SECOND EDITION

HACCP

A FOOD INDUSTRY BRIEFING

Sara E. Mortimore and Carol A. Wallace

WILEY Blackwell

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Editorial Offices
9600 Garsington Road, Oxford, OX4 2DQ, UK
The Atrium, Southern Gate, Chichester, West Sussex, PO19 8SQ, UK
111 River Street, Hoboken, NJ 07030-5774, USA

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Preface

Objective

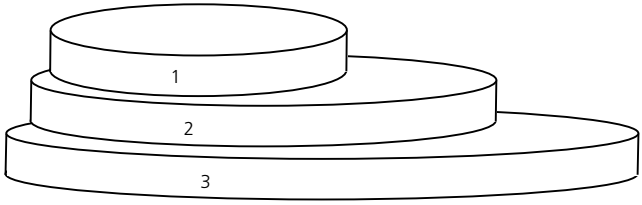
The food industry is exciting !. It is one of the oldest industries on the planet, yet is ever evolving. It is increasingly complex due to the globalization of the supply chain, changing consumer practices, scientific advancement and, on top of that, the enormous challenge of how to feed more and more people with diminishing resources over the coming years. This industry is peppered with acronyms and jargon, systems and software solutions many of which claim to assist in the prevention and control of foodborne disease. However, in reality to an outsider, they perhaps add to the air of mystery and intrigue.

The aim of this book is to provide a concise, easy-to-use, quick reference book aimed at busy food industry professionals or students who need to gain a working knowledge. *HACCP: A Food Industry Briefing* is an introductory-level text for readers who are unfamiliar with the subject either because they have never come across it or because they need to be reminded.

Readers who go on to become practitioners in the area of HACCP will need to further their understanding through attendance at symposia, training courses and use of more detailed texts.

Book format

The book is structured such that the reader should be able to skim through in a few hours (perhaps on a train, at an airport, at home in the evening) and arm themselves with the essentials of the topic. In order to achieve this, we decided to make it 'non-sequential', i.e. the reader does not need to read the whole book from beginning to end to grasp what HACCP is about. Instead, we chose an expanding modular format as shown in Figure 1. However, if the reader decides not to read the book from the beginning, but choose certain parts, then any acronyms or specific terms encountered will be explained in the Glossary (Appendix B).



Section 1: Brief introduction to HACCP (Who, what, why)
Section 2: HACCP system explained
Section 3: HACCP in practice

Figure 1 Book layout – Expanding modular format.

Section 1 is the shortest section, and it contains many of the questions typically asked by newcomers to the topic – as well as the answers.
Section 2 begins to build up in detail and explains the HACCP system in relation to other programmes likely to be in operation in a food business.
Section 3 is the largest section. It looks at how a company would develop a HACCP system, step by step and includes elements of a case study that is given in full in Appendix A.

After the three explanatory sections, we have written a short epilogue where current debates in this topic area are discussed along with likely future developments in the field.

The book includes checklists, bullet points, flow charts and schematic diagrams for quick reference. At the start of each section, we have provided 'Key points' summary boxes. These act not only to inform the reader of what the section will cover but also will be a useful way of going back to re-read any particular topic area. As some readers may be unfamiliar with some of the terminology used, when a new term appears for the first time, it will be in emboldened type.

Summary

This book *is*

- a quick, easy-to-use reference book;
- aimed at people who need a working knowledge;
- an introductory-level text.

This book *is not*

- the only learning resource material that should be used by those aiming to be practitioners in the field;
- highly technical.

We hope that we have succeeded in meeting these criteria and that you benefit from reading it.

What is described here is based on current best practices. Whilst many companies are still on the journey to full implementation of HACCP and a comprehensive food safety program, having the commitment and a plan to get there is important. In fact it will always be a journey as we all continue to learn and improve on past practices.

Sara E. Mortimore
Carol A. Wallace

SECTION 1

Introduction to HACCP

KEY POINTS

- HACCP is an acronym for the 'hazard analysis and critical control point' system.
- It provides structure for objective assessment of 'what can go wrong' and requires controls to be put in place to prevent problems.
- HACCP is a preventative food safety management system.
- It originated as part of the US manned space programme.
- It is recognised internationally as the most effective way of producing safe food.
- The HACCP principles apply a logical and common sense approach to food control.
- The application of HACCP is possible throughout the food supply chain from primary production (farmers and growers), to the consumer.
- Because it is a step-by-step approach, it is less likely that hazards will be missed. HACCP, therefore, offers increased confidence to the food business and its customers.
- HACCP is cost effective through prevention of waste and incident costs.
- HACCP helps demonstrate due diligence where required.

HACCP: A Food Industry Briefing, Second Edition. Sara E. Mortimore and Carol A. Wallace.

Frequently asked questions

By way of introduction to this book and to the subject of HACCP, we have attempted to answer some of the most commonly asked questions about HACCP: what it is, how it works, what it looks like and so on.

1.1 What is HACCP?

HACCP is an acronym used to describe the hazard analysis and critical control point system. The HACCP concept is a systematic approach to food safety management based on recognised principles that aim at identifying the hazards that are likely to occur at any stage in the food supply chain and put into place controls that will prevent them from happening. HACCP is very logical and covers all stages of food production from the growing stage to the consumer, including all the intermediate processing and distribution activities.

1.2 Where did it come from?

The HACCP concept was originated in the early 1960s by The Pillsbury Company working along with the National Aeronautic and Space Administration (NASA) and the US Army Laboratories. It was based on the engineering concept of failure, mode and effect analysis (FMEA), which looks at what could potentially go wrong at each stage in an operation and puts effective control mechanisms into place. This was adapted into a microbiological safety system in the early days of the US manned space programme to ensure the safety of food for the astronauts, to minimise the risk of a food-poisoning outbreak in space. At that time, food safety and quality systems were generally based on end product testing, but the limitations of sampling and testing mean that it is difficult to assure food safety. It became clear that there was a need for something different, a practical and preventative approach that would give a high level of food safety assurance – the HACCP system.

Whilst the system was not launched publicly until the 1970s, it has since achieved international acceptance, and the HACCP approach towards production of safe food has been recognised by the World Health Organisation (WHO) as being the most effective means of controlling foodborne disease.

1.3 How does it work?

In brief, HACCP is a structured, logical technique applied by following a few straightforward steps:

1. Looking at how the product is made – from start to finish and step by step, identifying possible hazards, deciding at what step in the process they are likely to occur and putting in controls to prevent these hazards from occurring.
2. Deciding which of these controls are absolutely critical to food safety.
3. Setting a limit for safety for the operation of these critical controls.
4. Monitoring these controls to make sure that they do not exceed the safety limit.
5. Identifying the likely corrective action should something go wrong.
6. Documenting the requirements and recording all findings as the products are produced.
7. Ensuring that the system works effectively through regular reviewing of performance and auditing.

These logical steps form the basis of the by-now well-known 7 **principles of HACCP** that are accepted internationally. They have been published by the Codex Alimentarius Commission (Current version: Codex 2009b), which is the food code established by the Food and Agriculture Organisation (FAO) of the United Nations and the WHO and also by the National Advisory Committee on Microbiological Criteria for Foods (Current version: NACMCF 1997) in the United States. The HACCP principles outline how to establish, implement and maintain a HACCP system. Codex and NACMCF are the two main reference documents and are very similar in their approach.

1.4 What are the seven HACCP principles?

The principles (Codex 2009b) are as follows:

Principle 1: Conduct a hazard analysis.
Principle 2: Determine the critical control points (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.

1.5 Is it difficult to use?

HACCP is often thought of as being complicated, requiring unlimited resources and the expertise associated with large companies. Several specialist skills are indeed required in order to use the HACCP principles successfully, but the basic requirement is a detailed knowledge of the product, raw materials and manufacturing processes alongside an understanding of whether any situation that may cause a health risk to the consumer is likely to occur in the product and process under consideration. With both training and education, all personnel involved in the application of HACCP should be able to understand and apply its concept. However, for small- and medium-sized enterprises (SMEs) and less developed businesses, the application of the HACCP principles is often found to be more difficult than it first appears. There are a number of reasons for this, and research and discussions on whether HACCP is appropriate for SMEs is still underway. In the view of the authors, it is not the size of the business that makes it difficult, but often the lack of knowledge and capability of the people who work within the business and the poor standard of existing systems such as good hygienic practice and the operating environment. This type of situation can be found in any type of company.

1.6 Why use it?

HACCP is a proven food safety management system that is based on prevention. By identifying where in the process the hazards are likely to occur, it is possible to put into place the control measures required. This ensures that food safety is managed effectively and reduces reliance on the traditional methods of inspection and testing.

Inspection and testing have traditionally been the methods used in quality control. 100% inspection would appear to be the ultimate approach towards producing a safe product, at least theoretically. In practice, however, it is not so. Take the example of fruit going down a production line where

operatives use visual inspection for physical contamination such as leaves, stones, insects, etc. The effectiveness of this technique is reduced by several factors such as the following:

- Distraction of employees by noise, other activities going on around them, people talking.
- The span of human attention when carrying out tedious activities.
- Peoples' varying powers of observation.

To detect chemical and biological hazards, 100% testing is simply not possible because such tests are nearly always destructive. Sampling plans are used instead which are based on the following:

- The ability to detect the hazard reliably using analytical techniques, which vary in sensitivity, specificity, reliability and reproducibility.
- The ability to trap the hazard in the sample chosen for analysis.

Often, random sampling is used and the probability of detecting the hazard is therefore low. The use of statistical sampling techniques will increase the probability of detection, but it can never be absolute unless the whole batch is analysed. Therefore, a preventative approach such as a HACCP is most appropriate.

1.7 What type of company would use HACCP?

HACCP is applicable throughout the food supply chain from raw material production through processing and distribution to final use by the consumer and can also be applied to non-foods such as primary packaging. Figure 1.1 shows in a simple way some of the different stages of food production where food safety is a fundamental issue. If hazards are not controlled at any particular part of this chain, problems could occur or increase later on; it is therefore important that control measures are put into place at each stage of the process, adopting a preventative approach for the entire supply chain.

The HACCP approach applies to all sectors of the food industry, but it is quite often the smaller companies that experience difficulties in implementing HACCP for a number of reasons, including lack of technical expertise and financial considerations (WHO 1999). Overcoming the difficulties is possible and will result in clear benefits such that businesses throughout the supply chain can really target control at the necessary *critical* points.

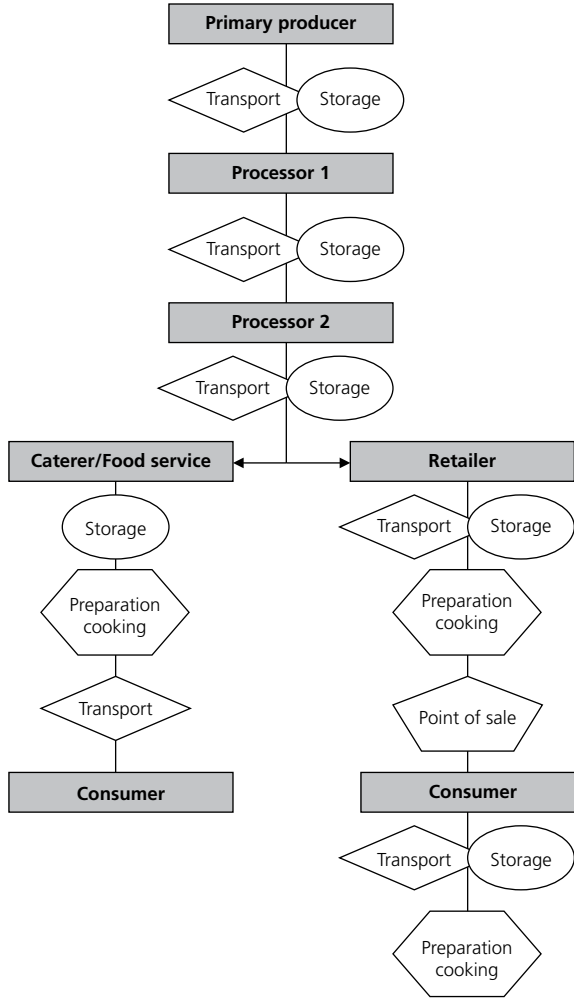


Figure 1.1 Example of supply chain.

Primary producers

These may be farmers raising livestock for the meat industry, fish farmers or harvesters or growers of crops, fruit and vegetables. HACCP use is increasing in this sector but has not been well established historically.

Example of HACCP use:
A tomato grower may require spraying with pesticide for controlling the presence of a particular pest and may identify pesticide contamination

as a possible hazard. The control measure is controlled spraying with pesticide. The critical control is monitored by reviewing the signing off of pesticide preparation and application records. The critical limits are the amount and concentration of approved pesticide used together with the length of time before harvest when the pesticide is applied.

It is also important that primary producers are made aware of the impact of their actions further down the supply chain. An issue not identified as a hazard on the farm may have an effect later on in further processing.

Processors

This includes primary and secondary processors of food. Primary processors are operations such as slaughter houses, dairies, sugar and oil refineries, etc., who process the raw materials from the farm into a form that can be used further down the chain by the secondary processors. Secondary processors are finished product manufacturers and packers.

This is a particularly complex area of the food supply chain because ingredients used in the final stage of the food manufacturing process may have already been through several stages of primary conversion carried out at different processing plants and even different countries. The potential hazards associated with storage and transportation in such cases must not be overlooked, and these will have similar considerations to that of warehousing and distribution of final products (see discussion below). It is important that HACCP is used throughout all these processing stages so that hazards can be prevented and any problems that may occur be traced to their source. It is in this area of the supply chain that HACCP has been most heavily utilised to date.

Caterers/Foodservice Operators

This is an area highly prone to food safety incidents because of its very nature, i.e. many operations often happening at once in a restricted area, a vast number of raw materials being handled, short timescales/high pressure to produce a finished product and a high turnover of staff.

Many large catering/foodservice chains have used HACCP to identify critical areas requiring control. Its use in smaller catering businesses has been somewhat limited and probably driven by regulatory requirements where

they exist. Various catering or foodservice versions of the HACCP approach have been developed. One well-known example in the United Kingdom is the safer food better business (SFBB) model (UK Food Standards Agency 2006). SFBB is similar to HACCP in that the process is analysed for hazards and controls are identified; however, it lacks the prioritisation in terms of qualitative risk assessment that a formal HACCP approach would take in identifying the CCPs and may be viewed as too simplistic for complex operations. As emphasised in the earlier discussion on SMEs, the skill base in many of the small catering establishments is very limited, which can act as a barrier to use of HACCP. Nevertheless, HACCP can be used very successfully in this sector if knowledgeable people are involved and appropriate training is received.

Retailers

The essential control measures in retail typically include appropriate temperature control and prevention of cross-contamination. HACCP application may be difficult to achieve in smaller shops where both raw and cooked products are sold by the same staff and from the same counter; but in using it, there is focus on the really critical aspects of the operation, i.e. where controls *must* be in place to minimise the likelihood of a food safety incident occurring. Some retailers process foods on the premises, e.g. butchers, bakers and larger retailers who cook deli counter offerings in store. In these cases, application of HACCP principles to the process stages involved is clearly essential.

Warehousing and distribution

Practices in this section of the supply chain are generally straightforward, but potential hazards must not be overlooked, particularly in view of the variety of climatic conditions and handling involved in a global food distribution system. There are different issues and challenges for bulk versus packaged goods, and security (adulteration, fraud risk) needs to be considered in both cases.

