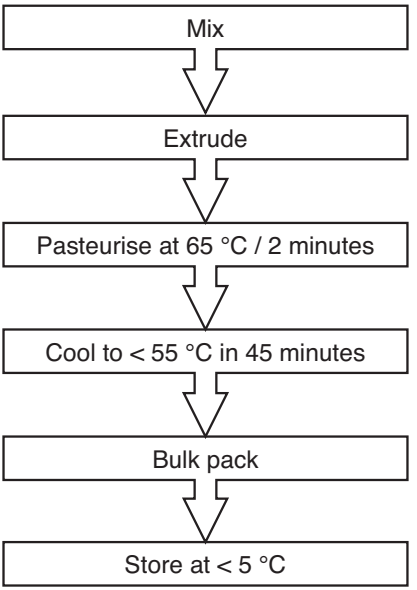
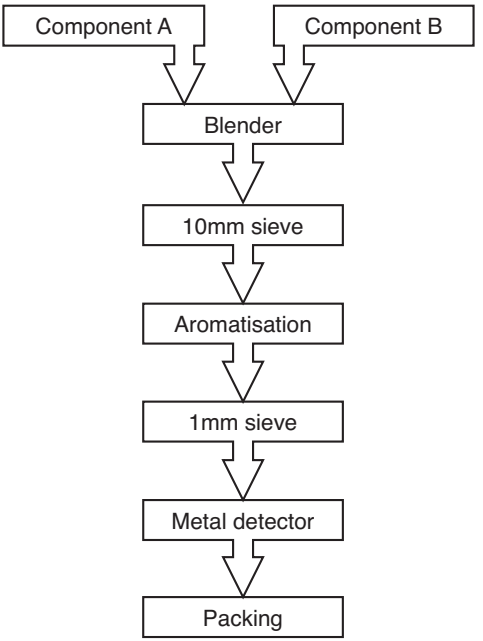


Fig. 5.2. Demonstration of the decision tree 1

TABLE 5.I
Process step decision tree record sheet 1

Process step and hazard	**Q1**	**Q1a**	**Q2**	**Q3**	**Q4**	**CCP Y/N**	**HACCP Team Comments**
Pasteurisation Survival of pathogenic micro-organisms	Yes	–	Yes	–	–	Yes	Pasteurisation is designed to give a log 6 reduction in microbial load
Cooling Growth of spore forming pathogens e.g. *B. cereus*	Yes	-	Yes	-	-	Yes	Rapid cooling will prevent germination of spores.
Store at <5 ºC Growth of *L. monocytogenes*	Yes	–	No	Yes	No	Yes	*Listeria* can grow at <5 ºC, albeit slowly. Storage at <5 ºC enables the product to remain safe for its shelf-life.

In Figure 5.3 a dry mix product is made by mixing two components in a blender, sieving them prior to aromatisation and then again prior to metal detection and packing.



(Note: the 10 mm sieve is included to ensure that no large lumps enter the aromatisation plant)

Fig. 5.3. Demonstration of the decision tree 2

TABLE 5.II
Process step decision tree record sheet 2

Process step and hazard	Q1	Q1a	Q2	Q3	Q4	CCP Y/N	HACCP Team Comments
10 mm sieve Contamination with foreign objects > 10 mm	Yes	–	Yes	–	–	Yes	10 mm foreign objects could damage the aromatisation plant, leading to pieces breaking off the plant and resulting in further foreign objects
1 mm sieve Contamination with foreign bodies >1 mm	Yes	–	Yes	–	–	Yes	No other point in the process will remove foreign bodies
Metal detector Contamination with metal including that from sieve failure	Yes	–	Yes	–	–	Yes	Metal contamination detection, within the bounds of the sensitivity of the metal detector

This scenario demonstrates that some hazards are controlled at more than one point in the process. If the 10 mm sieve was not in place or damaged, large particles could enter the process. They should be removed by the second, finer sieve, but the particles may damage the aromatisation plant, generating so much debris that the plant becomes unworkable, with a large quantity of fragments entering the process. The second sieve may become blocked or damaged, and the metal detector may reject a high proportion of finished packs.

The Codex decision does not always lend itself to the interpretation of CCPs for raw materials; in this case, other examples of decision trees may be helpful. An example of one such is given overleaf.

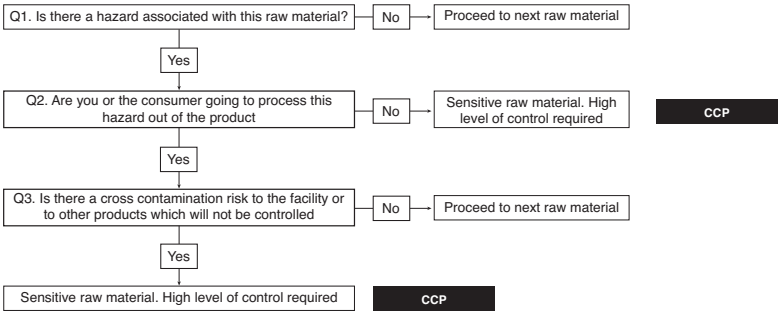


Fig. 5.4. Raw Material Decision Tree (Adapted from Mortimore and Wallace, 1998)

Essentially, the decision tree is asking whether a hazard will be processed out of the raw materials, or if there is a cross contamination risk to the facility which will not be controlled. In either of these cases the raw material must be handled very carefully and treated as a CCP.

5.5 Summary

Codex provides a decision tree, which is a quick guide to determining CCPs. However, it is possible that in some exceptional circumstances it will not work. If the results of applying the decision tree make no sense, the results should be revised using all available expertise.

Once the decision tree, or other method, has been used effectively to determine the CCPs within the HACCP system, the next stage is to establish critical limits for each of these CCPS, which will be discussed in the following chapter.

6. PRINCIPLE 3 – ESTABLISH CRITICAL LIMITS FOR EACH CCP

6.1 Introduction

Codex describes a critical limit as "a criterion that separates acceptability from unacceptability". This seems fairly straightforward but can be difficult to identify in practice. By unacceptable, Codex is referring to unsafe products; those likely to cause harm if the product reached the consumer. HACCP is only concerned with safety, not quality, and so a product could be out of technical specification, but remain safe.

Critical limits should be specified and validated for each hazard at a CCP. More than one critical limit may be defined for a single step, dependent upon the hazards being controlled. Sometimes it can be a procedure – washing, or blending, or having a certificate of conformance for a critical raw ingredient, but more frequently, there will be definite values attached to the critical limit.

Time and temperature are common critical limits for a thermal process. Criteria used to set critical limits must be measurable or observable. When critical limits have values these must be absolute and precise, for example, 75 °C for 90 seconds, not 72 - 75 °C, or for 95 - 110 seconds. Without the absolute and precise definition of critical limits it is not possible to tell when they have been breached.

6.2 Critical Limits

Critical limits must be easy and quick to measure, or there is the danger that a CCP moves out of control without it being realised for some time. It can be measured by test or observation. Each control measure at a CCP must have a critical limit. Typical critical limits include time and temperature of a

heating/cooling process, pH, concentration of sodium hypochlorite for a washing procedure, or preservative concentration.

If you are unsure how to control a particular hazard, critical limits may need to be determined by investigation. This can be by literature review, previous knowledge, mathematical modelling, customer or supplier experience, or by conducting experiments. In all cases product tests should be conducted to prove the safety of the process. The prior stages can be used to limit the number of laboratory and/or process trial experiments that need to be conducted. In the latter case, a defined set of experiments is required.

In the case of thermal treatments:

1. Validate the thermal profile of the cooker by temperature logging across the interior to determine hot/cold spots
2. Determine the core time/temperature profile to destroy the required level of pathogens in the product by challenge testing products with required levels of contamination
3. Determine the minimum oven air temperature required to achieve that core temperature in the product
4. Validate that time/temperature profile for differences in size, thicknesses, density and temperature of product
5. Validate the time/temperature profile for different loading patterns for the oven
6. Challenge tests should be set up using appropriate cocktails of strains of the organism

Obviously, limits must relate to the hazard that needs to be controlled. Some critical limits are actual process limits, and must be measured whilst the process is happening, for instance, temperature of a pasteuriser, or the pH of a batch of sauce. Such parameters must be measured as part of the process (‘in-process’). Others are ‘off-line’, and can be measured according to schedules that are independent of the speed of production, for example, mycotoxin levels for stable raw ingredients, or the presence of a certificate of conformance for a critical raw ingredient.

Comment:
It is important that critical limits relate to the hazard, and are clear and unambiguous. There should be a sufficient gap between target and critical limit to generate a 'buffer zone' for efficient process management.

Some critical limits are procedures – using an approved supplier, or start-up Cleaning In Place (CIP) cleaning schedules for aseptic processes.

6.3 Target Values

If the critical limits were used as the set points for a process, then it would be operating out of specification, and potentially unsafe about 50% of the time, since any heating or cooling process will fluctuate as the thermocouple clicks in and out. This may mean that the production line is stopping and starting, as the product is quarantined. To avoid this problem, a stricter set of controls called target levels, operating limits, or process controls, is used.

Codex does not describe target levels, being concerned only with the absolutes of food safety, but they are essential for the proper and efficient working of a food operation. Target levels are control parameters that are more stringent than critical limits, and give the food operation a buffer zone for product safety. Typical target values will be 2 - 5 °C above critical limits (for a cooking operation) or below critical limits (for a chilling operation), to allow for variability in measurement (± x °C).

6.3.1 Demonstrating the use of target and critical limits

If temperature control is required, a thermocouple is often used. This switches off the heat source when the temperature reaches the set point, and switches it on when the temperature falls below the set point. The resulting temperature therefore fluctuates around the set point.

In the first process (Figure 6.1) the critical limit is 75 ºC. However, it can be seen that for a total of four out of the first eight minutes the temperature

was below the critical limit. If the requirement of the process was to hold at 75 ºC for eight minutes, this record would show a failure in the process.