Consumers

This is a difficult area, as consumers do not necessarily have access to education and training in food safety as does the food industry. There are many similarities between catering and the way that a domestic kitchen

operates and studies carried out demonstrate that it is possible to use HACCP techniques to good effect in a domestic kitchen (Griffith 1994, Wallace *et al.* 2011). Basic knowledge of good food safety practice enables consumers to make informed choices both at home and on the move. At home, they will routinely use specific process steps (i.e. cooking) to control food safety, but the application of good hygiene practice and how to avoid cross-contaminating their food is generally less well understood. On the move, purchasing from reputable vendors, consuming hot or chilled foods fairly quickly and washing hands before eating should all be standard practice; but for many this is still a knowledge gap.

1.8 Are there any common misconceptions?

There are many, but we will focus on a few of the more common ones:

HACCP by itself ensures food safety.

The primary aim of HACCP is to control food safety, i.e. to ensure that all food produced is safe for consumption, but it needs to be supported by foundational programmes including a good hygienic operating environment. These programmes are known as 'prerequisite programmes' (PRPs) for HACCP implementation.

HACCP will also ensure that the end product will be of good quality and will meet all legal requirements.

HACCP implementation will often have a positive impact in these areas in that the company and its employees are more focused on doing what is right, but HACCP was developed as a food safety assurance system. In HACCP, therefore, we focus on safety issues for consumer health protection rather than including all quality issues.

For example:
Contamination of a cooked meat pie with a micro-organism likely to cause illness is a food safety hazard and should be controlled using HACCP and PRPs, but an over-baked cake is a quality issue, i.e. it may appear darker and be dry in texture. An under-filled bottle of lemonade is a legal matter, i.e. it does not meet the label quantity declaration. Including these wider quality issues could dilute the system and cause the essential food safety hazards to be seen as lower priority or, in the worst case, control of the food safety hazards may be missed.

HACCP is sometimes mistakenly confused with employee 'health and safety'.

Safety should be a core value for any company – for the food industry, this means safe foods *and* safe people. Employee health and safety statutory requirements are in place in most countries for employers in all industries, not just food, whether manufacturing goods or providing services, but this is *not* HACCP. HACCP is purely a management system controlling the safety of a product that will be consumed. That said, there is a cultural aspect to consider– by demonstrating that the company cares about the safety of its workers, then they are more likely to care about the safety of the food being made; however, the systems for managing safety of workers and food would operate separately. To develop a successful **HACCP system,** it is essential to understand what constitutes a food safety hazard and how to control it. Non-product safety issues are managed by other systems and should not be confused with HACCP and the application of its principles.

1.9 How do we know HACCP works?

There are a number of ways that companies using HACCP will check that it is working and many will be tracked as key performance indicators. Typically, these might include the following:

Consumer and customer complaint numbers

Using the information provided by consumers and customers as evidence that the food preparation is not causing problems. Quality complaints can be used as an indicator of all management controls being properly applied, i.e. if there are quality problems, then there *may* also be food safety problems.

Auditing

This is the same as auditing any management system except that the documents prepared using HACCP principles can be assessed for both completeness and compliance.

Test results

Routine and specifically planned tests may be used to verify HACCP effectiveness. Records should be reviewed to ensure that all such tests have been carried out properly, that no planned checks were missed and that the results were within specification.

Reduction in product losses

As a preventative approach, companies will often observe that less product is being made that is out of specification.

1.10 What actually gets implemented in the workplace?

A HACCP system is summarised in a document known as a **HACCP plan**. This is simply a document or folder, and it contains all the information related to the **CCPs** – together with the operating standards or **critical limits**. It also documents who is responsible for the monitoring of the CCPs and at what frequency, what corrective action should be taken if something goes wrong, the hazard that is being controlled and often includes a process flow diagram or stepwise drawing of each step in the process. It is actually the CCPs that are implemented in the workplace through the monitoring and corrective action activities.

1.11 How does a HACCP plan get written?

A HACCP plan is the output of the **HACCP study**. This is the application of the first five of the Codex HACCP principles, i.e. the raw materials and the processes used are evaluated to see what foodborne hazards may be a concern and the appropriate controls are identified.

Before the HACCP study commences, a certain amount of planning and preparation will occur – in fact, this is important at every stage. Once the HACCP study is completed and implemented, it needs to be kept up to date, i.e. verified as being correct and maintained to keep current with the product and process as they undergo changes. In simple terms, the whole process of actually using the HACCP principles could be broken down into four key stages as shown in Figure 1.2.

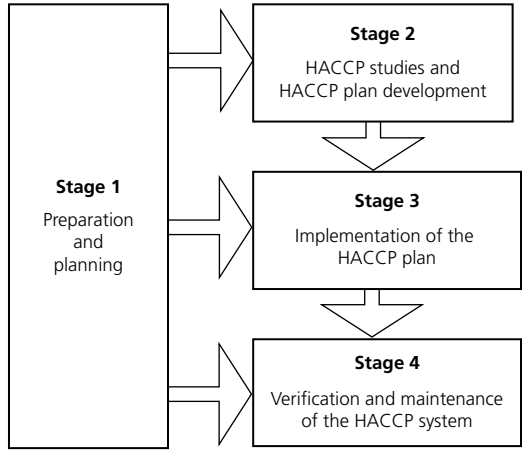


Figure 1.2 The four key stages of HACCP. Source: Adapted from Mortimore and Wallace (2013).

1.12 Who carries out the HACCP study?

This is done by the **HACCP team**. Normally, a multi-disciplinary team of about four to six people are trained in the HACCP approach. In a large business, the functions included may be quality assurance, manufacturing, engineering, research and development, microbiology and supplier quality assurance. In a smaller business, there may only be one or two people available. What is important is that the people on the team have an in-depth knowledge of how the product is made. They also need technical know-how, particularly for the hazard analysis; but if this is not available within the business, then it can often be bought in on a consultancy basis.

1.13 What is the regulatory position of HACCP?

Governments and enforcement authorities are increasingly recognising HACCP as the most effective means of managing food safety.

The European Community Regulation (EC) No. 852/2004 on the hygiene of foodstuffs states that 'food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles'. This is effectively a requirement to adopt the HACCP approach across

all sectors of the industry. Annex II of the regulation specifies the hygienic requirements; therefore, this is a comprehensive piece of legislation.

In the United Kingdom, the statutory defence of due diligence was first introduced within the Food Safety Act (1990). Current UK regulations (The Food Hygiene (England) Regulation 2006) are aligned with the European regulatory position and still retain this same provision. It requires that the person proves that he took 'all reasonable precautions and exercised all due diligence to avoid the commission of the offence by himself or by a person under his control'. In the event of litigation, this would give a defendant a strong case if HACCP was in place and working – and a very weak case if it was not.

In the United States, the HACCP techniques were used to identify the controls specified in the Low-Acid Canned Food Regulations as early as 1973 (USDA). This was followed by the US Department of Agriculture who decreed that HACCP programmes are required for all meat and poultry processing facilities (USDA 1995). It is also required by law in the area of seafood inspection and processing (FSIS 1996). More recently, the US Food Safety Modernization Act (FSMA 2011) requires that businesses develop and implement a preventative food safety plan. Whilst regulations under FSMA are still being finalised, this far-reaching legislation requires food (and animal feed) companies that are not already under the jurisdiction of the USDA (e.g. other than meat, poultry, eggs), to identify food safety hazards, have written plans that address control of these hazards and to implement and maintain these plans to ensure that hazards are eliminated or reduced to the greatest extent possible.
The new acronym of HARPC (Hazard Analysis and Risk-based Preventive Controls) is being used to indicate that hazards must be controlled not only through controls identified as *critical* (through HACCP) but also through control measures that fall under a prerequisite programme (more in Section 3 on the latter).

Canada and China are examples of two other major countries that have been very actively making significant changes to their food safety legislation and, at the time of writing, the final situation is still to be clarified. In Canada, these developments come in the wake of the largest beef recall in Canadian history in 2012 and the major listeria outbreak in 2008, and involve the introduction of the *Safe Food for Canadians Act*. This attempts

to streamline and consolidate several other pieces of legislation (The Meat Inspection Act, The Fish Inspection Act and The Food and Drugs Act) and transfer activities of the Canadian Food Inspection Agency from the Minister of Agriculture to the Minister of Health; the new legislation proposes to improve Canada's surveillance/inspection system.

While many countries are in the process of re-evaluating and developing their food safety policies, the use of the Codex HACCP principles as the international standard means that the HACCP systems implemented by trading partners are based on the same principles. At the time of updating this book (March 2014), we have some way still to go before equivalency in interpretation and implementation is agreed, but the General Agreement on Tariffs and Trades (GATT) Uruguay Round and the establishment of the World Trade Organisation (WTO) back in January 1995, has meant that mutual agreement of the standards of each trading partner's country and/or the equivalence of food safety system must occur before trade can proceed.

In summary, it is clear that international legislation is moving more and more towards making HACCP a mandatory requirement in the food industry. This will lead to greater regulatory assessment of HACCP systems as governments take up their responsibilities with regards to confirming that the business operators are properly complying with requirements (WHO 1998).

1.14 Are there other driving forces for the use of HACCP?

Customers and consumers

While the end consumer may not know what HACCP means, manufacturers, retailers and caterers increasingly expect that their suppliers develop and implement HACCP plans. Any inspection carried out on production premises nowadays includes an assessment of the competence of the management. An effective HACCP system is essential in demonstrating that the food business operator understands and is managing food safety hazards.

Media pressure

As consumers become more aware of food safety, they are encouraged to use social media to search for information but equally to publicise a grievance. Rapidly developing social media tools, internet search engines and

fast communication networks often mean that food safety issues (real or perceived) are escalated in a matter of hours. Companies can use these same tools to communicate back to the public, for proactive education as well as for response in times of failure.

The issues identified may not always be real in terms of food safety but can cause severe brand damage, and food companies need to be able to answer all claims made against them. Fully documented evidence in the form of efficiently maintained HACCP records may be essential in counteracting such claims and ensuring that the company stays in business. Doing everything possible to prevent a food safety issue is the very best approach that any food company can take.

1.15 What does it cost?

There is no fixed price that can be put on a HACCP system. Whichever way one looks at it, it is going to be variable depending on what is already in place and the complexity of the process.

At the planning stages of a HACCP system, it may appear that a lot of expense is required, but much of this is not direct HACCP cost.

For example:
HACCP may identify the need to improve hygiene practices within the operation or the additional training of staff, but these requirements existed anyway; HACCP has simply highlighted them.

The true cost of HACCP will include the following:

- Time for HACCP training
- HACCP training – external courses or hiring of a trainer
- Administrative support
- Additional temporary resources (e.g. technical and secretarial)
- Cost of validation
- Time cost for review/audit
- Equipment – if identified as a need
- Verification activities

Some of these costs, however, may well be offset by the savings resulting from the application of HACCP such as the following:

- Reduction of on-line product testing costs in terms of samples, human resource and testing materials.
- Possible reduction in analysis costs, both internal and external, if the HACCP study identifies alternative measures, e.g. certification of ingredients and in process controls.
- Earlier release of finished product, thereby reducing stock holdings.
- Cost avoidance: hazardous products have major implications for food manufacturers and retailers and the financial cost that ensues when control is lost is significant. The cost will include those associated with recalling products in the marketplace, lost sales, court costs and compensation, plus loss of consumer confidence and its effects on the company reputation.

Additional costs need to be budgeted at the planning stage to ensure that the project is fully financed through to its completion and subsequent maintenance.

1.16 What is third-party certification?

Third-party audits have been available for many years and have been used to independently verify compliance to a standard. The ISO22000 (2005) standard and a number of private standards that have been benchmarked by the Global Food Safety Initiative (GFSI) are HACCP based. These approaches are being used globally and can be a requirement for doing business. To become certified, an independent certification body will conduct an on-site audit against the requirements specified in the standard; and if compliant, then a certificate will be awarded, usually for a period of 12 months. This process provides a detailed independent assessment of the food safety management system, including HACCP.

1.17 Is there anything more that I should know?

HACCP is not an exact science. It is a tool, a way of thinking – where decisions taken must be based on sound science; but even after 50 years, its use and interpretation of the principles continue to be debated across international boundaries. This is worth bearing in mind when going into more detailed sections of the book.

SECTION 2

The HACCP system explained

KEY POINTS

- HACCP system development requires skills, activities and conditions that are not unique to HACCP alone.
- Business management practices such as project management and leadership skills are a key success factor.
- Prerequisite good hygiene practice programmes are the foundation to HACCP and also control quality or 'wholesomeness'.
- Quality and food safety management systems will provide an effective framework within which to implement HACCP.
- Management commitment is essential if HACCP is to be taken seriously, and the company needs to have a strong food safety culture.
- The HACCP team must have a broad variety of expertise and may include the use of external food safety experts.
- The structure of the HACCP plan must be decided based on the nature and complexity of the products and processes.
- It is important that the HACCP project is planned carefully in advance.

HACCP: A Food Industry Briefing, Second Edition. Sara E. Mortimore and Carol A. Wallace.

This section is broken down into three parts:

2.1 HACCP system overview – How does it all fit together?
2.2 HACCP in the context of other management activities – What is HACCP and what is not?
2.3 What is involved in getting started – i.e. the preparation and planning stage.

2.1 HACCP system overview – How does it all fit together?

In the previous section, a number of key terms were introduced – part of the HACCP jargon. To recap:

HACCP principles – there are seven principles published by Codex Alimentarius (2009b) and NACMCF (USA) (1997). These are as follows:

Principle 1: Conduct a hazard analysis
Principle 2: Determine the critical control points (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.

HACCP study – this is where the HACCP principles are applied to a segment or whole of the food chain process under consideration.
HACCP plan – the output of the HACCP study. This is a document prepared in accordance with the principles of HACCP to ensure control of hazards that are significant for food safety.
HACCP team – the people who carry out the HACCP study, usually four to six people making up a multi-disciplinary team. Typically, quality assurance, engineering and production personnel will be on the team.
HACCP system – the HACCP system is what you get once the HACCP plan has been implemented in the workplace.
HACCP documentation and records – used as evidence that the system is in place and working.

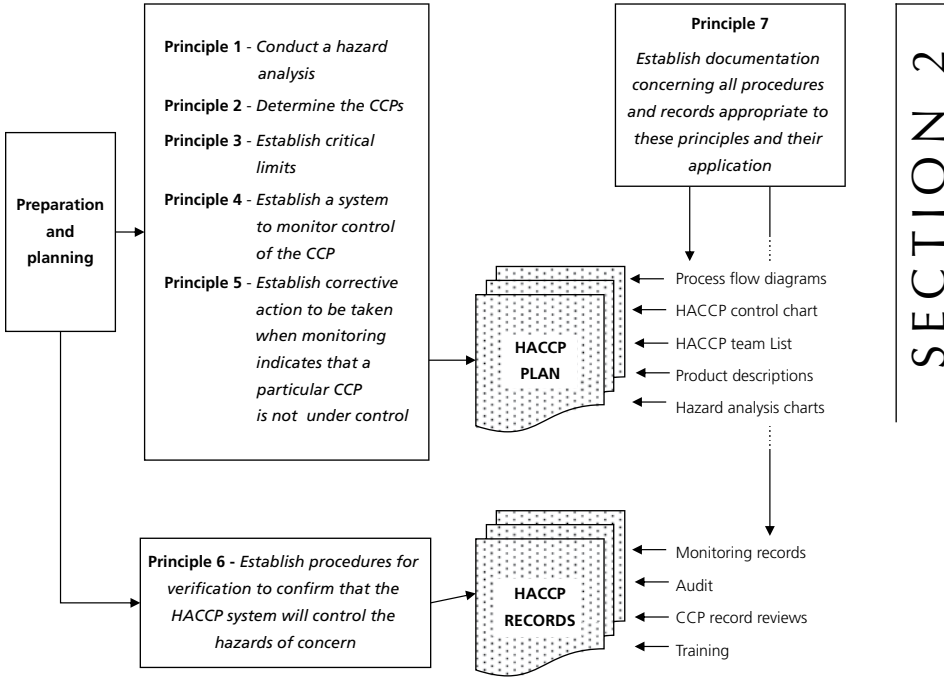


Figure 2.1 HACCP system overview.

An effective HACCP system needs to be planned, studied, implemented, verified and maintained in a logical systematic way. Figure 2.1 shows how the various elements fit together.

Preparation and planning is very important and can be a key element in ensuring that the process of setting up a HACCP system is as painless as possible. Later in this chapter, we will look at this activity in more detail. Before that, let us look very briefly at what the application of the HACCP principles involves:

The HACCP study itself is essentially made up of the first five of the seven principles. A HACCP team will start by applying the first principle; and to do this, they will map out the food process step by step. This is the HACCP study:

Taking the example of boiling an egg, the process can be broken down and documented on a process flow diagram as shown in Figure 2.2. At each of the six process steps identified, the HACCP team will assess whether there are any food safety hazards of concern (*Principle 1*). Therefore, at step 1, they may identify *Salmonella* spp. as a potential problem.

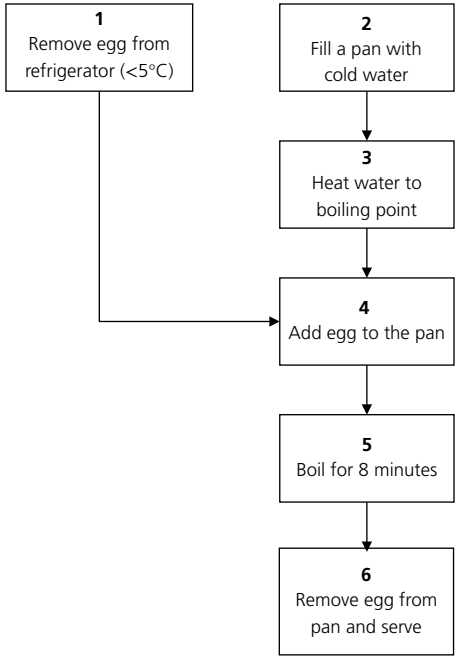


Figure 2.2 Boiling an egg – Process flow diagram.

They will then consider whether the step of removing the egg from the refrigerator is a critical step (*Principle 2*) with respect to the control of the hazard in question, i.e. *Salmonella*. They are likely to conclude that it is not, given that the egg is going to be boiled in water later on. At step 5 (where the egg is boiled) as they apply Principle 2, they are likely to conclude that the act of boiling is critical (a CCP) for control of *Salmonella* – it is a micro-organism that is easily destroyed by thorough cooking.

They will then consider how long the egg must be boiled (the critical limit) to ensure that any *Salmonella* is destroyed (*Principle 3*). In manufacturing facilities, this is usually determined through various tests and measurements, e.g. to assess the centre temperature of the egg over the course of the cooking time in relation to known information on thermal destruction of *Salmonella*, and therefore that the boiling time chosen is sufficient to reach the required centre temperature.

Having proven the relationship between time and temperature, the HACCP team has to decide how often to monitor the boiling time and the water temperature (*Principle 4*) and what to do if the requirements are not achieved (*Principle 5*).

All this information will be documented on a form often known as a *HACCP control chart* or worksheet that goes into the *HACCP plan*. Other pieces of information may also be recorded and retained within HACCP plans, e.g. details of who was on the HACCP team, a description of the product concerned and the notes taken during the hazard analysis. There are no hard and fast rules on what additional information to keep.

Once the study is complete, the team will need to carry out **validation** activities to confirm that all elements of the HACCP plan will be effective. For the example of boiling an egg, validation means confirmation that boiling an egg for 8 minutes will destroy *Salmonella*.

Verification activities (*Principle 6*) typically include tests, random sampling and analysis, reviews of monitoring records and audits – all designed to determine whether the HACCP system is working effectively once implemented in the operation. For the example of boiling an egg, verification will include a review of the monitoring records which show that the egg was boiled for 8 minutes.

In addition to monitoring, it is the verification activities that principally lead to the compilation of a number of documents and records, which is another (*Principle 7*) requirement though the HACCP plan itself is obviously a key document (see Figure 2.1).

The HACCP principles are logical and it is an easy-to-understand concept. However, even though the example given (boiling an egg) is very simple, it is clear that some technical knowledge is required, i.e. that *Salmonella* is associated with raw eggs and that boiling for 8 minutes will destroy it. Many people with basic hygiene knowledge (or cooking ability in this case) might know some of this, but consider the situation if the product was sushi or a pizza with a range of toppings – it is not so easy. There is also a whole range of other skills and activities that are needed when HACCP is put into business for real.

2.2 HACCP in the context of other management systems – What is HACCP and what is not?

This still comes as a surprise to some people, but HACCP by itself will not guarantee safe food. In order to be effectively developed and implemented, HACCP needs the support provided by other management systems operating within the business. These can be categorised into four groups as shown in Figure 2.3.

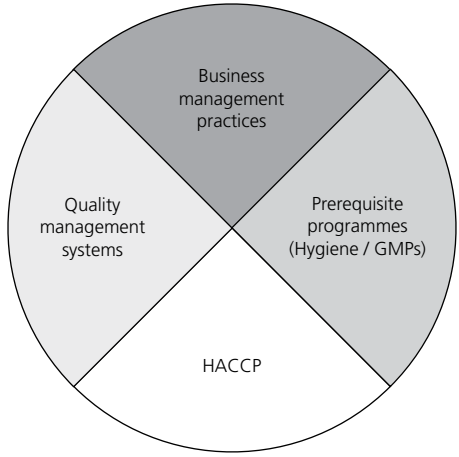


Figure 2.3 HACCP in the context of other management systems.

Business management practices are the day-to-day 'business' skills that, when thinking about HACCP as a project, will be invaluable in making sure that the work involved is carried out efficiently and effectively. **Prerequisite programmes** (PRPs) are the **good manufacturing practices (GMPs)** or **good hygiene practices (GHPs)** that any reputable food business operator would be adhering to in order to ensure that safe, wholesome food is provided to the consumer. **Quality management systems** (QMS) act as a framework within which any process activity can be managed, including HACCP. All of this needs to operate within a strong business food safety culture

2.2.1 Business management practices

There is a vast array of skills and activities that contribute to managing a business, many of which may not be formally recognised, particularly in a small business. Some of the skills, however, are needed during HACCP development and implementation. A few of these are considered in the following.

Management Commitment

This is needed for any project undertaken by a business and should be the driving force if the project is to be fully successful. Real commitment for HACCP will only be achieved if the management team understands what

HACCP is all about – the reason for using it, the expected benefits, what is involved, how long it might take, what costs would be incurred, any likely impact on other aspects of the business (e.g. improvements in GMP) and so on. It will also be helpful to confirm what has contributed to the decision to use HACCP – legislation, customer demand or a desire for self-improvement. Ultimately, the company will need to be moving towards the goal of having a strong food safety culture, where every employee feels a strong sense of commitment and responsibility for food safety. Culture is doing the right thing – when no one is looking, and it can make or break a food safety (and quality) system.

Leadership

The HACCP team will lead the process of developing and implementing a HACCP system. But leadership for food safety must come from the senior business executives. Food safety culture starts at the top, and the leadership team needs to be able to 'walk the talk'. In a food safety sense, it is critical that every single person in the organization has a sense of leadership for food safety and for doing the right thing.

Leadership skills will be needed not only within the senior management of the business but also within the HACCP team itself and will need to be further developed if not already in place. HACCP implementation is a good opportunity for motivating the workforce by reinforcing hygiene standards, talking openly about food safety and by making them proud of being part of the organisation. This can be achieved through a strong and visibly committed leadership team.

Project management

As will be discussed later in the preparation and planning stage, putting a HACCP system into a business is a major project and needs to be managed as such. The work involved can be considerable, particularly in a complex business.

Process mapping

This is used widely in business improvement programmes as it is a systematic way of getting to understand a given process. It can be used for any process, e.g. activities as diverse as 'customer order processing' through

to employee medical surveillance. Process mapping is of course one of the first activities undertaken by a HACCP team when they begin the **hazard analysis** step by constructing a process flow diagram.

Data analysis and administration

These are used in a number of business situations (e.g. accounting, labour and overheads management) and also in HACCP verification where CCP records are reviewed and customer complaints analysed. IT tools can be used to turn the test data into actionable information that drives improvement.

Problem solving

A very useful skill set and is frequently used in HACCP as in many other projects. It may involve a variety of techniques such as identifying the 'desired future state' and then analysing the drivers and restrainers that either prevent or expedite you getting there. It could also encompass 'cause-and-effect' analysis.

Auditing

Again, a key activity in HACCP verification, auditing is used to measure compliance with the documented HACCP plan, but is also a traditional management activity, for example, in accounting as well as in quality management.

Team skills

It is useful to build the HACCP team such that they enjoy a more efficient and supportive relationship based on openness and trust, all working towards the same goal. Again, these skills are needed in a number of other business teams and are not specific to HACCP alone.

Record-keeping and documentation

This is a HACCP principle, but it is also an activity that is not exclusive to the administration of HACCP.

There may be other skills and activities that are needed if a really sound HACCP system is to be developed and implemented and which will provide

a backbone for the company's food safety programmes. We have highlighted just a few of the more obvious ones.

2.2.2 Prerequisite programmes

There are many definitions for PRPs, but all basically saying the same thing. The World Health Organisation (WHO 1998) defines prerequisite programmes as 'Practices and conditions needed prior to and during the implementation of HACCP and which are essential for food safety'. The International Organisation for Standardisation (ISO) refers to PRPs as the 'food safety basic conditions and activities that are necessary to maintain a hygienic environment throughout the food chain suitable for the production, handling and provision of safe end products and safe food for human consumption' (ISO 2005). The Codex (2009b) guidelines for HACCP application states 'prior to the application of HACCP to any sector of the food chain, that sector should have in place prerequisite programmes such as good hygienic practices'. It goes on to say that this must include training and that they should be well established and verified.

There is nothing new about PRPs, but the term itself is still fairly new. In simple terms, PRPs are those practices that many would class as GMPs or GHPs.

The requirement to have an environment that is operating to good standards of hygiene and housekeeping is clearly fundamental to the day-to-day management of food safety and wholesomeness. PRPs control the general factory or kitchen 'good housekeeping' issues rather than specific process hazards that are managed through HACCP, and much of this is common sense.

Figure 2.4 shows some of the prerequisite elements that provide essential support to an effective HACCP system:

Building and equipment design

This includes the fabric and layout of the facility, i.e. the floors walls and ceilings. They need to be cleanable, be made of food grade materials and not have cracks and crevices that could harbour pests or micro-organisms. The layout of the facility needs to be thought about with regards to prevention of cross-contamination. This is one of the most frequently cited causes

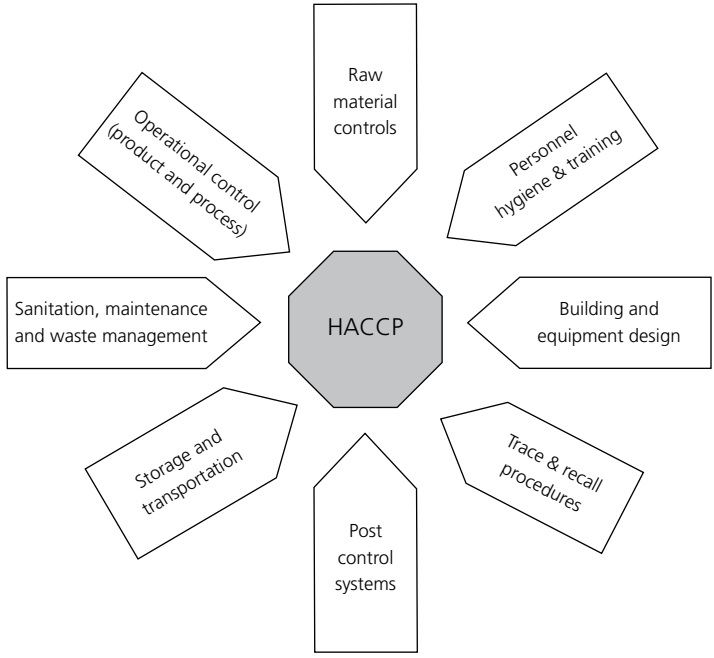


Figure 2.4 Hygiene prerequisites for HACCP. Source: Based on Codex Alimentarius Commission Food Hygiene Basic Texts (Codex 2009a).

of foodborne illness. The raw materials and product flow through the plant need to be such that once the product is considered safe, it will not be cross-contaminated or held in conditions that could lead to an increase in the microbial population. Chemical, in particular allergens, and physical cross-contamination hazards also need to be considered. The food must be adequately protected from passing traffic (people, waste removal, trucks and equipment, etc.) and any air- or water-borne contamination.

Lighting is often underestimated in its importance to food safety, but people need to be able to see properly for the maintenance of a hygienic operating environment and of course for inspection.

Sanitation, maintenance and waste removal

Sanitation (cleaning and disinfection) is a really important aspect of hygiene control in any food business and an area that can often be overlooked given that sanitation frequently occurs on a night shift and, if it is not given a high profile, often receives a low priority. There are many examples of

food safety (and spoilage) failures that are a result of poor sanitation. In some countries (e.g. the United States for the meat and poultry industries), sanitation programmes are a legislated prerequisite and are known as sanitary standard operating procedures (SSOPs).

Waste removal and drains can be ready sources of contamination if not managed. Waste should be covered and regularly removed from the facility so as not to attract pests. Drains should be kept clean, and the direction of flow should be such that cross-contamination from 'dirty' to 'clean' areas does not occur.

All equipment and buildings should be properly maintained and on a preventative schedule, i.e. rather than waiting until a breakdown occurs.

Pest control systems

Effective pest control programmes are essential in the food business and should include both preventative and corrective action programmes for insects, rodents, birds and other appropriate pests (e.g. snakes). Pests can act as a carrier of microbiological contamination (which is the primary concern) as well as being a source of physical contamination, which is aesthetically undesirable either through presence of particulates or through being the source of pack damage.

Personnel hygiene and training

Employees are a significant source of hazards. Hygiene education and training are very important in that the hygiene standards of a business will only ever be as good as the hygienic behaviour of the people who work within it. Inadequate hygiene is a known major source of cross-contamination, either directly (e.g. through sneezing over food, spitting or smoking) or indirectly (e.g. through lack of handwashing after using the toilet). It is essential that the company is able to rely on a consistent hygienic behaviour from the workforce. Personal effects including jewellery should not be allowed in the workplace as they can act as an indirect source of microbiological contamination as well as potentially being a physical contaminant. Any visitors to a food-handling area should also comply with hygiene rules regarding handwashing, absence of jewellery, the wearing of clean protective clothing, covering of hair and so on. Employees should be provided with adequate uniforms, lockers, toilets and handwashing facilities. Training

goes beyond hygiene and will include training in the requirements of specific job roles, e.g. CCP monitoring, HACCP principle application and so on.