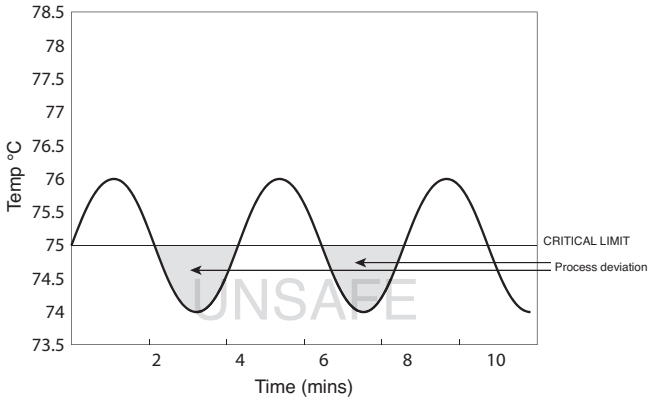


Fig. 6.1. Graph showing fluctuation of temperature around the critical limit

If a target value is set at 77 ºC as shown by the dashed heavy line in Figure 6.2, the temperature remains above 75 ºC for the whole eight minutes and so the critical limit is achieved for the entire process.

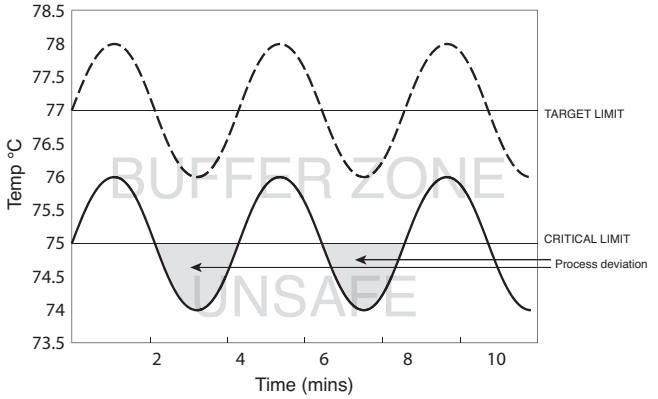


Fig. 6.2. Graph comparing fluctuation of temperature around target level compared with the critical limit

In this example the setting of the target at 77 ºC ensures that the critical limit is achieved.

When target limits are set, it is important for the HACCP team to consider what the food safety margin should be, as well as allowing for the variability of instrument readings and automatic operation control.

Comment:
Sometimes the critical limit and the target are the same - metal detection limits, limits for mycotoxins and other chemical contaminants.

At this stage, filling in the HACCP Control Chart can begin; an example of a Control Chart is given in Table 6.I. It is useful to record the CCP, process step, and control measure of critical and target limits in the HACCP control chart. We will keep referring to this document at different stages in this book as it needs to be completed at various points during the process. The part of the pasta production flow diagram (Figure 5.2), used for demonstrating the use of the decision tree, will be used as the example.

TABLE 6.I
HACCP control chart – stage 1

Process Step	Hazard & source/ cause	Control Measure	CCP no.	Target Value	Critical Limit
Pasteurisation of product	Survival of vegetative pathogens due to inadequate pasteurisation	Pasteurisation	1	74 °C for 2 minutes	72 °C for 2 minutes
Cooling	Growth of spore forming pathogens	Blast chiller	2	3 °C within 45 minutes	5 °C within 45 minutes
Storing of product	Growth of *L. monocytogenes*	Correct temperature control	3	3 °C	5 °C

6.4 Summary

All CCPs must have critical limits; target levels are more stringent limits that facilitate process control. Variability in process and measurement must be taken into account when these limits are set.

7. PRINCIPLE 4 – ESTABLISH A MONITORING SYSTEM FOR EACH CCP

7.1 Introduction

Monitoring is concerned with setting up a system that enables the CCPs determined by a HACCP study to be measured and recorded using either automated systems or quick, simple and robust manual measurements. The results of all monitoring activities must be recorded.

7.2 Establish a Monitoring System for Each CCP

Codex 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 involves planned measurement or observation of a CCP relative to its critical limits. Monitoring procedures must be able to quickly detect loss of control of the CCP. They should provide this information with sufficient speed to allow adjustments to be made to control the process before the critical limits are violated. Monitoring should either be continuous, or carried out frequently enough to ensure control at the CCP. Therefore, physical and chemical on-line measurements are considered preferable to those measurements that take longer, for example, microbiological testing. Microbiological testing in any case should be viewed as a verification tool, since it cannot guarantee the absolute safety of a food product or ingredient.

However, certain rapid methods, such as Adenosine Triphosphate (ATP) assay by bioluminescence may be useful for assessment of adequate cleaning, which could be a critical limit for some CCPs, such as pre-start up clean-downs before production commences.

Monitoring is normally conducted at the target level not the critical limit, as the process would otherwise be constantly veering in and out of control as the process control equipment oscillates around the mean.

Persons engaged in monitoring activities must have sufficient knowledge, training and authority to act effectively on the basis of the data collected. These data should also be properly recorded. It is critical that the monitoring activity is carried out at the correct time or, if not, that the actual time is recorded. There should be no falsification of records to make the process look good.

Comment:
Records that are poorly filled in are a common cause of non-compliances within audits.
Staff must understand that records must be filled in correctly, legibly, on time (or within 10 minutes or so of the designated time), by appropriately trained personnel, and not altered once filled in, or corrected in such a way that the original data value is no longer visible.

7.2.1 Elements of an effective monitoring system

There are many elements to be considered when introducing an effective monitoring system. The following are the most important;

1. Must be able to demonstrate that the CCP is under control.
2. Continuous monitoring is the ideal, but where this is not practical the testing must be sufficiently rapid and frequent to allow effective action to be taken on the basis of the results.
3. Every monitoring result at each CCP must always be systematically recorded.

4. Measurement methods for use at CCPs must be clearly documented and validated, with due consideration for the calibration requirements of the equipment used for the tests.
5. Staff must be fully trained in all monitoring procedures, including the care of the equipment used.
6. When target values are used, these must be clearly identified.
7. The positioning of monitoring in the process must be carefully considered. Measuring points are usually at the most likely point of infringement: cool spot in an oven, warm spot in a refrigerator, or after the addition of a critical ingredient.

7.2.2 Example of monitoring a CCP

The chart (Figure 7.1) shows the output from the monitoring of the temperature of a process, with the temperature being recorded at two-minute intervals.

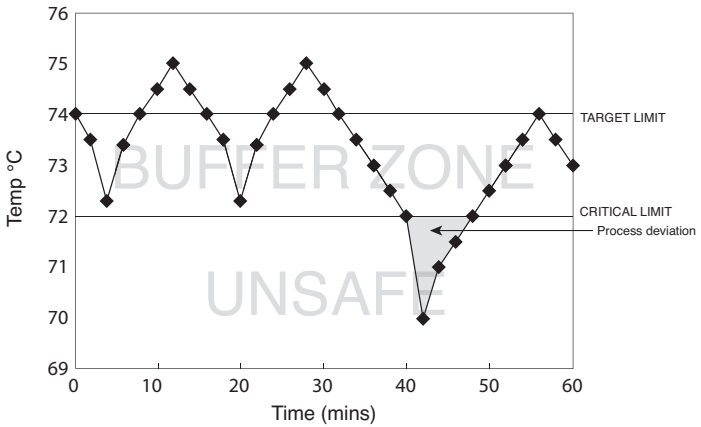


Fig. 7.1. Graphical representation of results of monitoring

The lower line on the chart is the critical limit of 72 ºC, below which the safety of the process is compromised. The higher line at 74 ºC is the target level. There are corrections evident at 4, 12, 20 and 28 minutes that keep the

process in control. These may have been manual adjustments or from a feedback control. At 40 minutes the process is out of control, and safety is compromised. The process is back in control at 50 minutes.

Following the monitoring stage, it is now useful to complete some additional columns in the HACCP control chart, as seen below in Table 7.I.

TABLE 7.I
HACCP control chart – stage 2

Process Step	Hazard & source/ cause	Control Measure	CCP no.	Target Value	Critical Limit	Monitoring		
						F	R	D
Pasteurisation of product	Survival of vegetative pathogens due to inadequate pasteurisation	Pasteurisation	1	74 °C for 2 minutes	72 °C for 2 minutes	Every 20 minutes	Line Operator	Line Pasteuriser record
Cooling	Growth of spore forming pathogens	Blast cooling	2	3 °C within 45 minutes	5 °C within 45 minutes	Hourly *	Line operator	Line Cooling Record
Storing of product	Growth of *L. monocytogenes*	Correct temperature control	3	3 ºC	5 °C	Twice a shift	Line Operator	Chiller record

* Monitoring is different for continuous vs batch production

Key: R = Responsible person F = Frequency D = Document

7.3 Summary

The key point about monitoring is that it should be carried out frequently enough to ensure process and product safety, but not so frequently (if carried out manually) that it creates an unnecessary burden upon staff.

8. PRINCIPLE 5 – ESTABLISH CORRECTIVE ACTIONS

8.1 Introduction

In the previous chapter, the elements of setting up a monitoring system were discussed. Corrective actions are taken when monitoring shows that the process is out of control (or about to become out of control). According to Codex a corrective action is "Any action taken when the results of monitoring at a CCP indicate a loss of control".

8.2 Establish Corrective Actions

For each CCP in the HACCP plan, there must be specified corrective actions to be applied if the CCP is not under control. If monitoring indicates a deviation from the critical limit for a CCP, action must be taken that will bring it back under control. Actions taken should include proper isolation and labelling of the affected product. Corrective actions can be manually implemented, or implemented as part of an automated control system. It is essential that all corrective actions are recorded.

Although Codex does not mention target levels, it is vital to take these into account when setting up corrective action plans. Corrective actions at targets are simpler than those at critical limits.

8.3 Corrective Action Plans

Corrective action plans must clearly describe what action is to be taken in the case of a failure at a CCP, including responsible personnel, the specific actions to be taken, and the records that are to be made. There must be a corrective action plan for every CCP.

8.3.1 Infringement of target level

A corrective action plan when a target level is infringed should:

1. Ensure that process control is maintained, and that the process does not slip through the critical limit. This is usually the responsibility of the operator, or it may be automatic.
2. Investigate why the process went out of control. This is normally the task of the safety or quality manager. This investigation and any actions arising from it should be recorded.
3. Make sure that this infringement does not happen again. Depending on the cause of the infringement, this could involve production and engineering staff, as well as all of the HACCP team.

8.3.2 Breach of critical limit

If a critical limit is breached a corrective action plan should:

1. Quarantine the defective product, since the process is now unsafe.
2. Regain process control. Usually the process operator or an engineer carries out this action.
3. As and when a target level is infringed, carry out a thorough investigation into why the process went out of control. This is normally the task of the safety or quality manager. This investigation and any actions arising from it should be recorded.
4. Decide the fate of the affected product; can it be reworked or used at a lower grade, or must it be discarded? Usually a combination of safety, quality or technical managers make this decision, which must be formally recorded.
5. Ensure that actions are taken to prevent the recurrence of the problem. A formal record of these must be kept, including confirmation that these actions have been completed.