Raw material controls

This is another essential aspect of a PRP. The approval of suppliers of critical raw materials is usually done through an on-site audit of the supplier's premises and raw material specifications will document all likely hazards together with control procedures and monitoring checks that are carried out by the supplier. Certificates of analysis are often provided by suppliers as evidence that their own HACCP systems are working. These should be supplied by reputable laboratories if results are to be relied upon. For SMEs, reliance on purchase from 'reputable' suppliers is often the best option for ensuring that wholesome raw materials are used.

Operational control

This includes the ability to control processes such as time and temperature, sifting, sieving and detection devices, segregation of allergenic ingredients and the ability to monitor the equipment and control within specified parameters.

Storage and transportation

During the storage and transportation of the food, it is important to ensure that it is protected against contamination. The environments, including buildings, vehicles and shipping containers, must be clean and free of pests, which could infest food products. Where temperature control is important (i.e. chilled and frozen food), this must be managed such that the growth of micro-organisms or production of toxins is prevented.

Traceability and recall

If control is lost, it is important to ensure that *traceability and recall procedures* are efficient and effective to ensure that any ensuing unsafe product incident is managed effectively and product could be rapidly removed from the marketplace if necessary. Operators need to be able to quickly trace raw materials (where were they used), and finished products (where were they sold). Usually, a company will aim at doing this within 4 hours though regulatory targets are often closer to 24 hours.

Documentation and record-keeping

Sometimes, documentation and record-keeping are considered elements of a PRP as they provide evidence of compliance though they are actually a HACCP principle. It is essential to manage and archive documentation in a manner that allows efficient retrieval, whilst ensuring that the documents themselves do not become a hygiene problem, e.g. through harbourage of pests.

Finally, the successful operation of PRPs requires the essential characteristics of business management practices (Section 2.2.1), in particular, management commitment and organisational culture. These are more and more being recognised as essential for successful food safety management. Absence of a food safety culture, documented procedures and work instructions will not be enough for food safety assurance. Everybody in the organization needs to understand their role in food safety (through education), and know what tasks they have to complete (through training). They also have to commit to doing the right thing and to speak up when it goes wrong. It starts with management commitment, but does not end there – everyone has to be engaged.

2.2.3 Quality management systems for effective operation and process control

QMS, such as those modelled on the International Organization for Standardization ISO9000 quality system standards, aim at primarily ensuring that customer requirements are met consistently. Both HACCP and such quality assurance systems aim at the prevention of non-conformity placing emphasis on effective corrective action and getting it right first time.

Whilst a QMS is not a 'prerequisite programme' in terms of GHP, it is often used to manage the PRP and HACCP systems so that any element of the operation can be effectively controlled (Figure 2.5). Whilst HACCP is the basis for ISO22000 and the GFSI-benchmarked food safety management schemes, these too include many of the elements that would be found in a formal QMS. Many companies have their own internally designed QMS that they use to manage both HACCP and PRPs.

There are many controlling steps in any process; some will be critical for food safety, but others will control the quality and legal attributes of the product. These are sometimes known as process or legal control points or

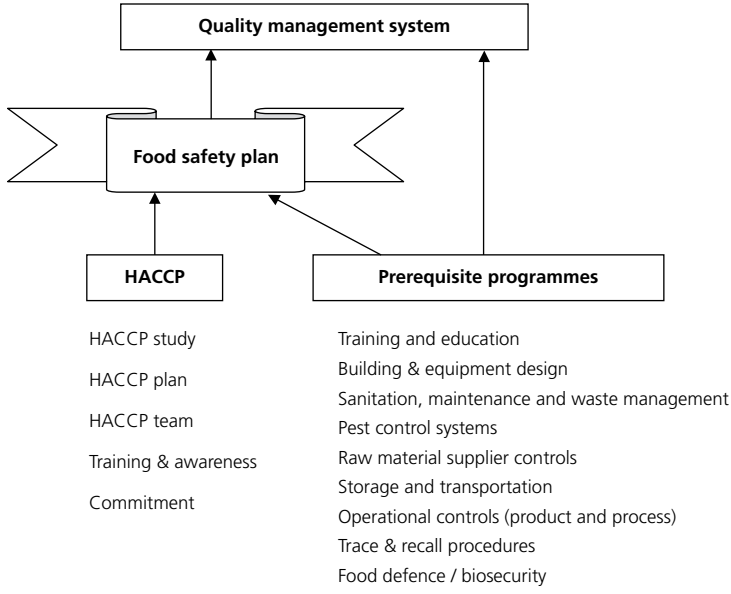


Figure 2.5 Quality management programme. Source: Adapted from Mortimore (2001).

simply control points (CPs). To recap, CCPs are the stages in a processing operation where the food safety hazards must be controlled. CCPs are essential for product safety as they are the points where control is affected. The CCP itself does not implement control. It is the action that is taken at the CCP that controls the hazard.

Some companies often implement extra control points in their processes in order to protect the process and process equipment or to relieve pressure from the CCP by reducing the hazard. These points are usually CPs, and they should not be confused with the genuine CCPs where the hazards *must* be controlled.

This simple relationship between CCPs and CPs must be understood if HACCP is to be used to its best effect. It is important that CCPs are identified as the points that are truly critical to product safety.

Figure 2.6 serves to illustrate how both CCPs and CPs may be documented and managed within the framework of a QMS.

Whilst business management practices, PRPs and QMS assist in managing both food safety and quality, before considering the development of a

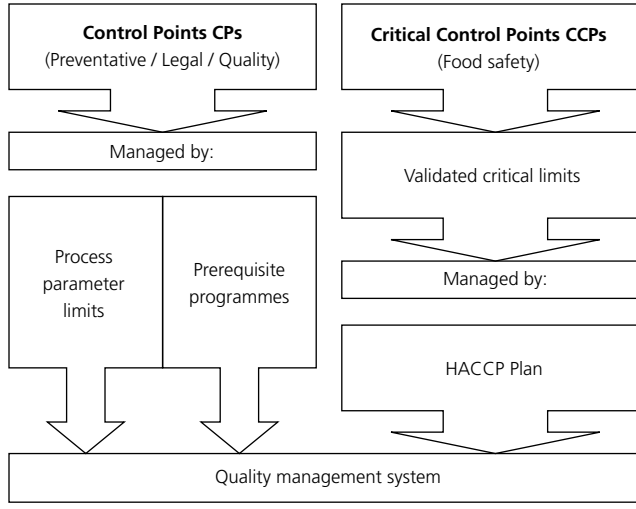


Figure 2.6 Control point differentiation. Sources: Wallace and Williams (2000), adapted from Mortimore (2000).

HACCP programme, it is important that their current status is evaluated in order to determine the following:

1. What skills, activities and conditions are required to combine with HACCP to enable effective food control?
2. What is actually already available?

The answers to these two questions will highlight the gaps that need to be filled, and this evaluation is often called a 'gap analysis' (see 'Baseline audit').

When identifying the deficiencies, it is important to be clear about what forms part of the HACCP system and what is, or should be, in place as a foundation or support to HACCP implementation. It can be helpful to communicate this relationship to employees early on in the programme.

For example:
Personnel hygiene practices such as handwashing facilities and suitable protective clothing are of upmost importance in helping to protect products in any food-handling operation.
Calibration of equipment, which is a requirement of management systems such as ISO9000 and ISO22000, is also a key requirement when it comes to ensuring that equipment used to control CCPs is working properly.

Understanding the relationship between these management frameworks and HACCP is likely to lead to a more structured and systematic approach. It will also aid understanding of what HACCP is really designed to do – identify and control significant food safety hazards through the management of CCPs, whilst providing a clear understanding of where additional control points can be effectively set up.

2.3 How do you get started with HACCP – The preparation and planning stage

Proper preparation and planning (Figure 2.7) is fundamentally important to developing a successful HACCP system. It is essential at the earliest stage of setting up a HACCP system that:

- senior management commitment is assured.
- the appropriate people are identified and trained.
- the prerequisite support systems already in place are established, and what needs to be further developed is planned for.

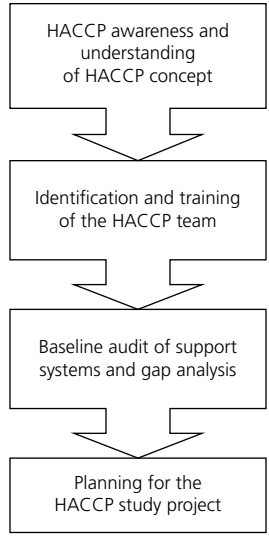


Figure 2.7 Key stage 1: Preparation and planning. Source: Adapted from Mortimore and Wallace (2013).

- the most appropriate structure for the HACCP system is selected after careful consideration.
- the entire project for the development and implementation of the HACCP plan is planned.

2.3.1 Management commitment, personnel and training

One of the first preparation activities is to gain an overall awareness and understanding of what is involved in using HACCP. In order to do this properly, it is essential to gain commitment for visible leadership at senior level, to manage expectations, and ensure proper allocation of resources. Real commitment can only be achieved if there is full understanding of the requirements for a food safety programme, of the benefits of HACCP, and what is involved and required at senior management level. This can be achieved through reading specialist publications and attending a HACCP briefing session undertaken by an expert within the organisation, if available, or through an external consultant, if not. Visiting other companies who have already implemented a system is invaluable in gaining an understanding of what the outcome of the project will look like, i.e. the HACCP system. It is an ideal way of seeing various styles if this is possible, talking to people who have done it, about what worked, what did not and what they might do differently if they were starting again. This will be useful knowledge at the start of the project.

It is highly desirable that the HACCP study is not carried out by one person alone, though in a very small business there may not be a choice. Ideally, HACCP development should be carried out by a multi-disciplinary team. Selection of team members should be based on knowledge of raw materials, products, processes and hazards. Ideally, the core HACCP team should consist of people having knowledge and expertise in the following areas:

- Quality assurance/technical – providing expert advice in handling microbiological, chemical and physical hazards, an understanding of the risks and knowledge of the measures needed to control the hazards.
- Operations or production – people who have responsibility and working knowledge of the operational activities needed to produce the product.
- Engineering – to provide a working knowledge of process equipment and environment with respect to hygienic design and process capability.

Additional expertise may be needed depending on the nature and complexity of the product. In a larger company, the following areas should be considered:

- Supplier quality assurance – for providing details of supplier activities and assessing risks associated with raw materials, particularly where high-risk materials are involved.
- Research and development – particularly where new products are constantly being developed.
- Distribution – especially where temperature control is essential to product safety.
- Purchasing – could be useful where factored goods are purchased and re-sold.
- Microbiologist – if a company has its own microbiologists, their expertise will be invaluable on the HACCP team. Smaller companies who do not have this option should consider an external source of such expertise.
- Toxicologist – may be needed where chemical hazards and their monitoring and control are a potential issue. A toxicologist could be located in a Food Research Association, consulting analytical laboratory or university.
- Statistical process control (SPC) – an external expert may be needed when setting up sampling plans or a detailed assessment of process control data.
- External HACCP 'experts' – may be appropriate initially as facilitators to guide the HACCP team through the selection of team members and initial studies.

A HACCP team needs to be small enough for effective communication but large enough to enable specific tasks to be delegated. This is why a range of four to six is usually quoted as the ideal number of HACCP team members.

The development, implementation and maintenance of a HACCP system require some skills and activities that are unique to HACCP and some that are not. Figure 2.8 emphasises the skills that are already considered as being business management practices and those that are unique to the use of the HACCP principles.

One member of the HACCP team should be selected for their leadership skills and appointed as the team leader. The team leader will be responsible for ensuring that:

- the team members have the necessary knowledge and expertise through training and development.

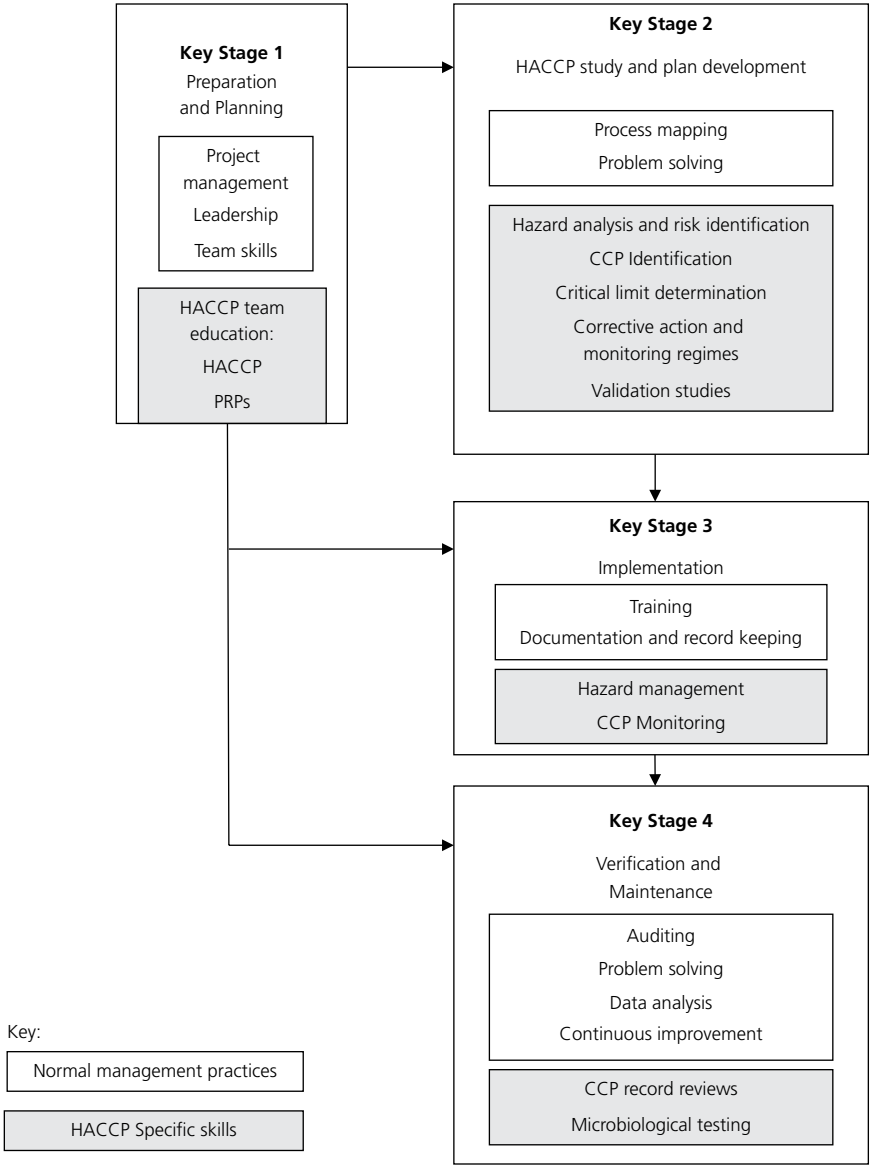


Figure 2.8 HACCP system development – Skills requirements.

- all tasks relating to the development of HACCP are organised adequately.
- time is used effectively and also is made available for reviewing progress on an ongoing basis.

- all skills, resources, knowledge and information needed are identified and sourced either from within the company or through external support.
- documents and records are maintained efficiently.

It is very useful to appoint a 'scribe' or secretary to the HACCP team. This is a key role and requires someone with good attention to detail. Since each part of the HACCP study builds on the previous part and may be completed at different times, accurate record-keeping is essential to ensure that the team's deliberations and decisions are captured precisely and in a way that will be easily understood.

Once selected, this team must be prepared with detailed training in the principles of HACCP and with additional training and understanding of the management skills and topics that underlie the application of these principles. Training of the HACCP team is the single most important element in setting up a HACCP system, and it is important that it is done properly. External training courses from reputable training providers or regulatory authorities are a good option but often only provide an introduction; therefore, it is not to be expected that the HACCP team will be experts after a two-day course.

2.3.2 Baseline audit

It is a good practice to conduct a thorough baseline audit or gap analysis of the current systems within the business at the start of the project to fully appreciate the scope of what might be involved during the development and implementation of HACCP. Not all companies will do this, but the ones who do are usually self-driven, i.e. they want to see real business benefits and do as good a job as possible. Companies who are putting in a HACCP system solely because of legal or customer requirements often want to do the bare minimum to gain compliance, i.e. to produce a HACCP plan that satisfies the regulator or customer, and therefore may not take the time to thoroughly understand their current systems and how they might be strengthened.

The baseline audit is a good opportunity to evaluate a number of elements:

- The status of the PRPs as described earlier.
- The skills base within the organisation and to begin talking about the actions needed to fill the gaps.

- The controls and procedures already in place and which will now be incorporated into the HACCP plan.

2.3.3 Planning the HACCP project

In planning the HACCP project, the HACCP team leader will need to ensure that the team has a complete understanding of the project vision and knows clearly where they are starting from and what the end result will look like in the factory or catering facility. This is most easily accomplished if the team is appointed early and participates in the initial awareness activities as well as the baseline audit and gap analysis so that they fully appreciate the current capabilities and the size of the task. If the vision and end goal is to have an independently certified food safety system, then now might be the time to have an independent (third party) gap assessment against the required standard.

In terms of the HACCP system, one of the key issues to be decided early on is the approach to be taken with regards to how it will be organised. This will depend on the complexity of the operation, as well as the types and number of processes being carried out.

There are three basic approaches:

Linear HACCP plans

In this approach the HACCP principles are applied to each product or process on an individual basis starting with the raw materials coming in and ending with the finished product. This approach works best in simple operations where there are few product types and a small number of processes.

For example:
A bakery producing one type of bread.

Modular HACCP plans

This approach works best where there are several basic processes used to produce a number of products.

For example:
A factory producing several types of pizza and other dough products where several basic processes are in place, but each product type may

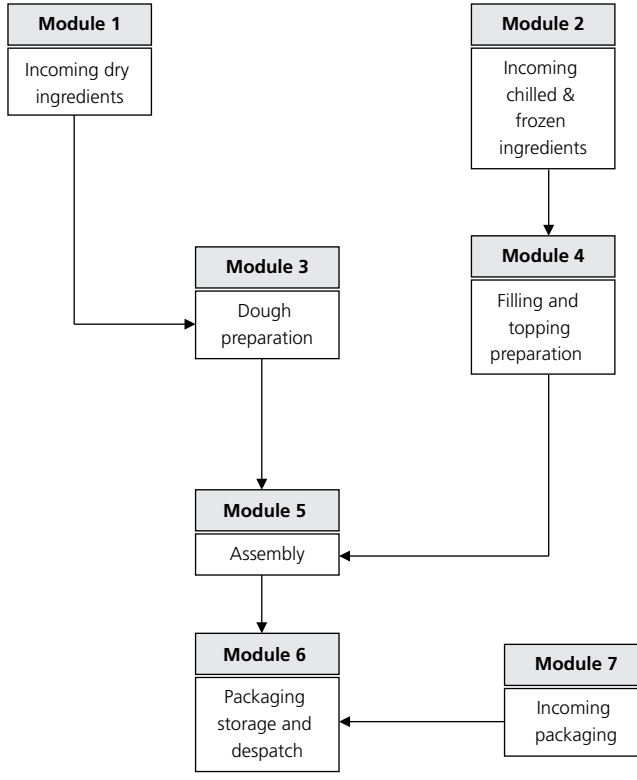


Figure 2.9 Modular HACCP plan example – Pizza and dough products modules.

go through a combination of different processing steps and be made up of some similar and some different raw materials.

The HACCP principles are applied separately to each basic process (or module), and these modules are finally combined to make up the complete HACCP system, as shown in Figure 2.9. In this example, the business will have seven separate HACCP plans, i.e. one for each module. Care should be taken to define the specific start and end points of each module to ensure that no hazards are missed out. The case study (Appendix A) provides a further detailed example of a modular HACCP plan.

Generic HACCP plans

This approach is used where similar operations are carried out at different locations in the manufacture or handling of similar products.

For example:
Primary meat processing carried out at several processing sites using the same basic methods.
A fast food restaurant chain using the same ingredients, equipment and process steps.

Generic HACCP plans can be either linear or modular and can make a helpful starting point. An effective HACCP system can be built around them by tailoring the generic HACCP plan to the operating requirements of each specific site, but there are limitations, because no two operations are exactly the same, and there is a danger that hazards may be overlooked if an 'off-the-shelf' HACCP plan is used without modification.

Increasingly, generic HACCP plans and guidance are being developed for sectors of the industry which do not have the ability to develop their own. Trade associations, governments and universities around the world have posted many good examples. For example, generic HACCP guidance materials are available through the UK Food Standards Agency website for the dairy and meat industries, as well as small caterers and retailers, and in the United States, the Seafood HACCP Alliance is very well established having first convened in 1994 and continues to provide training and guidance to that sector of the industry.

These generic plans and guidance materials are arguably better than not having anything at all and could work well if:

1. mature prerequisite hygiene programmes are in place appropriate to the industry.
2. they are adapted to fit the local needs – perhaps with the help of the regulatory enforcement authorities, though this activity is not normally regarded as being part of their role (WHO 1998).

Once the team has agreed the structure of the HACCP system, the HACCP team leader can more precisely estimate the resources and time required to complete the task. This will help ensure that the programme stays on track and that problems are discussed as they are identified. A Gantt chart (see Figure 2.10) is a useful aid to planning the whole process and ensuring that all implementation of each stage is kept under control.

The team should, now, also be able to provide the rest of the organisation with a picture of what the final system will look like. This will include an

TASK	MARCH w/c				APRIL w/c				MAY w/c					JUNE w/c			
	6	13	20	27	3	10	17	24	1	8	15	22	29	5	12	19	26
Identify and train HACCP Team																	
Baseline audit and gap analysis(PRPS and hazard management)																	
Preparation																	
Process flow diagrams																	
Hazard analysis																	
Identify CCPs																	
Complete control charts																	
Training of operatives																	
Set up monitoring systems																	
Train monitoring personnel																	
Set up facilities and equipment																	
Confirm closure of PRP gaps and audit to verify implementation																	
HACCP Plan re-validation																	

Figure 2.10 Example of a Gantt chart for HACCP system development.

indication of the documentation format, how it will link with other prerequisite systems such as sanitation programmes or the QMS, and an indication of the people who will be involved as the project gets underway.

When the project plan has been completed and authorised, the HACCP team can move on to key stage 2 with the knowledge that the required foundations for an effective HACCP system have been identified and will be built into the overall food safety system.

SECTION 3
HACCP in practice

This section is broken down into a number of parts:

3.1 Preparation for the HACCP plan development
3.2 Applying the principles (the HACCP study)
3.3 Implementation of the HACCP plan
3.4 Maintenance of the HACCP system

Throughout this section, we will be using a case study to illustrate how a fictional medium-sized manufacturing company might set about developing a hazard analysis critical control point (HACCP) system. In the Appendix A, a fully detailed HACCP plan is provided for the same fictional company; whereas within the text, only partial details will be given as an illustration of the points being made. This fictional company is a manufacturer of a range of chilled and frozen cheesecake products.

We will be concentrating on the practical application of the seven HACCP principles as defined by Codex (2009b).

As a reminder:

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.

HACCP: A Food Industry Briefing, Second Edition. Sara E. Mortimore and Carol A. Wallace.

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.

3.1 Preparation for the HACCP plan development

KEY POINTS

- The product description is a useful point of reference for the hazard analysis critical control point (HACCP) team as well as for future audits of the plan.
- Formulation intrinsic factors and process technologies are essential elements of product safety and must be understood.
- The process flow diagram is the basis for hazard analysis, and it must contain sufficient technical detail for an effective study.
- The process flow diagram must be validated to ensure that is accurate and representative of the process at all times.

In Section 2, we learned a little bit about the HACCP principles and also what types of preparatory and planning activities should be conducted in a business as it moves towards the use of HACCP. Here, we start by seeing how a trained HACCP team will begin to develop their HACCP plan, i.e. how the HACCP study is carried out. The steps detailed in Figure 3.1 indicate that at this stage the first five HACCP principles are being used. Principle 6 includes validation, which is done at the end of the study.

As these steps are followed systematically, questions are asked and the answers are recorded on documents that are compiled to produce the HACCP plan. The HACCP plan is the main reference document within the HACCP system, and it consists of several essential elements that are developed at this time, the process flow diagram and the HACCP control chart. It is usually kept together with other developmental documentation such as hazard analysis charts, CCP decision records, product description information and HACCP team details. There are no hard and fast rules dictating how the management and organisational aspects of the HACCP study must be done. Here, we provide an example of a best practice approach.

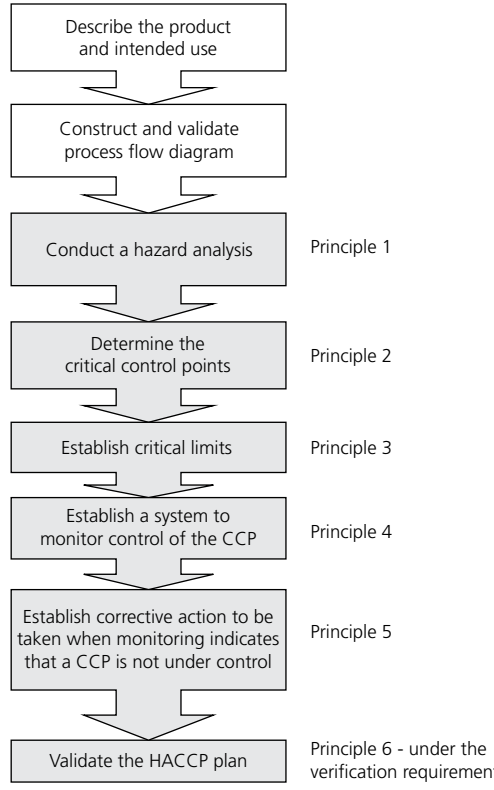


Figure 3.1 Key stage 2: The HACCP study. Source: Adapted from Mortimore and Wallace (2013).

3.1.1 Terms of reference

At the start of a HACCP study, the team will confirm the following:

The scope of the hazard analysis, i.e. will all three hazard groups (biological, chemical and physical) be considered at the same time?

Some HACCP teams prefer to carry out a study on just one hazard group at a time. This can be simpler for inexperienced teams, but it does mean that they usually have to go back and do it all over again for the other two groups once they have finished the first one. It can be useful if expertise has to be bought in from outside the company, for example use of a consultant microbiologist for biological hazard identification.

The status of the prerequisite programmes

Whilst a prerequisite programme (PRP) gap analysis will usually be well underway or completed by the time that the HACCP team is ready to start the study, the team needs to understand what programmes are operating well and what work has to be done in this area. It is essential to connect the management of food safety hazards with both the HACCP programme (through the CCPs) and control through the preventative PRPs. HACCP skills, particularly the ability to identify and analyse hazards can be applied to very good effect when deciding what PRP improvements are going to be needed. This is often the most costly aspect of upgrading a company's food safety programme; therefore, it is important to be able to support the investment decisions with a science-based risk evaluation. Where capital investment and building work is required, this can take some time; therefore, it is also important to determine how the gaps in the programme will be managed in the short term, i.e. whilst the improvements are being carried out.

The structure of the HACCP system

The team members need to have a clear understanding of the structure of the HACCP system, i.e. whether the HACCP study approach will be linear or modular, and whether one product or a range of products be considered. This should have already been determined in the planning stage.

The start and end points of the study

Linear HACCP studies generally start with raw materials and end with the finished product. However, modular HACCP plans need to be added together to cover the entire operation. It is important to clearly identify the start and end points of each individual HACCP study to ensure that every step is included.

CASE STUDY: CHILLED AND FROZEN CHEESECAKE HACCP STUDY

- All three types of hazards are being considered.
- PRPs are in place throughout the factory.
- The HACCP study approach is modular (eight modules), and it covers a range of five different cheesecake products.

Once these terms of reference have been decided and discussed, the actual HACCP study begins. Referring to Figure 3.1, the first step in the process is concerned with making sure that the HACCP team truly understands the products being studied. This is foundational in being able to identify likely hazards, i.e. what types of biological, chemical or physical hazards might be found in the product, where might they come from and would they survive and grow in the product.

3.1.2 Describe the product and intended use

This is normally done by looking at all the information available, including the product specification. Often findings are recorded, resulting in a brief document of about two pages. The purpose is to ensure that all HACCP team members have a good understanding of the product and process to be studied. The product description stage covers a review of the potential use of the products, the raw materials and technologies used, the main types of hazards to be considered and in general the control measures needed. This document is a vital point of reference not only for the HACCP team but also for subsequent auditors of the HACCP plan.

When designing food safety into a product, two main areas are considered: (i) the product formulation and (ii) the process technologies involved. These criteria are normally reviewed by the HACCP team at this stage.

Product formulation

To understand how the raw materials and product formulation affect safety, the intrinsic factors of the product need to be understood. Food safety intrinsic factors are the compositional elements of the product, which can affect microbial growth and, therefore, product safety. The main intrinsic factors to be considered in foodstuffs are pH and acidity, preservatives, water activity (a_w) and the ingredients.

pH and acidity

- Acidity is one of the most important factors in food preservation in that it will prevent the growth of food-poisoning and food-spoilage organisms. It has been used traditionally in products such as yoghurt and pickled vegetables.
- Acidity itself may be a factor in determining the organoleptic properties of a product, but pH measurement is the most important factor in assessing

food safety because the growth and survival of micro-organisms is usually based on the pH scale.

- The optimum pH for the growth of most micro-organisms is around neutrality (pH 7), but many also grow in the range of pH 4–8.
- A small number of bacteria may grow at pH <4 or pH >8. Those growing at pH <4 are not normally associated with food poisoning; but as their growth may raise the pH to a level where pathogens could grow, such implications must be considered in the course of the HACCP study.
- Yeasts and moulds will grow at pH <4.
- Certain micro-organisms may survive at pH values outside their growth range.

  For example:
  Bacterial spores present in a low-pH raw material are unable to grow; but if they are mixed with other raw materials to make product of higher pH, they may germinate and grow to levels that would render the product unsafe.

Preservatives

- Chemical preservatives can be added to foodstuffs to control microbial growth, subject to legal limits, and these are widely used in many products.

  For example:
  Nitrites in cured meat products, sorbates in bread and cakes and meta-bisulfites in drink products.

- The traditional method of the smoking of food to preserve it also acts as a preservative by inhibiting microbial growth. This is due to the chemical compounds present in the smoke.

Water activity

Water activity (a_w) is a measure of the water available in a food for microbial growth and chemical reaction. As micro-organisms require water to grow, it is possible to inhibit growth by making water unavailable to them. This can be achieved by

- adding solutes such as sugar and salt to a food. Sugar inhibits growth by the reduction of water activity and osmotic pressure, as in the production of jam, whereas salt reduces water activity and interferes with the bio-chemical processes in microbial cells, as in dry cured meat products.

- dehydration, or the removal of water by drying foods, as in the conversion of milk to milk powder.

It is important to remember that whilst removal of water can inhibit growth of micro-organisms, it does not necessarily inhibit presence; and therefore, they may be able to grow again once favourable moisture conditions are available.

Ingredients

The intrinsic properties of ingredients should be assessed individually and after interaction with each other.