8.4 General Principles

Procedures must be in place to fully assign the staff responsible for investigating failures at CCPs, and the reporting route through the management of the company. These procedures should contain time limits.

An investigation of a failure at a CCP is required; it must identify the cause of the problem and ways of preventing its recurrence. If the investigation identifies a training requirement, this should be fulfilled as a matter of priority.

8.5 Example of Corrective Action

The monitoring system has shown that the metal detector at a CCP is not functioning and has failed to detect the metal test piece; Table 8.I details the corrective action to be taken.

It is expected that the relevant PRPs will contain procedures for dealing with quarantined product, incident reporting and installing new or repaired equipment onto the production line.

TABLE 8.I
Corrective action

Action	Responsibility
Divert all current production to 'Quarantine status'	Production Supervisor
Inform Line Quality Supervisor	Production Supervisor
Quarantine all product produced since the last satisfactory check	Line Quality Supervisor
Repair or replace metal detector	Factory Engineer
Prepare incident report	Site Quality Manager

Figure 8.1 is intended as an example of a possible layout and communication method for the immediate corrective actions to the line operators, or other personnel who carry out the monitoring tests; a usable form is provided in Appendix 1.

CCP No. . . . . Description . . . . . .
Critical Limit . . . . . Procedure reference . . . . . .
Target Limit . . . . . Date . . . . . .

Time	Result	Comments	Operator

In the event of the TARGET being infringed, the operator must ……..... and record the action taken (using the comments column) and repeat the test. If the TARGET is still infringed treat as CRITICAL.
If the Critical limit is infringed the operator must:-

1. Quarantine the production
2. Inform the Line Quality Supervisor immediately
3. Record the time of the infringement of the critical limit

Fig. 8.1. Example of a CCP monitoring record sheet

8.6 Summary

Corrective actions must be defined for those occasions when monitoring shows that a critical limit or target value is infringed. The responsibility for corrective actions must be clearly designated. Once this stage has been completed, the final columns in the HACCP control chart can be filled in (Table 8.2). Appendix 1 contains a HACCP Control Chart that can be downloaded for use. Once this has been repeated for all process steps, there will be a complete HACCP control chart detailing all CCPs and the monitoring and corrective action required for these.

TABLE 8.II
HACCP control chart – stage 3

CCP for potential hazards associated with process steps **Product:** Pasta **Date:** 29th April 2006

Process Step	Hazard & source/cause	Control Measure	CCP no.	Target Value	Critical Limit	Monitoring			Corrective Action		
						F	R	D	Method	R.	D
Pasteurisation of product	Survival of vegetative pathogens due to inadequate pasteurisation	Pasteurisation	1	74 °C for 2 minutes	72 °C for 2 minutes	Every 20 minutes	Line Operator	Line Pasteuriser record	Quarantine affected product Restore process defect Investigate problem to prevent recurrence	Line Operator Engineer Production Manager	Corrective Action log Investigative Report
Cooling	Growth of spore forming pathogens	Blast cooling	2	3 °C within 45 minutes	5 °C within 45 minutes	Hourly	Line operator	Line Cooling Record	Isolate affected product Restore process defect Investigate problem to prevent recurrence	Line Operator Engineer Production Manager	Corrective Action log Investigative Report
Storage of product	Growth of *L. monocytogenes*	Correct temperature control	3	3 °C	5 °C	Twice per shift	Line Operator	Chiller record	Move product to another refrigerator Restore	Line Operator Engineer	Corrective Action log

9. PRINCIPLE 6 – ESTABLISH VERIFICATION PROCEDURES

9.1 Introduction

There are two aspects to verification of a HACCP study:

1. Validation: is the system capable of making safe food; is the product safe?
2. Verification: is the system being run as planned and documented; is the product consistent?

Analytical testing, data collection and auditing are some of the methods commonly used to answer these questions. Verification is not carried out in 'real time'. Verification can also be carried out on suppliers. Verification should be a regular, scheduled event.

9.2 Validation – When and How?

Validation is ensuring that the various parts of the HACCP plan actually work, and achieve the desired result. Some examples of validation are given below. Additionally, when the team has completed the first five principles of the study, the whole study should be reviewed, to ensure that all the controls for all the relevant hazards have been identified, that the critical and target limits are correct, and that no hazards have been omitted. It is useful to call on an expert from outside the HACCP team to carry out this validation.

One of the confusing aspects of validation is that it is included as part of verification, but this is an activity that is carried out much later, when the HACCP system is running. Another difference is that validation is usually

carried out by members of the HACCP team - production, technical or safety, but verification must be independent, as we will see later.

Another variance is that validation is carried out as a 'one off', until changes to the system occur, whereas verification is carried out regularly.

As with all parts of HACCP, records must be kept of these investigations and activities. Validation will require reviewing if and when changes are made to the process or product.

You may not have the experience to validate some aspects of your process; in this case, you can use outside help from the manufacturer of the equipment concerned, or a trade body or research association, or a consultant who has worked in the product and process area. As ever, documentation of the validation process is vital. Statistics should be used where appropriate to determine if the process is capable of working.

9.2.1 Some examples of validation

1. A step in the process is to cook a product at 120 ºC for 15 minutes, with a critical limit that the core temperature must reach 75 ºC for five minutes. The monitoring procedure is to check the temperature of the oven. However, to validate the control measure the product is to be probed at its core, to check that the core temperature does reach 75 ºC for five minutes.
2. On an automated control continuous pasteuriser the minimum temperature required is 72 ºC. Validation would involve carrying out an investigation to confirm that the temperature of the product in the pasteuriser does reach the temperature indicated by the probe and sensor on the equipment.
3. The pH of the product is intended to control the growth of a particular organism. The process is validated by laboratory testing, to ensure absence of the organism in the finished product before it goes on sale.

As noted in the section on critical limits, it is a little more complex than that, however, as the oven also needs validating under varying loads, unless this has been carried out already. Variability in product that could affect the cook will also require investigating.

Validation usually requires two elements: validation of the process to ensure that the required critical limit can be achieved, and validation of the target, to ensure that the process is safe at this point.

Once all of the CCP critical limits have been validated, the process can be implemented.

Comment:
Validation is a complex process that must be carried out carefully and thoroughly to ensure applicability of critical limits under all likely variations in the process.

9.3 Verification

According to Codex, verification is "the application of methods, procedures, tests and other evaluations, in addition to monitoring, to confirm compliance with the HACCP plan".

Verification should be scheduled on a regular basis. Verification includes random sampling and analysis, including microbiological testing. Although microbiological analysis is generally too slow for monitoring purposes, it can be of great value in verification, since many of the identified hazards are likely to be microbiological.

In addition, reviews of HACCP records are important for verification purposes. These should confirm that CCPs are under control, and should indicate the nature of any deviations and the actions that were taken in each case. It may also be useful to review customer returns and complaints regularly.

9.3.1 Verification procedures

Audits must be executed by people who were not part of the HACCP team. They can be carried out by suitably qualified members of staff from other departments, other HACCP teams in a large company, or an external consultant. If the company holds accreditation under a manufacturing standard that includes implementation of HACCP, third party audits carried out as part of the maintenance of this standard will provide a valuable contribution to the verification of the HACCP system, as will customer audits.

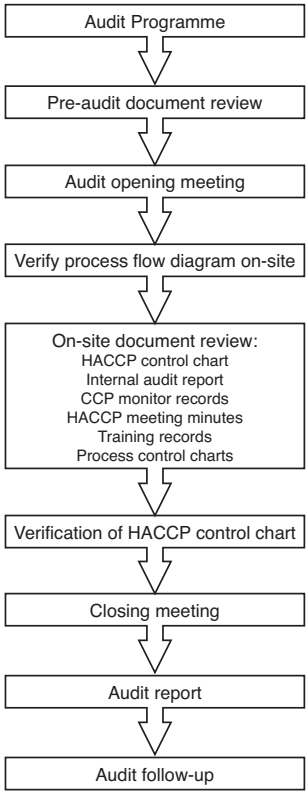


Fig. 9.1. The Audit Process (Adapted from Mortimore and Wallace, 1998)

Two main procedures used for verification are auditing and product testing.

Internal vs external audits: external audits are carried out to ensure compliance to a recognised standard: ISO 9001-2000, ISO 22000, BRC Global Food Issue 5. Internal audits are carried out for company verification, to maintain readiness for a third party audit, and to comply with a third party audit scheme.

Comment:
Independence of auditing is one of the biggest problems within HACCP. For external audits, the independence of the auditor is easy to establish; the problem arises for internal audits.
For a system audit, using members of the finance department, for example, is a suitable route and should ensure impartiality since they are used to examining paperwork for compliance. For a technical or hygiene audit, using staff from other departments is suitable. In the latter cases, audit staff must understand the process or the principles that they are auditing.

What is audited?

1. Raw material records
2. Production records - thermal logs of key processes, chillers, freezers
3. Process deviation records and actions taken
4. CCP log sheets
5. Finished product test results
6. Process control charts
7. HACCP team meeting records
8. HACCP review records
9. Customer complaints and actions taken
10. Previous Internal Audit reports, non-compliances and actions completed

11. Glass register
12. Pest control records
13. Hygiene audits
14. Training register/log

The frequency of audits will depend upon the complexity of the process, severity of hazards and the confidence of the company through historical data. A relatively new company or one producing a novel product for which they have no prior knowledge may review records more frequently than a more established one or a company producing low risk products, for example dried foods other than infant formula or other food for special applications.

Records can be subjected to trend analysis, either simple graphical, or statistically applied.

Product testing can be both compositional and microbiological, and is often an excellent verification that the HACCP system works. Using product testing is rarely useful for "positive release" of product. Large stocks must be stored whilst the tests are completed, and the relatively high level of sampling required for sensibly confident positive release decisions can be prohibitively expensive. In any case, it can still be difficult to guarantee absolute food safety after microbiological testing.

9.4 Summary

9.4.1 HACCP Review

If the HACCP study has been carried out properly it will be working shortly after implementation, but it is important that procedures are established to continue the verification. The HACCP team needs to decide what events are to trigger a review of part or all of the HACCP system. The review can be in the form of an audit, and/or possibly revalidation of a particular control.