- The ingredients should be examined closely, and any hazards associated with them considered in their own right as well as after the ingredients are mixed.

  For example:
  Preservatives and acid present in a syrup used to flavour a milk shake will stop microbial growth in the syrup itself but will have little or no effect after dilution in the mixed drink.

- Allergenic ingredients such as nuts need to be controlled through careful handling and segregated storage and processing to eliminate cross-contamination to other materials.
- Adulteration of ingredients for economic reasons is difficult to predict. However, when high-priced ingredients are scarce, this should act as a trigger for more in-depth review of sources.

CASE STUDY: CHILLED AND FROZEN CHEESECAKE HACCP STUDY (SEE APPENDIX A FOR FULL CASE STUDY)

The cheesecake in this study has a pH of 4.6–4.8 in the cheese layer and a water activity of >0.90. Individually, these will have limited or no effect on the growth of pathogenic micro-organisms; however, the final product will be either chilled or frozen and this, in combination with the pH and a_w for the chilled product, will prevent growth.

- A wide range of raw materials are used – some of which may contain pathogens and are added after thermal processing, e.g. chocolate flakes.
- The presence of allergens, e.g. through the use of nuts as well as a range of other allergenic ingredients, needs to be addressed.

Process technologies

The technologies used in the manufacture of a food product have different effects on its safety; it is therefore essential that each one of them is examined closely in the HACCP study. Some examples of process technologies and their effects on potential hazards are as follows:

Thermal processes such as heating and cooling can lead to hazards if not properly controlled. For example, spore-forming pathogens such as *Bacillus cereus* in rice or pasta may survive a sub-sterilisation heat process that is not designed to destroy them. As long as the product is held hot or chilled rapidly, the spores will be unable to germinate and grow to toxin-forming levels. However, if left at room temperature after the heat process, then microbial growth and toxin formation could result. Similarly, failure to achieve the correct combination of time and temperature in a pasteurisation process designed to kill vegetative pathogens such as *Salmonella* spp. or *Listeria monocytogenes* could result in their survival and potential proliferation in the product, depending on other formulation hurdles present.

In *freezing processes,* the holding stages before freezing and length of time to freeze may be significant in allowing time for an increase in the microbial population. Cross-contamination risks are also important if the food is to be consumed without any further processing or cooking.

In *fermentation processes,* the culture system needs to be controlled and identified accurately to avoid growth of undesirable micro-organisms.

Where *irradiation* is used, mishandling of the food before the irradiation process may result in toxins that would not be eliminated by the irradiation process.

The *packaging system* used must also be considered as it may have an effect on product safety. This is particularly important in the case of aseptic packaging and canned products.

For example:
Thermally processed low-acid canned foods will only be safe if the can seams are secure. Packaging integrity is also essential in vacuum packaging and modified atmosphere packaging systems.

CASE STUDY: CHILLED AND FROZEN CHEESECAKE HACCP STUDY

- The product is baked and then chilled or frozen so that the likelihood of surviving spores growing during storage is reduced.
- There is no subsequent processing by the consumer and the shelf life is limited after thawing. Therefore there is a potential for consumer abuse and microbiological hazards are a concern.

3.1.3 Construction and validation of a process flow diagram

The next step is the construction of the **process flow diagram**, which will be used as the basis of the hazard analysis. This is stepwise description of the entire process. It can be done as one diagram covering the entire process or as a series of smaller diagrams, where the modular approach is being used. It must contain sufficient technical details for the team members to be able to follow each step of the process from the delivery of the raw materials to the delivery of the end product.

The process flow diagram should include data such as the following:

- Details of all raw materials and packaging
- All process activities
- Storage conditions
- Temperature and time profiles
- Transfers within and between production areas
- Equipment/design features

It is generally useful to include as much detail as possible, although engineering drawings and symbols may cause confusion and are best avoided. It is also helpful if each step of the diagram is numbered as this can be used for cross-referencing at the hazard analysis stage.

In the modular approach, it is essential that the start and finish points of each module have been well defined so that no steps are missed out accidentally, and the process flow diagrams can be added together to show a picture of the whole operation. The benefits of using a modular approach include the following:

- The ability to include more detail within each modular diagram without the diagram appearing over-complicated.
- Operatives from each unit of operation feeling greater ownership.

CASE STUDY: CHILLED AND FROZEN CHEESECAKE HACCP STUDY

This HACCP system is a modular structure consisting of eight modules that cover the entire production process (see Figure CS.3).

The completed process flow diagram must then be checked for accuracy by following the process in action and comparing each step with the diagram. During this validation process, it is often found that steps have been missed out and also that on occasions production operatives use 'short cuts' that they consider acceptable but may form the basis for potential hazards. This is more likely in a highly manual operation than an automated process. Varying practices may be carried out by different operatives doing the same job; it is therefore necessary to check for accuracy on several shifts. It is rare that a completed process flow diagram will not require modification following on-site confirmation; therefore, the importance of doing this *prior* to the hazard analysis stage cannot be stressed enough.

3.2 Applying the principles

Here we give a consideration to how each of the seven principles of HACCP may be applied and consider the key points for each.

3.2.1 Principle 1: Conduct a hazard analysis – What can go wrong?

KEY POINTS

- Hazard analysis of the process is where the team members systematically analyse each raw material and step of the process and identify and analyse all potential hazards and their control mechanisms (measures).
- Hazards are biological, chemical and physical in nature.
- Hazard analysis must be based on sound science.
- Assessment of the likelihood of occurrence and severity of outcome are essential parts of hazard analysis, and it should use all sources of information available.
- Hazards are considered to be significant if they are likely to cause harm to the consumer.
- Significant food safety hazards are managed through a HACCP system. Non-significant hazards are managed through preventative control points and prerequisite hygiene programmes.
- Control measures are specific for each hazard and can be either process steps or activities.

Hazard analysis is the part of the HACCP study where the team looks at each step of the process, identifies the hazards likely to be present, evaluates their significance and ensures that adequate measures for their control are in place.

HACCP was conceived as a means to control food safety hazards. Codex (2009b) refers to the identification of hazards that are 'of such a nature that their elimination or reduction to safe levels is essential to the production of safe food' and considers the definition of a **hazard** to be thus:

A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect. (Codex 2009b)

In other words, a hazard is considered to be significant if it is likely to cause harm to the consumer unless it is properly controlled. All significant hazards are managed through HACCP, whereas non-significant hazards are controlled by other systems.

For example:
Unpasteurised milk may carry pathogenic micro-organisms that are significant safety hazards whereas an apple pip in a pie, undesirable as it may be, will not cause injury or illness.

It is essential that HACCP team members are able to understand what constitutes a significant hazard. This involves considering each potential hazard in turn and attempting to answer the following questions:

- Could this hazard occur in the raw materials, process or finished product?
- Would it cause severe harm to the consumer, i.e. through serious injury or illness?

To answer these questions, it is important that the appropriate, experienced personnel are consulted, otherwise, the resulting HACCP system could be unsound.

Hazards may be biological, chemical or physical contaminants. They may originate from the raw materials, the packaging, the process and handling in the food chain or the environment.

Biological hazards

These occur in the form of pathogenic micro-organisms, and they present the biggest danger to consumers in many product groups. Pathogenic micro-organisms exert their effect either directly through growing in or contaminating food products and being ingested (foodborne infection), or indirectly by forming toxins (food poisoning). In both the cases, the illnesses may be serious, even fatal.

Pathogenic bacteria are extremely diverse in their nature, and they grow in various environments.

For example:

- *Bacillus cereus* forms heat-resistant spores that can only be eliminated by severe heat treatment.
- *Listeria monocytogenes* can grow slowly at chill temperatures. However, it is easily destroyed by cooking.
- *Clostridium botulinum* requires the absence of oxygen to grow, e.g. canned foods, and produces a deadly toxin.
- *Staphylococcus aureus* and *B. cereus* can form toxins in food under the right conditions.
- *Salmonella* can infect in low doses, particularly in high-fat products but is easily destroyed by cooking.

Other pathogenic micro-organisms include viruses (e.g. Norovirus), toxigenic fungi (e.g. *Aspergillus*), and protozoan parasites (e.g. *Cryptosporidium parvum*).

Table 3.1 shows the profile of some of the more widespread pathogenic micro-organisms, how they can find their way into food and their optimum growth conditions. Using information such as this and additional more detailed data are essential to HACCP teams as they compare the information gathered during the product description stage with the growth conditions needed by these pathogenic micro-organisms. The ability to interpret such microbiological data is important for products that are sensitive to microbial contamination and growth; consideration should therefore be given to the inclusion of an experienced microbiologist in the HACCP team.

In summary, micro-organisms have basic needs related to the following:

- Optimum growth temperature
- Moisture
- Optimum acidity
- Food source

Table 3.1 Pathogen profiles

Organism	Sources	Associated foods	Optimum growth characteristics
Bacillus cereus	Soil, cereal crops, dust, vegetation, animal hair, fresh water and sediments	Spices Cereal ingredients Rice	Aerobic 30–40 °C pH 6.0–7.0 a_w 0.995
Campylobacter jejuni	The intestinal tract of animals	Poultry, meat, untreated water and inadequately pasteurised milk	Microaerophilic 42–43 °C pH 6.5–7.5 a_w 0.997
Clostridium botulinum	Spores found in soil, shores, intestinal tract of fish and animals, deposits of lakes and coastal water	Can appear in all foods	Obligate anaerobic 25–30 °C pH 7.0 a_w 0.99–0.995
Clostridium perfringens	Soil, dust, vegetation and the intestinal tract of humans and animals	Raw, dehydrated and cooked food	Aerobic 43–47 °C pH 7.2 a_w 0.995
Listeria monocytogenes	Soil, silage, sewage and faeces of healthy humans and animals	All food processing environments	Aerobic 37 °C pH 7.0 a_w 0.998
E. coli O157:H7	The small intestine	Undercooked ground beef, raw milk, raw produce and infected fruit juice	Aerobic 35–40 °C pH 6.0–7.0 a_w 0.995
Salmonella spp.	The intestinal tract of humans and animals; sewage	Pork, poultry, eggs, raw milk, shellfish, low-moisture foods, e.g. nut products and infant formula	Aerobic 35–43 °C pH 7.0–7.5 a_w 0.99
Shigella spp.	Hands soiled with faeces; flies	Water, milk, salads, processed potato, cooked rice and hamburgers	Aerobic 35–43 °C pH 5.5–7.5

(*Continued*)

Table 3.1 (*Continued*)

Organism	Sources	Associated foods	Optimum growth characteristics
Staphylococcus aureus	Mucus membrane and skin of warm-blooded animals and humans	All cooked foods	Aerobic 37 °C pH 6.0–7.0 a_w 0.98
Vibrio parahaemolyticus	Inshore warm coastal waters	Shell fish and fish	Aerobic 37 °C pH 7.8–8.6 a_w 0.981
Aspergillus (aflatoxins)	The environment	Nuts and oilseeds	33 °C pH 5.0–8.0 a_w 0.98–>0.99
Viruses (e.g. Norwalk, enterovirus and hepatitis A)	Infected food handlers, sewage and contaminated water	Bivalve molluscs. Passive transfer to any ready-to-eat foods	Viruses do not grow in foods

Source: Adapted from Mortimore and Wallace (2013).

With time to grow in the right conditions, they will be a problem. Preventative control measures must therefore be based on elimination of these basic needs.

Chemical hazards

Chemical contamination of foodstuffs can occur via the ingredients, during the production process, or during storage and distribution, and their effect on the consumer can be long term (e.g. carcinogenic), short term (e.g. allergic reactions) or teratogenic (e.g. BSE in animals). Chemical hazards seem to be continually emerging as our ability to detect at lower levels increases. What is often difficult for a HACCP team is to decide whether chemical adulterants are true food safety hazards. Governments will often provide advice and frequently carry out surveillance and report on the known likely concerns. The problem is that different countries' governments do not always agree on what levels are acceptable. Economic adulteration (food fraud) is often associated with chemical hazards. Past issues

include dioxins and melamine – neither of which could have been predicted. But short supply of high-value raw materials is a good indicator of the possibility of economic adulteration. HACCP teams need to stay up to date in terms of chemical issues as it is a very difficult area.

Some examples of known chemical contamination:
In raw materials: pesticides/herbicides, toxins (natural or microbial), allergens, (frequently responsible for product recalls by being an unknown component of an ingredient, and therefore not listed on the label) antibiotics, hormone residues and heavy metals.
During process: often the mode of failure is cross-contamination with cleaning agents, lubricants, refrigerants, pest control chemicals, toxins and allergens. The HACCP team needs to review any toxic chemicals on the premises.
From packaging: plasticisers and additives, ink, adhesive, metal leaching from cans.

Physical hazards

These are the foreign materials that can contaminate a foodstuff at any time during production. Strictly speaking, they are only significant safety hazards if they are likely to cause injury or a health risk to the consumer; otherwise, they should be considered in terms of quality, wholesomeness or legality and managed through hygiene and quality PRPs. A HACCP study can identify all potential foreign matter, and it can be extended to include quality and legality issues, but the controls should be clearly separated from those that are critical to food safety.

Foreign material items are considered as food safety hazards if they fall under the following categories:

- Items that are sharp and can cause pain and injury, e.g. wood splinters and glass fragments.
- Items that can cause severe dental damage, e.g. metal and stones.
- Items capable of causing choking, e.g. bones, plastic or anything that by virtue of its size and shape could get stuck in an airway.

Another reason for managing foreign matter contamination is that it can act as a vehicle for microbiological cross-contamination. An example of this is

a fly in a fresh cream cake where the transfer of pathogenic micro-organisms from the fly to the cake would present the hazard, not the fly itself.

Some of the useful sources of information when carrying out a hazard analysis in all three groups are:

- Published information in books, scientific journals and on the Internet
- Consultants/specialists
- Research organisations
- Suppliers/customers
- Government and other reputable websites

All information must be researched and evaluated thoroughly before any conclusions are drawn.

The hazard analysis is carried out by following the process flow diagram and discussing the hazards that may potentially occur at each raw material and process step. This is often done by a brainstorming approach and capturing output on a flip chart. The source or cause of each hazard should also be documented as this provides the team with a better understanding of how to control the hazard.

Risk assessment is an important part of hazard characterisation that helps determine the significant hazard. In terms of HACCP, a **risk** is defined by Codex (1998a) as: 'A function of the probability of an adverse health effect and the severity of that effect consequential to a hazard(s) in food' – in other words as the probability or likelihood that a severe health effect will be realised. It is important at this stage that the HACCP team has complete knowledge of their raw materials and processes when deciding whether a hazard will realistically occur but also that they are aware of their own limitations when making judgements.

The topic of risk, its analysis and assessment is still being discussed widely within governments and academia (see Epilogue). For the purpose of HACCP at business level, HACCP teams will be making a qualitative evaluation during the hazard analysis process, i.e. is the hazard significant enough to require management through the HACCP plan, or can it be managed through PRPs and/or through the quality system? Formal risk assessment is a quantitative, global process where a numerical degree of risk can be calculated for a particular hazard (Sperber 2000). It is undertaken at government level usually with involvement of academia and industry.

Qualitative hazard analysis is the responsibility of the individual HACCP team and should include the following:

- The likely occurrence of hazards and the severity of their adverse health effects.
- Qualitative and/or quantitative (if data are available) evaluation of the presence of hazards.
- Survival or growth of pathogenic micro-organisms.
- Presence of toxins, chemical or physical agents.
- Conditions that may lead to the above.

When all the significant hazards have been determined, the HACCP team must consider what required **control measures** must be in place for each identified hazard. These may already be in operation at the particular step examined or occur later in the process, but they need to be re-evaluated to ensure that they are adequate. Additional control measures may also be required, and these will have to be planned and developed.

Experienced HACCP teams may decide to review the control measure options as each hazard is identified. This can lead to long discussions that divert the focus away from the objective of hazard identification and introduce the possibility of missing out potential hazards. It can be simpler to identify all the significant hazards before starting to consider control measures.

The sources of biological hazards are extremely diverse, and they have to be controlled through various control measures. These may be at any specific point of the food supply chain, and it is important that each control measure is applied at the correct point to ensure that it is effective. Table 3.2 shows some examples of biological hazards and how they can be controlled.

In addition to those measures shown, formulation controls as described earlier can be used to prevent growth. Many chemical hazards are controlled through PRPs such as supplier ingredient control and good manufacturing practices, but it is often found that where nut-containing products are manufactured on a non-dedicated line, the risk of allergen cross-contamination needs to be managed through a HACCP system. Table 3.3 shows some examples of chemical hazards and how they can be controlled.

Physical hazards are mainly foreign material items that can be controlled by PRPs (see Table 3.4).

Table 3.2 Examples of control measures for biological hazards

Biological hazard	Control measures
Vegetative pathogens (e.g. *Salmonella*, *Listeria monocytogenes* and *E. coli*	**Raw materials:** **Lethal heat treatment during process** • Specification and surveillance (SQA) • Effective supplier process • Certificate of analysis • Temperature control **Cross-contamination:** • Intact packaging • Pest control • Secure building (no roof leaks; ground water) • Logical process flow (segregation of people, clothes, equipment, etc.; direction of drains) **Formulation Control:** • pH, a_w, chemical preservatives
Spore formers (e.g. *Clostridium botulinum* and *B. cereus*	**Raw materials:** • Specification and surveillance (SQA) • Effective supplier process • Certificate of analysis **Lethal heat treatment during process** **Temperature control – prevention of spore outgrowth, e.g. after heat treatment** **Cross-contamination:** • Intact packaging • Pest control • Secure building (no roof leaks; ground water) • Logical process flow (segregation of people, clothes, equipment, etc.; direction of drains) **Formulation Control:** • pH, a_w, chemical preservatives
Heat-stable pre-formed toxins (e.g. *Staphylococcus aureus, B. cereus* and emetic toxin)	**Raw materials:** • Specification for organism and/or toxin and surveillance (SQA) • Effective supplier process • Certificate of analysis **People:** • Handwash procedures • Covering cuts/wounds, etc. • Occupational health procedures • Management control of food handlers **Build-up during process:** • Control of time that ingredients, intermediate and finished products are held within the organism's growth temperature range • Design of process equipment to minimise dead spaces • 'Clean as you go' procedures • Control of rework loops • Validation studies on maximum length of production run without cleaning **Formulation Control:** • pH, a_w, chemical preservatives

Table 3.2 (*Continued*)

Biological hazard	Control measures
Mycotoxins (e.g. patulin, aflatoxin and vomitoxin)	• SQA control of harvesting and storage to prevent mould growth and mycotoxin formation • Heat treatment during process to destroy mould • Controlled dry storage

Source: Adapted from Mortimore and Wallace (2013).

Table 3.3 Examples of control measures for chemical hazards

Hazard	Control measures
Cleaning chemicals	• Use of non-toxic, food-compatible cleaning compounds • Safe operating practices and written cleaning instructions • Separate storage for cleaning reagents • Designated, covered containers for all chemicals
Pesticides, veterinary residues and plasticisers in packaging	• Specification to include suppliers' compliance with maximum legal levels • Verification of suppliers' records • Annual surveillance programme of selected raw materials
Toxic metals/ polychlorinated biphenyls	• Specifications and surveillance where appropriate
Chemical additives (e.g. nitrates and nitrites)	As contaminants: • Specifications and surveillance where appropriate (quality assurance or SQA) As additives: • Safe operating practices and written additive instructions • Special storage in covered, designated labelled containers • Validation of levels through usage rates, sampling and testing
Allergens/food intolerance	• Awareness of the potential allergenic properties of certain ingredients and training of the workforce. Special consideration given to adequate labelling, production scheduling and cleaning, segregation or cross-contamination controls, dedicated equipment, and to the control of rework • Final rinse water testing should be considered as a verification method where possible
Economic adulteration	• Vigilance and surveillance of issues and indicators such as shortages of high-value foodstuffs; melamine in pet foods and infant formula, and Sudan Red in spices are examples of this and hard to have predicted.

Source: Mortimore and Wallace (2013).

Table 3.4 Examples of control measures for physical hazards

Hazard	Control measures
Intrinsic physical contamination of raw materials (e.g. bone in meat/fish, fruit stones, stalks, pips and nutshells)	**Liquids:** • Filtering, magnets and centrifugal separation **Powders:** • Sifting, magnets and metal detection
Extrinsic physical contamination of raw materials (e.g. glass, wood, metal, plastic and pests)	**Flowing particles** (e.g. nuts, dried fruit, IQF fruit and vegetables): • 100% inspection – electronic or human • Screening, sifting, magnets and metal detection • Washing, stone and sand traps • Air separation, flotation and electronic colour sorting **Large solid items** (e.g. carcasses, fish, cabbages, cauliflowers, frozen pastry and packaging): • X-ray detection and metal detection • De-boners and vision sorters
Physical process cross-contaminants (e.g. glass, wood, metal, plastic and pests)	• Elimination of all glass except lighting that must be covered – light breakage procedure • Glass-packed products – glass breakage procedures and inversion/washing/blowing of glass packaging before use • Exclusion of all wooden materials such as pallets, brushes, pencils and tools from exposed product areas • Segregation of all packaging materials • Equipment design – preventative maintenance • Avoidance of all loose metal items – jewellery, drawing pins, nuts and bolts, and small tools • Metal detection – sensitivity appropriate for the product, calibrated (3-monthly intervals) and checked (hourly); ferrous, non-ferrous and stainless steel; fail/safe divert systems; locked reject cases; and traceability • Avoidance of all loose plastic items – pen tops, buttons on overalls and jewellery • Breakage procedure in place where brittle plastic is used • Pest control programme: ◦ Prevention (facility design, avoidance of harbourage areas, waste management and ultrasonic repellents) ◦ Screening/proofing (strip curtains, drain covers, mesh on windows, air curtains and netting) ◦ Extermination (electric fly killers, poisoning, bait boxes, traps, perimeter spraying and fogging)
Building fabric	**Sanitary design and maintenance** • Regular inspection and repair

Source: Adapted from Mortimore and Wallace (2013).

More than one control measure may be needed to control an identified hazard. Also, more than one hazard at a process step may be controlled by a single control measure. Control measure should not be confused with monitoring – the control measure actually controls the hazard by preventing, eliminating or reducing it to an acceptable level, whereas the monitoring activities simply provide an indication that control is being achieved.

CASE STUDY: CHILLED AND FROZEN CHEESECAKE HACCP STUDY

Several biological, physical and chemical hazards are identified in the raw materials and process steps requiring a wide variety of control measures.

For example:
Several raw materials (e.g. nut ingredients) are considered to have associated allergen-contamination hazards that are controlled through effective supplier management. In addition, allergen cross-contamination issues will need to be considered during the process. The allergen issue is two-fold:

1. Consumers may be allergic to specific nuts, e.g. hazelnuts and may wish to avoid eating any products containing them. Effective labelling of hazelnut-containing products and prevention of cross-contamination to other products will be important here.
2. People who can safely consume certain nuts, e.g. hazelnuts, may be allergic to other nuts, e.g. peanuts or pecans, therefore cross-contamination both at the nut supplier (no peanuts are purchased) and on site through segregation and handling procedures must be considered.

At the baking step, survival of vegetative pathogens is considered to be a significant hazard, and this is controlled through ensuring that the correct heat process occurs. At the blast cooling step, germination and outgrowth of spores is considered a hazard, and this is controlled by effective management of the cooling process – time and temperature.

All the identified hazards and their control measures for each raw material and process step are usually recorded on a hazard analysis worksheet or chart. An example is given in Table 3.5. This particular worksheet includes space for CCP identification, which is discussed in the following.

Table 3.5 Example of a worksheet for hazard analysis and CCP identification

Process step	Hazard and Source	Control measures	Q1	Q1a	Q2	Q3	Q4	CCP	Justification

3.2.2 Principle 2: Determine the Critical Control Points (CCPs) – At what stage in the process is control essential?

KEY POINTS

- The identification of CCPs relies on sound science and expert judgement.
- To identify CCPs, all hazards associated with raw materials, process steps and their control measures can be assessed using the CCP decision tree as a tool.

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' (Codex 2009b). CCPs relate to control of significant food safety hazards only.

As discussed earlier, control points (CPs) relating to quality or legal issues are managed by other programmes. It is essential that this relationship (CCPs vs CPs) is clearly understood by the HACCP team members ensure that only safety points are determined as CCPs. Sometimes, there is a tendency to designate too many CCPs 'to be on the safe side'. This can actually undermine the system and increase risk through loss of credibility. For example, if a CCP fails yet the HACCP team decides that there is no food safety risk as it was not a 'real' CCP, then the operatives will see that some of the CCPs are real and important, but there are some which are not. The next time something happens there is the risk that operatives will be less likely to raise the issue or take action – how do they know which ones are important? On the other hand, too few CCPs may result in the production of unsafe food through the presence of uncontrolled hazards. There should be as many CCPs as are needed for food safety. The number of CCPs cannot be predetermined.

If there is any difficulty in telling the difference between CPs and CCPs, ask the simple question:

If control is lost, is it likely that a health hazard will occur?

If the answer is 'yes', then the point must be managed as a CCP. If the answer is 'no', i.e. food safety is not necessarily compromised, then the point may be managed as a CP.

Identification of CCPs can be carried out by using tools such as CCP decision trees, an example of which is given in Figure 3.2. The most widely used decision trees are those published by Codex (2009b) and NACMCF (1997) though variations exist (ILSI 2004, Mortimore and Wallace 2013). Raw materials can go through the Codex style decision tree, but the wording does not always lend itself to a raw material situation. Where companies are introducing new raw materials on a frequent basis and/or undertake a lot of new product development, it can be helpful to evaluate those hazards separately using a more specific raw material decision tree tool (e.g. ILSI 2004, Mortimore and Wallace 2013).

The essential skills required for CCP identification are thorough knowledge of the product (what is making it safe), the process, and the scientific background to the identified hazards and measures for their control. The information collated during the product description and hazard analysis stages is used by the team to determine the CCPs. Whilst decision trees are helpful tools in providing a structured approach, expert judgement must always be used and specialist advisers can be usefully drafted into the team at this stage if necessary.

Decision trees consist of a number of questions that are applied to each identified hazard listed in the hazard analysis chart as follows:

Q1. Do control measures exist?

This is answered by referring to the control measure data that were documented on the hazard analysis chart and also making sure that those control measures really are in place and operational within the business.

If the answer to Q1 is 'Yes', move to Q2. If the answer is 'No', move to Q1a.

Q1a. Is control at this step necessary for safety?

If the answer is 'No' (for example, a control measure may be in place further along in the process that will control the hazard) move to the next process step or hazard.

If 'Yes', a modification in the process (e.g., add a sieve or increase a process temperature) or product (e.g., reformulate to reduce the pH or add preservatives)

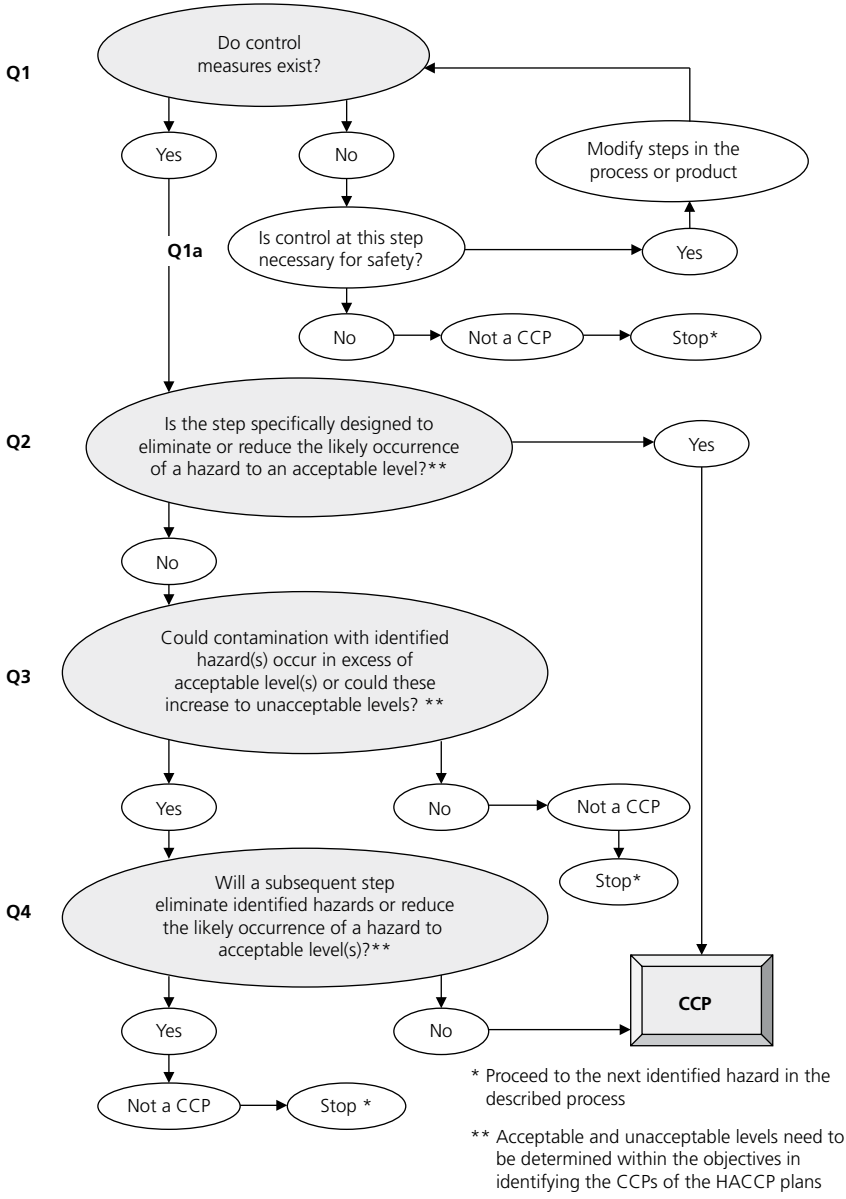


Figure 3.2 Example of decision tree for process steps. Source: Adapted from Codex (2009b).

must be implemented to ensure that control measures can be built in. When a suitable control measure has been identified, go back to Q1 (the answer will now be 'yes') and progress through the tree.

Q2. Is the step specifically designed to eliminate or reduce the likely occurrence of a hazard to an acceptable level?

This question aims at finding out whether the step under consideration is effective at controlling food safety. The thing to remember when asking this question is that it refers to the process step and not the control measure. If the control measure is considered at this stage, the answer will always be 'Yes' and, consequently, the step may be wrongly labelled a CCP.

For example:
Milk must be heat-treated at a specified temperature/time in order to eliminate all vegetative pathogens that may be present. This process step is designed to reduce the likely occurrence of a hazard to an acceptable level and is therefore a CCP.

If the answer to Q2 is 'Yes', the process step is a CCP. Start the decision tree again for the next process step or hazard. If the answer is 'No', move to Q3.