The following are examples of events that should trigger a review:

- Repair of equipment following major breakdown
- Change of supplier or origin of one or more ingredients
- Recipe modification
- Adverse comment from Enforcement Officer or customer audit
- Unexpected level of a particular type of consumer complaint
- Process modification
- Emergence of a hazard not considered in the original HACCP
- New information about an existing hazard

Regardless of the events listed above, the HACCP plan should be reviewed annually.

Scheduled vs Triggered Audit?
The annual audit is an example of a scheduled audit, whereas the audit or review after a change listed above is a triggered audit. Both are vital within HACCP. One of the purposes of the scheduled audit is to capture any changes that may have slipped through during the year.

10. PRINCIPLE 7 – ESTABLISH DOCUMENTATION AND RECORD KEEPING

10.1 Introduction

As discussed throughout this book, the HACCP study must be fully documented at all stages. It is important that this documentation is prepared and stored systematically, and is readily available to all relevant members of staff.

10.2 The HACCP Manual

Documents should contain the operational procedures for the HACCP system; records should be ongoing and show that the system is being monitored. The degree of documentation required will depend partly on the size and complexity of the operation.

The records contained in this provide the objective evidence of the implementation of the HACCP study. These records are important for internal, external and customer audits. In the event of litigation, HACCP records are vital. Records can be electronic, paper or both. They should be stored for an appropriate period of time, related to the shelf-life of the product or any legal requirements. Typically records are kept for at least a year beyond the shelf-life of the product; in practice it can vary from 1-7 years, in most cases, three years on average for most larger food businesses.

10.2.1 What should the HACCP Manual contain?

1. Records of the original study including
   - Process flow diagram
   - Product description and intended use

- Records of the original hazard analysis
- HACCP plan
- Minutes of the HACCP team meeting
- HACCP team list

It is vital to preserve the records of any hazards that were dismissed by the HACCP team, together with the reasons for the dismissal of any such hazards.

2. Other HACCP Records
   - Product specification
   - Plan of the factory and process line
   - Work instructions for monitoring at CCPs
   - Processing records
   - Equipment calibration records
   - Cleaning and disinfection records
   - Corrective action records (including product disposal)
   - Process deviation records
   - Process verification data

These are HACCP records, but it is not always necessary to make a separate copy for the HACCP manual; it may be more practical to reference other factory operating manuals from the HACCP manual. In any case, the HACCP manual and supporting systems in the factory must have the same version of the document.

3. Documents related to change and audit of the HACCP system
   - Details of HACCP audits and corrective actions
   - Details of HACCP reviews and modifications made
   - Details of the events that trigger a review of the HACCP system

10.3 Summary

Proper documentation of the HACCP system is absolutely vital, but should be carried out in the least bureaucratic way possible, so that maintenance is as straight forward as possible. The documentation system should be designed so that all parts of the business have the same version of any procedure.

11. IMPLEMENTATION

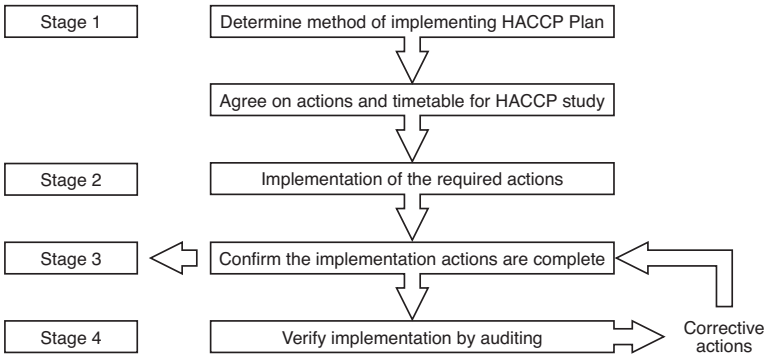


Fig. 11.1. Stage 3: Implementation (Adapted from Mortimore and Wallace, 2001)

11.1 Introduction

Implementation is an important part of HACCP. The way this is carried out depends on the company and the particular study. There are many different approaches that can be used. It is imperative that everyone involved with this stage is adequately trained and fully briefed before implementation.

11.2 Approach to Implementation

The exact approach to implementation can be vary significantly and, although it is impossible to cover all of them, it will be illustrated here by the use of three different scenarios.

11.2.1 Scenario 1: The factory has just completed its first HACCP study, and is ready to start implementation.

There are two possible approaches; either implement in all areas at the same time, or area by area.

The first option has merit in that the entire factory is covered at once, but the preparation for this has to be thorough and must also cover the whole factory. This means that every monitoring and corrective action plan must be ready, all improvements to PRPs in place, and that all staff are trained to the appropriate level. If this option is chosen, it is possible that an unrealistic burden is placed on the HACCP team and other managers. This approach can also be problematic if a particular department cannot be ready by the planned date. The HACCP team must then decide to go ahead without the entire factory being ready, or to delay implementation unnecessarily.

A second option is to implement on a stage by stage basis. In this case, implementation could start in the incoming materials section, then progress to the mixing area, and so on through the various stages of processing and packing. This option means that full implementation takes longer, but is hopefully less burdensome on the HACCP team. There are some advantages; the cost of training can be spread over a longer time, the later stages can learn from the previous ones and the implementation can be reviewed at the various stages.

A variation on the second option is to implement on a line by line basis.

11.2.2 Scenario 2: The factory has just completed the HACCP plan for a new production line; the rest of the factory is covered by HACCP.

In this case, implementation must also take account of the HACCP plan that applies to the other production lines. In particular, the first stage must be to check that the existing HACCP has been reviewed to take account of the new line, and any new ingredients or packaging that may have accompanied it.

The HACCP plan for the new line could be implemented in stages. A useful way of dividing this could be to implement all the parts of the HACCP concerned with the mixing and processing of product on the new line as one stage, and then to implement the handling of the new products and any new raw materials with the co-operation of existing departments.

11.2.3 Scenario 3: A HACCP plan has just been completed on a new product to be produced on an existing line.

In this instance, the best option is to add the new product to the whole process from the beginning to the end in one operation.

11.3 Requirements for Implementation

Whatever approach to implementation is adopted, an essential element is training of the staff that are affected. Some elements of this will involve training in relatively simple operations, others will be more complex. It must be remembered that assessment of the effectiveness of training is a vital part of the training process. The implementation plan must include specific time for training and its assessment, so that retention of information can occur before incorrect practice becomes established.

Implementation of a new HACCP plan invariably involves changes to documentation. All these amended documents should be available prior to implementation and should replace the previous issues when the HACCP plan is implemented. All previously issued documentation should be removed from the factory.

Table 11.I provides a summary of the advantages and disadvantages of immediate and phased implementation of the HACCP plan.

TABLE 11.I
Summary of advantages and disadvantages of immediate and phased implementation

	Advantages	**Disadvantages**
Immediate	• Potential for rapid implementation • Works well in companies with well established quality assurance systems • Whole work force involved (more effective than trying to change the behaviour of a small group within the existing culture) • Ease of workforce briefing	• May take a longer period overall than anticipated as all HACCP monitoring and control procedures must be developed before implementation starts • No trial of individual system elements and therefore no testing of system elements before the system goes 'live' • Loss of credibility if it is poorly managed • Large immediate training requirement • Resources thinly spread, particularly regarding the HACCP team

TABLE 11.I cont'd
Summary of advantages and disadvantages of immediate and phased implementation

	Advantages	Disadvantages
Phased	• Quality system support elements can be developed as required and alongside implementation • Staged training allows more individual attention • System can be trialled and refined as implementation progresses • More manageable approach - system less likely to fail • HACCP team resource focused at each stage	• Longer overall implementation timetable • Working with small groups of people in isolation - difficult to change culture • Implementation may lose momentum

12. MAINTENANCE OF THE HACCP SYSTEM

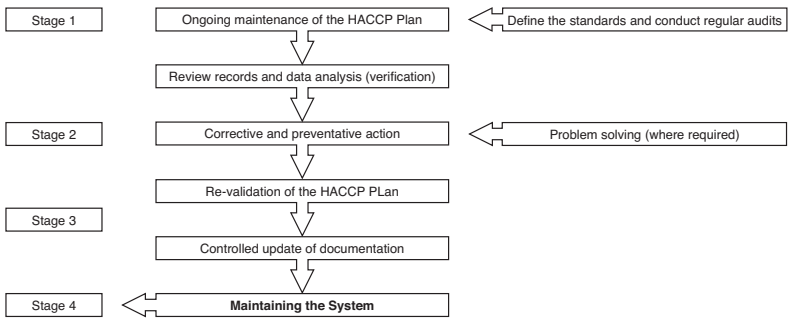


Fig. 12.1. Stage 4: Maintaining the System (Adapted from Mortimore and Wallace, 2001)

Neither maintenance nor implementation are one of the seven HACCCP principles but they are vital aspects of HACCP none the less.

There is a need for a mechanism for updating the HACCP plan following a change in;

- Raw materials - location, supplier or type of delivery (from unground to ground, for example)
- Process
- Layout or environment
- Prerequisites
- Packaging
- Introduction of a new product
- Receipt of information relating to food safety

There is therefore a need to devise a mechanism to manage change. This starts with HACCP system maintenance. Records need updating, a staff training policy should be devised and systems put in place for training and education of staff, including refresher training, and induction training for new staff. The HACCP Team need a basic minimum understanding of HACCP and risk assessment. Mechanisms for capturing changes include amendment records and document control. Figure 12.2 demonstrates some processes that can be involved in maintaining the HACCP system.

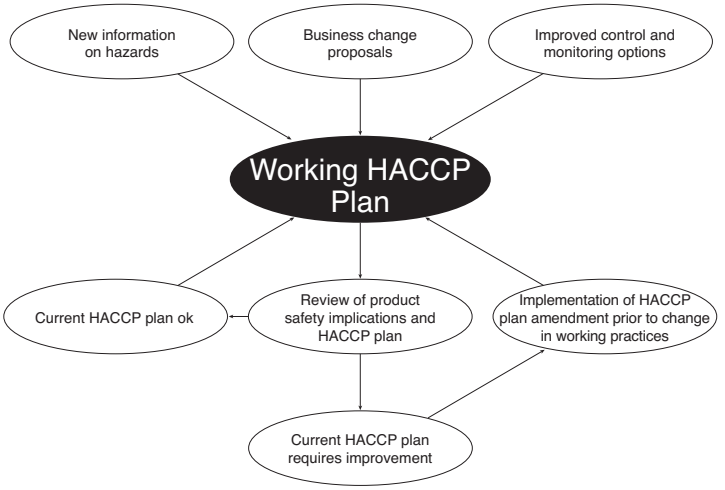


Fig. 12.2. Managing Change within HACCP (Adapted from Mortimore and Wallace, 2001)

Records are essential to provide evidence of safe food production, they provide the basis for review and trend analysis. They can be used to provide data for internal investigations.

HACCP systems are found to be inadequate if:

- The HACCP plan does not meet Codex requirements
- Personnel are not performing tasks specified in the HACCP plan
- Records are inaccurate or falsified
- They fail to take corrective actions
- HACCP records are not properly maintained

- They should be easily accessible, kept for an adequate length of time and controlled.

Comment:
1. Adequate training is essential to ensure effective implementation.
2. It is vital that the HACCP plan be reviewed following any changes to the process, including changes to raw materials, processing conditions or equipment, packaging, cleaning procedures, and any other factors that may have an effect on product safety, as noted in the previous chapter.

Now you have reached the end of this book, you should be ready to use HACCP in practice, but here are a few final points to remember:

- HACCP should make life easier
- Your HACCP plan must be developed "in-house" and not bought in
- If you do use someone to help you, make sure you are still involved in writing the HACCP plan
- Good HACCP plans are simple in design and easy to use
- The HACCP plan must be properly documented
- Further books and training are available from a number of different sources – see the Further Reading section.

13. ADDITIONAL FLOW DIAGRAMS AND CASE STUDY

This chapter contains a worked case study to demonstrate the application of the forms provided throughout this book in the HACCP process.

13.1 UK Regional Cheese Production Case Study

Introduction

This case study illustrates a typical HACCP process for a small scale UK cheese producer from Wales. A small scale producer was chosen as a demonstration of some of the problems encountered in the application of HACCP in small businesses.

Company

The company is a small dairy producing specialist cheeses for supermarkets. Most of the processes are manual. The company comprises the two owners and four other staff.

HACCP team

Technical manager
Production manager
Cheese maker

Note that since the company is very small, it would be difficult to have a team with more than three people, and probably not necessary.

Terms of Reference

1. This HACCP study will examine chemical, biological and physical hazards occurring in the raw materials and the manufacturing process.
2. This study will deal with cheese made from unpasteurised milk.
3. Prerequisite programmes are in place. Of particular importance are supplier assurance, training, personal hygiene, cleaning, pest control and transport.
4. This process is designed as a linear study, since the process is simple, and all cheeses made in the creamery are similar.

Key processes

Heating
Mixing
Fermentation
Cutting
Packing
Maturation

Hazard Analysis - Broad Outline and Likely Controls

Hazards

Pathogens in raw materials
Hygiene of premises and during operations
Poor fermentation
Physical contamination of raw materials

Controls

Supplier assurance
Temperature control
GHP
Operational controls

TABLE 13.I
Product description and intended use

Name of product	**Caerphilly Cheese**
Description	Traditional, farmhouse, unpasteurised, vegetarian cheese made from cows' milk. Wheel-shaped with ivory-white rind dusted with fine flour. Aged in a moist cellar. This cheese has a fresh taste when young, with a moist yet supple texture. As it ages the edges become creamy and the flavour becomes more rounded. Technical data of finished product: Water activity approx. 0.85, pH <5.5 No chemical preservatives used.
Packaging	Waxed paper
Conditions of storage	Less than 5°C
Shelf life	Use by date: eight weeks from date of manufacture. Use within three days of opening.
Instructions on the label	Store at less than 5°C. Consume within three days of opening. Allergen advice: contains milk and lactose.
Consumer group	General public, but see below. Made using unpasteurised milk. Unsuitable for pregnant women, children, the elderly and anyone with low resistance to infection.
Recommendation of further processing required before consumption	None.

TABLE 13.II
Ingredients

Ingredients	Physical Condition	Source	Country of Origin
Cows' milk	Unpasteurised, chilled, delivered by tanker	Five named farms via First Milk: Farm A: 50 herd Farm B: 75 herd Farm C: 80 herd Farm D: 60 herd Farm E: 120 herd	UK
Salt	Crystalline, delivered in 10 kg paper sacks, blue plastic lined	Good Food Distribution	Spain
Starter cultures	Frozen, individual sachets	Chr. Hansen	Denmark
Microbial rennet (non-GMO)	Chilled	Chr. Hansen	Denmark

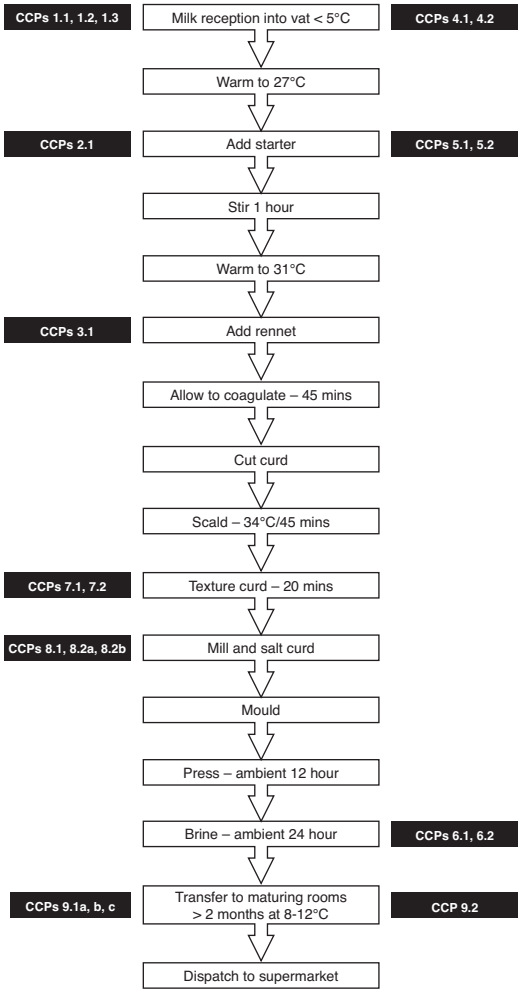


Fig. 13.1. Caerphilly Cheese Flow Diagram.

TABLE 13.III
Hazard Analysis Chart – Raw Materials

Raw Material	Hazard and source/cause	Sig hazard? (Y/N)	Control Measures	Comments
Milk	Vegetative bacterial pathogens (teats, udder, equipment)	Y	Purchase from approved farms Only use approved supplier	Use named farms, require tanker dockets. Only accept first delivery after tanker CIP Verify with pathogen testing (batch)
	Bacterial spores (above)	N	-	No known to be a significant problem in British territorial cheeses
	Antibiotic residues (veterinary treatment)	Y	Purchase milk from approved farms Antibiotics test (batch)	Main CCP is antibiotics test upon milk reception
	Foreign matter from teat and milking environment	Y	Milk sock in farm dairy	Milk purchased from approved farms
Salt	Paper, plastic and metal from packaging	N	-	Not experienced a problem with salt supply yet
Starter cultures	Bacterial pathogens introduced during manufacture	Y	Purchase from approved supplier Certificate of Conformance (batch)	Could run pathogen tests on each batch on delivery
Rennet	Bacterial pathogens introduced during manufacture	Y	Purchase from approved supplier Certificate of Conformance (batch)	Could run pathogen tests on each batch on delivery

TABLE 13.IV
Hazard Analysis Chart – Process Steps

Process Step	Hazard and source/cause	Sig hazard? (Y/N)	Control Measures	Comments
Milk reception	Antibiotic residues from cow	Y	Antibiotics test upon delivery (batch)	Antibiotic failures returned
	Growth of vegetative pathogens because milk too warm	Y	Accept milk within temperature specification	Only applies to unpasteurised cheeses
Storage of starter culture	Pathogen growth in milk caused by slow vat if starter inactive	Y	Correct storage temperature and stock rotation	
Storage of rennet	Pathogen growth in rennet caused by incorrect storage	N	-	Not known to be a problem
Storage of brine	Survival and growth of pathogens due to poor brine hygiene management	Y	Measure brine strength and change brine monthly	Brine pasteurisation is not practical Verify with monthly pathogen tests
Warming	Growth of pathogens due to slow warming	N	-	
Addition of starter	Pathogens present in starter	N	-	
Stirring	Metal from stirring paddles	N	-	Preventative maintenance of equipment
Warming	None	N	-	

TABLE 13.IV (cont'd)
Hazard Analysis Chart – Process Steps

Process Step	Hazard and source/cause	Sig hazard? (Y/N)	Control Measures	Comments
Addition of rennet	Pathogens present in rennet	N	-	
Coagulating	None	N	-	
Cutting curd	Metal from cutting knives	N	-	Preventative maintenance of equipment
Scalding	Growth of pathogens due to slow scalding	N	-	
Texturing	Pathogen growth due to insufficient acid due to slow vat	Y	Correct make temperature and healthy starter Measure acid	Make conditions – GMP Starter health – CCP Step where final acid is measured
Milling and salting	Metal from mill pegs	Y	Inspection of mill pegs	
	Survival of pathogens due to low salt level	Y	Control weight of dry salt input and distribute evenly	
Moulding	None	N	-	
Pressing	None	N	-	
Brining	Pathogen growth due to insufficient salt	Y	Control brine during brine storage	
Maturing	Growth and survival of pathogens due to wrong storage conditions	Y	Control temperature, humidity and time	
	Listeria contamination from environment	Y	GMP/GHP to ensure clean environment	Good control of PRPs
Despatch to supermarket	None	N	-	

TABLE 13.V
CCP Identification using Decision Tree

Raw Material Hazard	Q1	Q2	Q3	CCP (Y/N)	Comments
Milk (Vegetative bacterial pathogens)	Y	N		Y	Eight weeks maturation might remove pathogens but not guaranteed, therefore CCP
Milk (Antibiotic residues)	Y	Y		N	Each delivery tested on receipt and rejected if fails test
Milk (Foreign bodies – faeces, flies from teat and parlour)	Y	N		Y	Assurance required that farmer controls integrity of milk sock. Farmer assurance scheme
Starter cultures (Pathogen contamination)	Y	N		Y	Use approved supplier only. Verify by pathogen test on delivery
Rennet (Pathogen contamination)	Y	N		Y	Use approved supplier only. Verify by pathogen test on delivery

TABLE 13.V (cont'd)
CCP Identification using Decision Tree

Process Step hazard	Q1	Q1a	Q2	Q3	Q4	CCP (Y/N)	Comments
Milk reception							
Antibiotics	Y	-	Y			Y	Antibiotics test rejects milk
Pathogen growth	Y	-	N	Y	Y	Y	Only accept milk within temperature specification (≤ 4°C) (Unpasteurised products only)
Starter storage							
Pathogen growth	Y	-	N	Y	N	Y	Controls acid production during cheese making
Brine storage							
Survival & growth of pathogens	Y	-	N	Y	N	Y	Correct brine strength make up and monthly change of brine to control pathogens. Pasteurisation of brine not feasible
Texturing							
Pathogen growth	Y	-	N	Y	N	Y	Control measures are (a) correct 'make temperature' and (b) healthy starter. CCP because where final acidity measured.
Milling and salting							
Metal from mill pegs	Y	-	N	Y	N	Y	Inspect mill pegs before and after each make.
Survival and growth of pathogens	Y	-	N	Y	N	Y	Control correct weight and distribution of salt.
Brining							
Survival and growth of pathogens	Y	-	N	N	-	N	Maintain brine strength (see above) and change monthly. No control possible at this point.
Maturation							
Growth and survival of pathogens – wrong storage	Y	-	N	Y	N	Y	Maintain control of temperature, humidity and maturation time.
Pathogen contamination from environment	Y	-	N	Y	N	Y	Clean environment. Maintain PRPs.

TABLE 13.VI
HACCP Control Chart – Raw Materials

Product: Caerphilly Cheese Date:

Raw Material	Sig. haz. & source/cause	Control Measure	CCP no.	Target Value	Critical Limit	Monitoring			Corrective Action		
						Meth./freq.	Resp.	Docs / recs	Meth.	Resp.	Docs / recs
Milk	Vegetative pathogens (teats, udder, equipment)	Use only approved farms	1.1	All milk from named, approved farms	All milk from named, approved farms	Audit farms every 6 months	Farm liaison officer	Audit/01	Review supplier status	HACCP team	CA/01
	Vegetative pathogens (contamination during transport)	Use approved haulier only	1.2	Tanker dockets - first delivery after CIP	Tanker dockets - first delivery after CIP	Each delivery – check dockets	Milk reception supervisor	Log/01	Reject delivery Review haulier status	Milk reception supervisor	CA/02
	Foreign bodies (teat and parlour)	Milk sock	1.3	Always used and intact	Always used and intact	Audit farms every 6 months	Farm liaison officer	Audit/01	Review supplier status	HACCP team	CA/03
Starter cultures	Bacterial pathogens (from supplier)	Approved supplier & cert .of conformance	2.1	Always use authorised brand and check cert.	Always use authorised brand and check cert.	Each delivery	Store supervisor	Log/02	Reject if no certificate	Store supervisor	CA/04
Rennet	Bacterial pathogens (from supplier)	Approved supplier & cert .of conformance	3.1	Always use authorised brand and check cert.	Always use authorised brand and check cert.	Each delivery	Store supervisor	Log/03	Reject if no certificate	Store supervisor	CA/05

TABLE 13.VII
HACCP Control Chart – Process Steps

Product: Caerphilly Cheese Date:

Process Step	Sig. haz. & source/cause	Control Measure	CCP no.	Target Value	Critical Limit	Monitoring			Corrective Action		
						Meth./freq.	Resp.	Docs / recs	Meth.	Resp.	Docs / recs.
Milk reception	Antibiotic residues from cow	B-STAR test	4.1	Pass	Pass	Standard method, each delivery	Milk reception supervisor/lab	SOP/01 Lab/01	Reject delivery	Milk reception supervisor/ lab	CA/06
	Pathogen growth – milk too warm	Temperature on receipt	4.2	<5 °C	7 °C	Each delivery	Milk reception supervisor	SOP/02 Log/04	Reject delivery	Milk reception supervisor/ lab	CA/07
Starter storage	Pathogen growth in cheese – slow vat or inactive starter	Storage temperature	5.1	-50 °C	-45 °C	Daily manual reading	Cheese maker	Log/05	Discard stock	Cheese maker	CA/08
		Stock rotation	5.2	In life	In life	Each vat	Cheese maker	Log/06	Discard stock	Cheese maker	CA/09
Brine storage	Survival & growth of pathogens due to poor brine management	Brine strength	6.1	90% saturated	85% saturated	Salometer every make	Cheese maker	SOP/03 Log/07	Add more salt	Cheese maker	CA/10
		Monthly brine change	6.2	Changed	Changed	Remake brine monthly	Cheese maker	SOP/04 Log/08	Discard non-compliant cheese	Cheese maker	CA/11

TABLE 13.VII (cont'd)
HACCP Control Chart – Process Steps

Product: Caerphilly Cheese Date:

Process Step	Sig. haz. & source/cause	Control Measure	CCP no.	Target Value	Critical Limit	Monitoring			Corrective Action		
						Meth./freq.	Resp.	Docs / recs	Meth.	Resp.	Docs / recs.
Texturing	Pathogen growth due to slow vat	Acidity measurement	7.1	0.4% lactic acid at milling	0.3% lactic acid at milling	Titration each make	Cheese maker	SOP/05 Log/09	Discard curd	Cheese maker	CA/12
		Time for acidity to develop	7.2	4 hours	6 hours	Time record for each make	Cheese maker	Log/10	Discard curd	Cheese maker	CA/13
Milling and salting	Metal from mill pegs	Visual inspection	8.1	Intact	Intact	Each make, before and after	Cheese maker	Log/11	Discard or metal detect (if available)	Cheese maker	CA/14
	Survival of pathogens due to too low salt level	Weight of salt and distribution	8.2a	1.7% of make	1% of make	Weigh – x Kg salt to y Kg curd	Cheese maker	Log/12	Discard make	Cheese maker	CA/15
			8.2b	Even distribution	Even distribution	Evenly distribute	Cheese maker	SOP/06 Log/13	Re-mill	Cheese maker	CA/16
Maturation	Growth and survival of pathogens – wrong storage conditions	Temperature	9.1a	10 °C	12 °C	Daily record	Cheese maker	Log/14	Discard or test and positive release	Cheese maker	CA/17
		Humidity	9.1b	95%	97%	Daily record	Cheese maker	Log/15	Discard or test and positive release	Cheese maker	CA/18
		Maturation time	9.1c	4 months	2 months	Stock dates on release	Cheese maker	Stock/01	Discard or test and positive release	Cheese maker	
	Pathogen contamination from environment	Cleaning procedures	9.2	Cleaning done	Cleaning done	Weekly	Hygiene supervisor	CS/01 Log/16	Discard or test and positive release	Cheese maker	CA/19

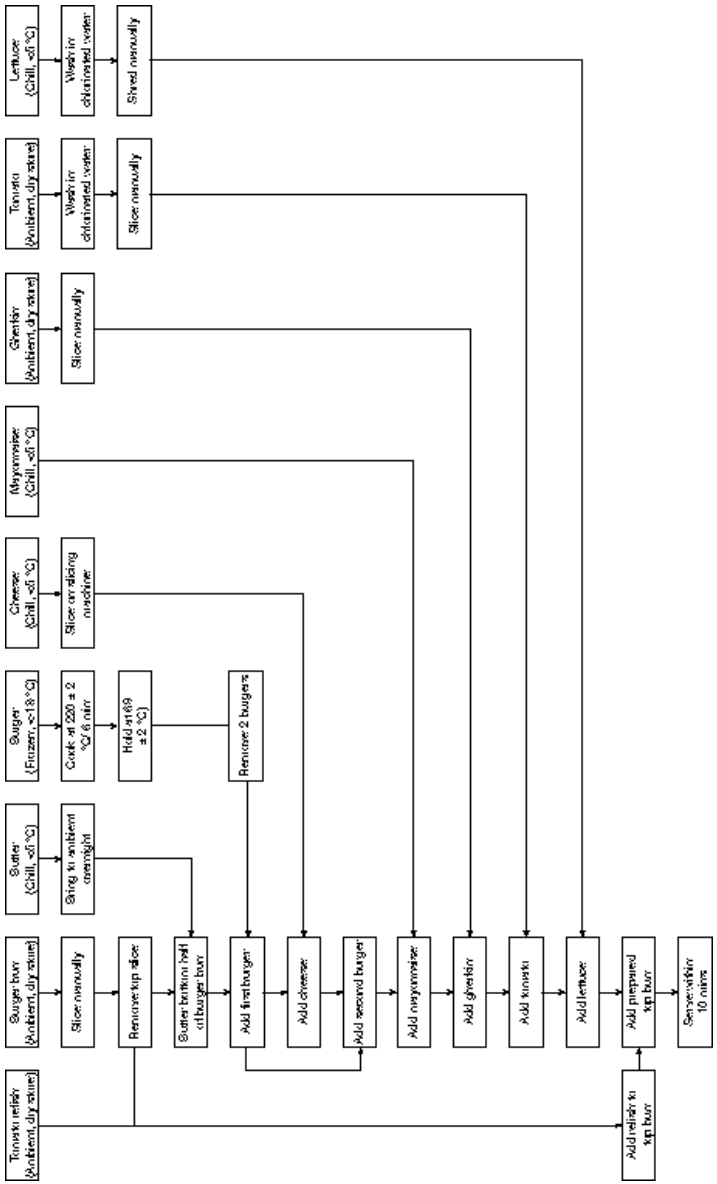


Fig. 13.2. Cheeseburger Flow Diagram

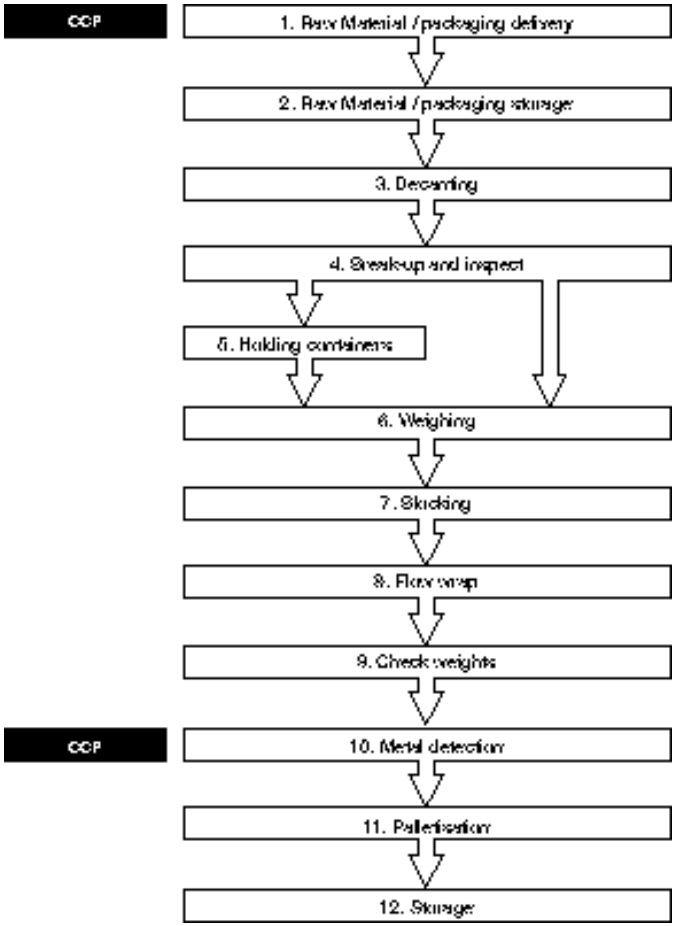


Fig. 13.3. Blocked Fruit Flow Diagram

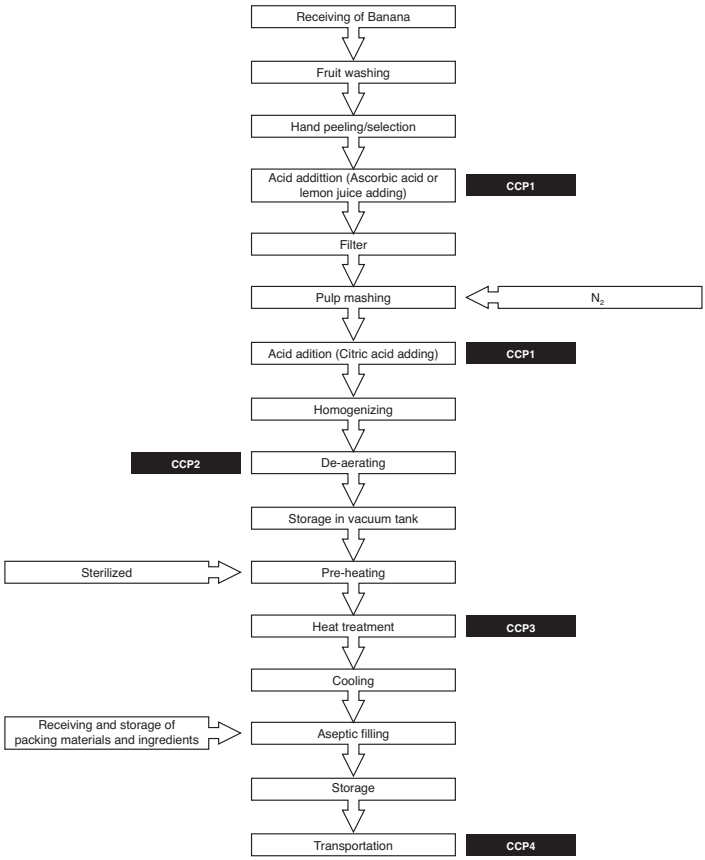


Fig. 13.4. Banana Puree Flow Diagram

INDEX

APPENDIX 1 – HACCP Toolkit

Appendix 1 contains a number of templates that can be photocopied. These have been designed to aid with the implementation of HACCP, and completed examples of these have been included throughout the main body of the text. Obviously these are just a few of the many forms needed to complete a HACCP plan, but will, at the very least, provide a starting point.

Included in Appendix 1 are:

- List of Prerequisite Programmes (PRPs) Form
- HACCP Team and Scope of Study Form
- HACCP Team Meeting Notes
- Progress Record Sheet
- Product Description and Intended Use Form
- Hazard Analysis Chart
- Raw Material Decision Tree
- Raw Material Decision Tree Record Sheet
- Process Step Decision Tree
- Process Step Decision Tree Record Sheet
- HACCP Control Chart
- CCP Monitoring Record Sheet

List of Prerequisite Programmes (PRPs) Form

Programme	Area of control	Procedures	Manager/Department responsible

HACCP Team and Scope of Study

HACCP of:

Start Date:		
Target implementation date:		
Scope of the study:		
Team Members:		
Core Team	**Name**	**Job title/role**

Other Team members

Name	**Job title**	**Area of expertise**

HACCP Team Meeting Notes

Present:

Issue	Decision or Action (D/A)	Details of action	Who is responsible?	Target date

Other comments from the meeting:

Date of next meeting:

Team members other than the core required?:

Progress Record Sheet

	Planned date	Completion date	Comments
Assemble HACCP Team			
Describe product			
Identify intended use			
Construct flow diagram			
On-site confirmation of flow diagram			
List all the potential hazards, conduct a hazard analysis, consider control measures			
Determine Critical Control Points (CCPs)			
Establish Critical Limits for each CCP			
Establish a monitoring system for each CCP			
Establish corrective actions			
Establish verification procedures			
Establish documentation and record keeping			

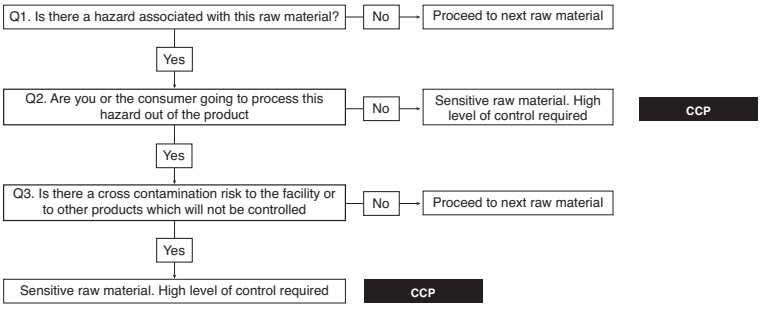
Product Description and Intended Use Form

Name of product	
Description	
Packaging	
Conditions of storage	
Shelf life	
Instructions on the label	
Consumer group	
Recommendation of further processing required before consumption	

Hazard Analysis Chart

Process step	Hazard	Source/Cause	Significant hazard? (Y/N)	Control measure(s)	Comments

Raw Material Decision Tree

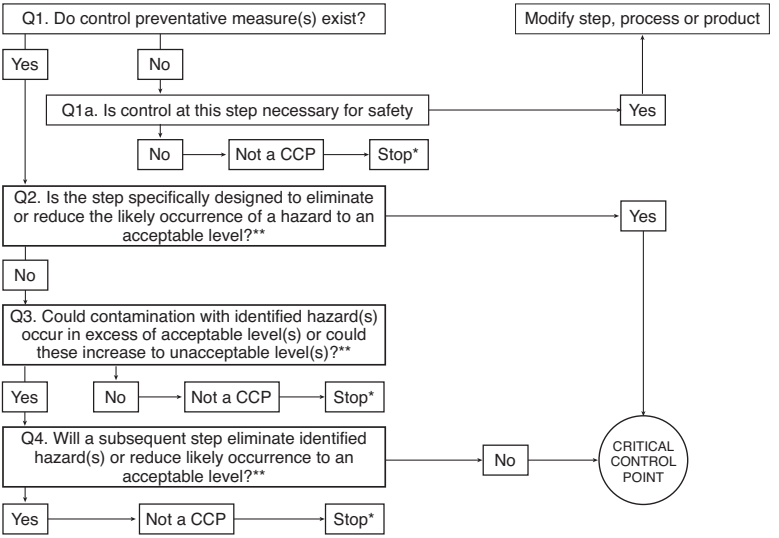


(Adapted from Mortimore and Wallace, 1998)

Raw Material Decision Tree Record Sheet

Raw Material	Q1	Q2	Q3	CCP	HACCP Team Comments

Process Step Decision Tree



* Proceed to the next identified hazard in the described process.
** Acceptable and unacceptable levels need to be defined within the overall objectives in identifying the CCPs of the HACCP plan.

(Adapted from Codex, 2003)

Process Step Decision Tree Record Sheet

Process step and hazard	Q1	Q1a	Q2	Q3	Q4	CCP Y/N	HACCP Team Comments

HACCP Control Chart

CCP for potential hazards associated with process steps: **Product:** **Date:**

Process Step	Hazard & source/cause	Control Measure	CCP no.	Target Value	Critical Limit	Monitoring			Corrective Action		
						F	R	D	Method	R	D

Key: **R = Responsible person** **F = Frequency** **D = Document**

CCP Monitoring Record Sheet

CCP No.: **Description:**
Critical Limit: **Procedure reference:**
Target Limit: **Date:**

Time	Result	Comments	Operator

In the event of the TARGET being infringed the operator must …… and record the action taken (using the comments column) and repeat the test. If the TARGET is still infringed treat as CRITICAL.

If the Critical limit is infringed the operator must:-

1. Quarantine the production
2. Inform the Line Quality Supervisor immediately
3. Record the time of the infringement of the critical limit

APPENDIX 2 – Food Pathogens

The growth requirements and food infection / poisoning characteristics associated with the important pathogens.

INFECTIONS
Growth/survival characteristics

	Temperature (°C)		Heat resistance	Min pH*	Min a_w*	Aerobic/ anaerobic
	Min*	Optimum				
Salmonella	4	35 - 37	Heat-sensitive† $D_{60\ °C}$ 1 - 10 minutes	3.8‡	0.93	Facultative
Campylobacter	30	42 - 43	Slightly more heat sensitive than *Salmonella* $D_{55\ °C}$ 0.74 - 1 minute	4.9	0.98	Fastidious micro-aerophile – capnophilic
L. monocytogenes	-0.4	30 - 37	Slightly less heat sensitive than *Salmonella* $D_{60\ °C}$ 5 - 8 minutes	4.3	0.92 in glycerol	Facultative
Yersinia enterocolitica	-2	28 - 29	Heat-sensitive $D_{60\ °C}$ 27 seconds	4.2	0.95	Facultative
Vibrio parahaemolyticus	5	30 - 35	Heat-sensitive $D_{41\ °C}$ 0.8 – 65.1 minutes	4.8	0.94**	Facultative
Clostridium perfringens	15	43 - 45	Forms heat-resistant spores	5	0.93	Anaerobic
Verocytotoxigenic *E. coli*	7	37	Heat sensitive $D_{63\ °C}$ 0.5 minutes	4.0 - 4.4	0.97	Facultative
Cronobacter (formerly *Enterobacter*) *sakazakii*	5.5	41 - 45	Thermotolerant $D_{60\ °C}$ 2.5 minutes		Survives at 0.2	Facultative

* Under otherwise optimal conditions - limits will vary according to strain, temperature, type of acid (in the case of pH), solute (in the case of a_w) and other factors. They will normally be higher in foods. However, variabilities in measurement, etc., must be allowed for – a margin of error must be incorporated.

† *Salmonella senftenberg* 775W is much more heat-resistant at high a_w. D-values for other strains of *Salmonella* increase at lower a_w, approaching or exceeding those for *S. senftenberg* 775W

‡ Most *Salmonella* serotypes will not grow below pH 4.5.

** Has a minimum requirement for salt – it is a halophile

INFECTIONS
Food infection characteristics

	Incubation time*	Symptoms*	Duration*	Mortality rate	Infective dose
Salmonella	8 - 72 hours	Abdominal pain, diarrhoea, nausea, fever, (vomiting)	2 - 5 days	Low, but important exceptions	Usually high (10^6+), low in some foods (10 - 100 cells)
Campylobacter	1 – 11 days, usually 2 - 5 days	Fever, diarrhoea (sometimes with blood and mucus), nausea, abdominal pain	1 - 7 days+	Rare	Low, 50 - 500 cells
L. monocytogenes	3 - 70 days ‡	Flu-like symptoms, meningitis, septicaemia, meningoence-phalitis	Variable	30 - 40%	Not known
Y. enterocolitica	1 - 11 days	Abdominal pain,† diarrhoea, fever, others, incl. pharyngitis	1 - 3 weeks	Rare	Not known probably high $>10^4$
V. parahaemolyticus	4 – 96 hours, usually 12 - 24 hours	Diarrhoea (in severe cases with blood and mucus), abdominal pain, nausea	1 - 7 days, usually 3 – 5 days	Rare	10^5+
C. perfringens	8 - 22 hours	Diarrhoea, abdominal pain	1 - 2 days	Rare	High: 10^5/g+
Verocytotoxigenic *E. coli*	1 - 14 days Usually 3 - 4 days	Diarrhoea, abdominal pain	5 - 10 days	1%**	Very low, between 2 and 2,000 cells
C. sakazakii	18 - 30 days (premature babies)	Ventriculitis, brain abscess hydrocephalus, neonatal necrotising enterocolitis		40 - 80% in neonates	Not known

* Typical - can vary quite widely
‡ Depends on dose, immune state of the host, and virulence of the strain
† Can resemble appendicitis
** VTEC-associated haemolytic-uraemic syndrome (HUS) infection

INTOXICATIONS
Growth/survival characteristics

	Temperature (°C)		Heat resistance		Min pH*	Min a_w*	Aerobic/
	Min*	**Optimum**	**Spores**	**Toxins**			**anaerobic**
Clostridium botulinum Group I	10	37	$D_{121\ °C}$ 0.21 minutes	Destroyed by 5 min. at 85 °C	4.6	0.94	Anaerobic
Group II	3.3	25 - 30	$D_{100\ °C}$ <0.1 minutes		5	0.97	
Staph. aureus	7	30 - 37	NA	Heat-resistant, $D_{56\ °C}$ 1 - 2 minutes in phosphate buffer	4.2†	0.86**	Facultative
B. cereus	4	30 - 35	$D_{95\ °C}$ 1.2 - 36 minutes	Emetic toxin, extremely heat-resistant	4.3	0.95x	Facultative

* Under otherwise optimal conditions – limits will vary according to strain, temperature, type of acid (in the case of pH), solute (in the case of a_w) and other factors. They will normally be higher in foods. However, variabilities in measurement, etc., must be allowed for – a margin of error must be incorporated.

† Minimum for enterotoxin production ≈ pH 5.2, under aerobic conditions.

** Range from 0.86 - >0.99

x Possibly as low as 0.91 or less.

INTOXICATIONS
Food poisoning characteristics

	Incubation time*	Symptoms*	Duration*	Mortality rate	Infective dose
C. botulinum	12 - 36 hours	Impaired vision, dryness of mouth, nausea, vomiting, paralysis†		Formerly 30 - 65%, now much lower (<10%)	0.005 - 0.5 mg of toxin
Staph. aureus	1 - 7 hours	Nausea, vomiting, abdominal pain, diarrhoea		Rare	10^5+ cells needed to produce toxin <1 mg of toxin
B. cereus					
emetic	1 - 5 hours	Nausea, vomiting	6 - 24 hours	Nil	10^5+ cells (+ toxin)
diarrhoeal	8 - 16 hours	Abdominal pain	12 - 24 hours		10^5+ cells

* Typical - can vary widely
† Affects the nervous system

APPENDIX 3 – Frequently Asked Questions

Q. Why do I need HACCP in my small food business, I'm not a major manufacturer?

A. The application of a HACCP-based approach to food safety is a legal requirement for all food business operators, large and small, within the EU, and in many other countries worldwide.

Q. HACCP seems like a lot of additional paperwork to me, isn't there anything I can do to ease this burden?

A. If you are a small business, then the law says that you can simplify.

Q. Do I need training before I can start to undertake a HACCP study?

A. If you are going to lead a HACCP team then a practical HACCP course is a good idea, so that you can understand the basic principles, but relevant experience also counts.

Q. What sort of training does a team member need?

A. Some HACCP awareness training such as a Foundation Course would be fine. Again, previous experience is valuable.

Q. Is there an optimum number of CCPs for the HACCP study?

A. The number of CCPs will vary from project to project. For simple processes with few hazards it can be as few as 1 - 3; for ready meals and similar products 5 - 8; and for retorted products, aseptically processed products anything from 15 - 25 or more. Experience will help.

Q. Is there anything I need to do with my process before I start?

A. You should assess your PRPs to make sure they are in place and up to date, or your HACCP plan may be too complex.

Q. Do I need to control all hazards I have identified?

A. You need to review your process for hazards, and then assess the severity and likelihood of their occurrence. HACCP requires control of any significant hazard that is reasonably likely to occur.

Q. The CCP decision tree looks complicated, do I have to use it?

A. Codex allows flexibility in the use of the decision tree, but you may find it useful to use it if you are starting out in HACCP. Experienced HACCP practitioners use it where necessary, but in many cases, the CCP is obvious – pasteurisation, for example, rapid cooling after cooking (where applied), or metal detection.

Q. Why do I need target levels as well as critical limits?

A. Target levels ensure that your process stays on the right side of the line with respect to food safety, providing a buffer zone for product safety.

Q. Why can't I put all of my process points on the HACCP Control Chart, it would make life simpler for me?

A. HACCP is a method for assuring safety of food produced. Quality attributes are not necessarily the same. Having just CCPs on your HACCP Control Chart helps staff to focus on food safety aspects of production, and should avoid confusion between safety and quality. Have an overall chart if you wish, but make sure you have one with just CCP process points as well, in that case.

APPENDIX 4 – HACCP Glossary

This glossary is based on Codex (2003) definitions for HACCP terms

Control (verb): To take all necessary actions to ensure and maintain compliance with criteria established in the HACCP plan.

Control (noun): The state wherein correct procedures are being followed and criteria are being met.

Control Measure: Any action or activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Corrective Action: Any action to be taken when the results of monitoring at the CCP indicate a loss of control.

Critical Control Point (CCP): 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 criterion which separates acceptability from unacceptability.

Deviation: Failure to meet a critical limit

Flow Diagram: A systematic representation of the sequence of steps or operations used in the production or manufacture of a particular food item.

HACCP (Hazard Analysis and Critical Control Points): A system which identifies, evaluates and controls hazards which are significant for food safety.

HACCP Plan: A document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for safety in the segment of the food chain under consideration.

Hazard: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

Hazard Analysis: 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.

Monitor: The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.

Step: A point, procedure, operation or stage in the food chain including raw materials, from primary production to final consumption.

Validation: Obtaining evidence that the elements of the HACCP plan are effective.

Verification: The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan.

Other Useful Definitions

ATP (Adenosine Triphosphate): The energy currency of all cells. Total ATP can be used to give a measure of the degree of soiling of a food contact surface.

Audit: A systematic and independent examination to determine whether activities and results comply with the documented procedures; also whether these procedures are implemented effectively and are suitable to achieve the objectives.

BRC (British Retail Consortium): A trade organisation that produces standards for the retail industry, including food. The Global Standard for Food Safety is applicable to food products and ingredients.

CCP Decision Tree: A logical sequence of questions to be asked for each hazard at each process step. The answers to the questions lead the HACCP team to decisions determining which process steps are CCPs.

CIP (Cleaning in Place): The cleaning of pipework and equipment, while still fully assembled, through the circulation of cleaning chemicals

FMEA (Failure Mode and Effects Analysis): A method that looks at potential failures in products or processes, by taking a description of the parts of a system, and then listing any consequences if each part fails.

HACCP Control Chart: A matrix or table detailing the control criteria (i.e. critical limits, monitoring procedures and corrective action procedures) for each CCP and preventative measure. It is a part of the HACCP plan.

HACCP Study: A series of meetings and discussions between HACCP team members in order to put together a HACCP plan.

HACCP Team: The multi-disciplinary group of people who are responsible for developing a HACCP plan. In a small company each person may cover several disciplines.

Hazard Analysis Chart: A working document which can be used by the HACCP team when applying HACCP Principle 1, i.e.conducting a hazard analysis.

In-process: Something that is done or happens close to a process while the process is actually running.

Intrinsic Factors: Basic, integral features of the product due to its formulation, for example, pH, a_w, preservatives.

Mycotoxin: A toxin produced by some moulds under particular conditions.

Off-line: An activity that is carried out away from the line, the timing of which is not dependent on the progress of the process.

Preventative Measures: Control measures.

Process Flow Diagram: A detailed stepwise sequence of the operations in the process under study.

PRP (Prerequisite programme): Policies, practices and procedures that control the operational conditions within a food establishment allowing conditions favourable for the production of safe food.

QA (Quality Assurance): Aims to ensure that the product or service an organisation provides is fit for its purpose and meets customer expectations.

QMS (Quality Management System): A structured system for the management of quality in all aspects of a company's business.

Quarantine (product): All the procedures and activities that are undertaken to prevent unsafe products leaving the producer's control.

SQA (Supplier Quality Assurance): The programme of actions to ensure the safety and quality of the raw material supply. Includes preparation of and procedures to assess supplier competency, e.g. inspections, questionnaires.

Target level: Control criteria which are more stringent than critical limits, and which can be used to take action and reduce the risk of a deviation.

Water Activity (a_w): A measure of the "free" water in a substrate that is available for microorganisms to use; it is defined as 'vapour pressure of the substrate / vapour pressure of pure water'.

APPENDIX 5 – Further Reading

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