Q3. Could contamination with identified hazard(s) occur in excess of acceptable level(s), or could these increase to unacceptable levels?

To answer this question, the team should use the information recorded on the hazard analysis chart and their expert knowledge of the process and its environment. The issues to be considered here include the following:

- Time and temperature conditions
- The production environment (design, hygiene and maintenance)
- Cross-contamination from personnel, another product or raw material
- Acceptable levels for significant hazards

Expert advice should be sought when necessary.

If the answer to Q3 is 'Yes', proceed to Q4. If the answer is 'No', move to the next process step or hazard.

Q4. Will a subsequent step eliminate identified hazards or reduce the likely occurrence of a hazard to acceptable level(s)?

This question is designed to acknowledge the presence of any hazards that will be removed by subsequent steps later in the process or by the consumer.

If the answer to Q4 is 'Yes', move to the next process step or hazard. If the answer is 'No', the process step is confirmed as a CCP. Start the decision tree again for the next process step or hazard.

In addition to expert judgement, the identification of the CCPs in a process also requires some common sense. Panisello and Quantick (2000) suggest that it is unlikely that a CCP would be appropriate in the following circumstances:

Where a hazard cannot be controlled

Quite often cross-contamination issues would come into this category. By following all PRPs, environmental cross-contamination should be reduced, but it would be wrong to say that it could be guaranteed as eliminated. Where human operatives are involved, there is a heavy reliance on behaviour which is unpredictable.

Where there is no possibility of establishing a scientifically based critical limit

This is again where prerequisite hygiene issues such as 'cleanliness of equipment' is cited as being the control measure. It's difficult to set a true value on the cleanliness required for food safety control.

Where the step cannot be monitored

For example in a small retail or catering situation where they are unlikely to have metal detectors to control metal contamination.

CASE STUDY: CHILLED AND FROZEN CHEESECAKE HACCP STUDY

The steps identified as CCPs are outlined in Form CS.1. These include incoming **raw materials** (chocolate flakes, nuts and freshly prepared fruits) where the control measures involve supplier control and also, where appropriate, the baking process. Several process steps on site are also identified as CCPs in their own right, e.g. *baking* to control vegetative pathogens, *blast cooling* to control spore-forming pathogens, *scanning* packed product to control the risk of allergenic product in unlabelled packaging and *metal detection* for effective removal of any product containing metal.

The answers to all the questions in the decision tree together with any justifying comments made by the team are usefully recorded on a hazard analysis worksheet or chart. This is a good reminder of why particular process steps are or are not identified as CCPs, particularly when the system is being audited or updated at a later time.

Once identified, the CCPs should be documented on a HACCP control chart (also known as a HACCP worksheet). An example is given in Table 3.6.

Table 3.6 Example of a HACCP control chart (or worksheet)

Raw material/ process step	CCP no.	Hazard to be controlled	Control measure	Critical limits	Monitoring			Corrective action	
					Procedure	Frequency	Responsibility	Procedure	Responsibility

3.2.3 Principle 3: Establish critical limit(s) – What criteria must be met to ensure product safety?

KEY POINTS

- Critical limits are the criteria that differentiate between 'safe' and potentially 'unsafe'.
- Critical limits are defined by regulations, safety standards and scientifically proven values.
- They are measurable parameters that can be determined and monitored through testing and observation.
- Operational limits are often set at more stringent levels to provide a buffer or action zone for process management.

Once all the CCPs have been identified, the team has to decide the criteria that distinguish between 'safe' and potentially 'unsafe' for each CCP. These are represented by defined parameters called **critical limits**. When the product falls outside these limits, the CCP is out of control and a safety hazard may be present. Critical limits may be defined by regulations, company safety standards or scientifically proven values.

The Codex (2009b) definition of a critical limit is 'a criterion which separates acceptability from unacceptability'; in other words, 'critical limits are the safety limits that must be met for each control measure at a CCP'.

The HACCP team must fully understand the criteria that govern safety at each CCP and the factors that are associated with them in order to decide the appropriate critical limits. These factors are related to the type of hazard that the CCP is designed to control and must be measurable parameters that can be determined and monitored through testing or observation. Criteria often used include measurements of temperature, time, moisture level, pH, a_w, available chlorine and allergen labelling. Critical limits must be validated, i.e. the criteria specified must control the identified hazard.

In addition to the critical limits, it is usual to have operational limits that provide a buffer or action zone for process management. These are designed to allow for a certain amount of deviation in normal process operation while ensuring that food safety is not compromised.

For example:
If in a heat process, the critical limit is 72 °C for 2 min, the operating limit of 75 °C for 2 min may be set.

Once defined, the critical limits are recorded on the HACCP control chart.

CASE STUDY: CHILLED AND FROZEN CHEESECAKE HACCP STUDY

- The critical limits are validated through testing, e.g. at the baking step a validation study is done to confirm that the heat process of 140 °C for 55 min will achieve the required minimum product core temperature of 72 °C in all areas of the oven.
- In the raw materials that have been identified as CCPs, the critical limit is only purchasing from suppliers approved through an effective supplier quality assurance/vendor assurance (SQA/VA) programme. Some people consider that SQA/VA programmes are prerequisites and should not be identified as CCPs. However, it is useful to know which raw materials are critical in terms of the hazards they might introduce, and few companies have SQA/VA programmes that are so well developed that this focus on critical raw materials is unhelpful.

3.2.4 Principle 4: Establish a system to monitor control of the CCP – What checks will indicate that something is going wrong?

KEY POINTS

- Monitoring is the measurement or observation required to ensure that the process is under control and operating within the defined critical limits.
- Monitoring of the CCPs is carried out through tests or observations.
- The frequency and responsibility for monitoring will be appropriate to the control measure.
- All personnel responsible for monitoring must be trained and have a clear understanding of their role.

Monitoring is the measurement or observation that the process is operating within the critical limits (or more likely the operating limits) at the CCP. The Codex (2009b) definition of monitoring is 'the act of conducting a

planned sequence of observations or measurements of control parameters to assess whether a CCP is under control'. Therefore, the reason for monitoring the CCPs is to confirm that they are working and that safe food is being produced.

The procedures for monitoring the CCPs will depend on the nature of the control measure and also on the capabilities of the monitoring device or method used. Monitoring MUST be able to detect loss of control; otherwise, the system becomes invalid.

As stated earlier, monitoring should not be confused with control measures. Monitoring is the act of carrying out tests and observations to ensure that the process is under control, i.e. that control measures are working. It is a surveillance activity and provides the records that will be used later as part of the verification process.

Establishing monitoring procedures involves a number of elements:

Equipment and methods

Referring back to the earlier discussion on critical limits, we stated that criteria used may include, and therefore require, measurements of the following:

1. Physical parameters, such as temperature, time and moisture levels. Other types of physical measurements include checking the operation of metal detection, magnets, x-ray detection and inspecting sifters and sieves.
2. Chemical tests, such as chlorine analysis, pH, a_w. Other types of chemical tests might include pesticide residue analysis, allergen residue testing and heavy metals analysis.
3. Sensory tests, such as visual appearance and texture. Although such tests are often associated with quality criteria, visual appearance monitoring may be involved in foreign material CCPs and texture may be critical to effective heat penetration in, e.g. a canned product.

These lists are not exhaustive. Microbiological testing is not usually used for monitoring as the results are not immediately available. Real-time results are preferable as this allows timely corrective action to be taken.

The equipment used for monitoring must be

- accurate – it needs to be calibrated to ensure reliable results.
- Easy to use – it is not always practical to have to use a piece of complicated equipment, particularly if the monitoring is carried out by operatives in a production environment.
- Accessible – having the equipment close to the point of testing means that the test is likely to be quick in terms of providing results to the people who are involved in the process.

Monitoring procedures may involve the following:

- On-line systems where the critical factors are measured during the process continuously or at intervals.

  For example:
  A temperature chart recorder (thermograph) operating continuously.

- Off-line systems where samples are taken and measurements made later.

  For example:
  Samples of product taken for pH checks.

- Observational systems

  For example:
  Confirming that the metal detector will detect metal when test pieces are passed through it at defined intervals and that the automatic reject mechanism is synchronised to reject the product of concern.

Most monitoring systems are based on traditional forms of inspection and testing, which have limitations, i.e. offline and at intervals. They are however useful to demonstrate that control has been achieved provided that they have been designed properly. On-line sensors are being increasingly used to provide a higher level of confidence.

Frequency determination

The frequency of monitoring will depend on the nature of the CCP, and it must be determined as part of the control system.

For example:
Whilst a metal detector will be monitoring the presence of metal continuously, it will need to be checked as working at defined intervals (e.g. hourly).

Acidity monitoring may be done by measuring the pH of each batch of product produced.

People

The allocation of responsibility, as with setting the frequency of monitoring, also depends on the nature of the CCP. People assigned monitoring duties should be (NACMCF 1997):

- familiar with the process.
- trained in the monitoring techniques.
- trained in HACCP awareness, i.e. so that they appreciate their role and its importance in relation to the business's HACCP plans.
- unbiased in monitoring and reporting.
- trained in the corrective action procedures, i.e. what to do when monitoring indicates loss of control.

Record-keeping

This is worth mentioning here though it will be discussed again later under HACCP principle 7.

The results of monitoring activities should be recorded by the CCP monitors. Log sheets used to document all checks must contain the correct information to ensure that the CCP is under control, and they must be regularly reviewed and signed off by a trained supervisory-level authority. In some countries where HACCP is mandatory, the monitoring records are legal documents. CCP monitoring records can be kept as part of general production log sheets.

In any situation, it is the monitoring records that provide the evidence that the process was under control and that food has been made in accordance with the critical controls identified, i.e. those that ensure safe food.

Details of the monitoring procedure, frequency and responsibility are recorded in the HACCP control chart.

CASE STUDY: CHILLED AND FROZEN CHEESECAKE HACCP STUDY

- Monitoring of the raw material CCPs is performed through checks against the approved supplier list and certificates of analysis.
- The baking and blast cooling CCPs are monitored by visually checking the chart recorders; Cooling records (time to get down to a safe temperature) are checked at the blast cooling stage. Checks are signed off by the person performing the monitoring in both cases.
- The scanning and metal detection CCPs are monitored by checking that the equipment is functioning at regular intervals.

3.2.5 Principle 5: Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control – If something does go wrong what action needs to be taken?

KEY POINTS

- Corrective actions must be properly defined to ensure that the consumer is protected and that control is regained.
- Since HACCP is a preventative system, corrective actions should be such that further deviations are prevented.
- Following a deviation, there are two priorities: to deal with product produced during the deviation period and to bring the process under control.
- Responsibility for corrective action must be assigned by management.

When monitoring results show a deviation from the critical limits at a CCP, **corrective action** must be taken. Since HACCP is designed to prevent such deviations happening in the first place, corrective actions should be considered at two levels:

1. What needs to be done following a deviation at a CCP (i.e. *corrective action*)?
2. Modification of the process so that further deviations are prevented (i.e. *preventative action*)?

What needs to be done following a deviation at a CCP

When a deviation at a CCP occurs, quick action is essential. The aim is to:

- deal with the material produced during the deviation period.
- bring the process under control.

All material produced during the deviation period should be put securely on hold while the likelihood of the hazard being present in the non-complying product is considered. Where appropriate, the product may be tested and the test results assessed statistically in terms of product safety. After all considerations have been made, the product may be destroyed, re-worked, re-tested and released or put to alternative use, e.g. sold as a raw material that receives further processing sufficient to eliminate the hazards of concern or reduce it to an acceptable level.

Off-line responsibilities for this type of corrective action are usually handled by more senior personnel, and the HACCP team leader may also need to be involved.

Bringing the process under control may involve stopping the line and a temporary solution put into effect so that the line can be restarted while a permanent corrective action is sought.

For example:
The provision of a temporary off-line metal detector while the on-line detector is repaired.

Responsibility for this type of corrective action needs to be agreed with the production management who are implementing the HACCP plan. Responsibilities will often lie with the operator monitoring the CCP who will take immediate corrective action and/or will notify the supervisor for further action.

Modification of the process so as to prevent further deviations

This involves adjusting the process or product so that control is maintained. Typical examples of such changes are increasing specified cooking time or adjusting the pH through product reformulation. This would involve adjusting the operating limits to give a bigger buffer/action zone.

Responsibilities for this type of activity will always include the HACCP team as the HACCP plan will need to be re-assessed for any proposed changes updated where necessary.

All corrective actions do need to be thought through before being listed in the HACCP plan. It is not helpful if the HACCP team simply decides that the corrective action would be to ‘report to supervisor’ if the supervisor is unclear as to what to do next.

Details of the corrective action and responsibility are recorded in the HACCP control chart. At this stage, the HACCP control chart should be complete.

CASE STUDY: CHILLED AND FROZEN CHEESECAKE HACCP STUDY

- Corrective actions for the raw material CCPs include rejecting the batch.
- For scanning and metal detection, the corrective action involves identifying and rechecking product since the previous satisfactory check.
- For cooking, the line manager is informed and the main corrective action is to continue cooking or re-cook, depending on when the problem is identified for the batch.
- For blast cooling, the corrective action includes a risk-based decision by operations manager and the HACCP team leader depending on actual temperature found, and this may include disposal of product or further blast chilling as appropriate.
- Responsibility at each CCP lies with personnel of various levels; but in many cases, a management decision will need to be taken.

3.2.6 Principle 6: Establish procedures for verification to confirm that the HACCP system is working effectively – How can you make sure that the system is working in practice?

KEY POINTS

- Verification of the system is essential to ensure that all hazards can be controlled and that all controls are operating correctly.
- A HACCP plan is only valid after all the details have been checked to ensure that all control measures will control the identified hazards and that the HACCP plan is complete.
- The use of expert resource may be beneficial in ensuring the validity of the plan.
- Verification is carried out through auditing, product testing and reviewing records, procedures and practices where necessary.
- Production and monitoring equipment should also be checked for its ability to achieve what is required, i.e. that it is calibrated.

The Codex (2009b) definitions of validation and verification are as follows:

Validation is ‘obtaining evidence that the elements of the HACCP plan are effective’.

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

To appreciate the importance of this principle, it is worth considering the consequences in the event of getting it wrong. These will be grave, ranging from human suffering, to bad publicity and possible prosecution, and will most certainly prove expensive through compensation payments, brand damage and loss of business.

The application of principle 6 is achieved through a number of activities that broadly fall into the two categories of validation and verification.

Whilst validation is a one-off activity during the plan development, it does need to be repeated periodically and whenever there is any change in the product or process. Verification however is an ongoing activity once the HACCP plan has been implemented.

Validation

Once the study is complete, the team will need to carry out validation activities to confirm that all elements of the HACCP plan will be effective before moving into implementation. Slightly confusingly, validation appears as an activity within the verification requirement in the Codex Alimentarius guidelines, however, validation is really asking: 'Does this HACCP plan ensure that the relevant hazards have been identified and can be controlled?' It is an important task and should be done thoroughly for each CCP identified. Validation involves working back through all the HACCP principles with the aim of making sure that control criteria have been set correctly to ensure that all the significant hazards can be controlled. It is the confirmation that the control measure and critical limit will control the identified hazard, i.e. that the information in the HACCP plan will effectively manage food safety.

It may be appropriate to use expert resource from outside the organisation to cross-check the study and ensure that all relevant issues have been covered, particularly if the HACCP plan is compiled by a team of limited experience or if the study covers a type of product or technology that is new to the company.

CASE STUDY: CHILLED AND FROZEN CHEESECAKE HACCP STUDY

The critical limit for the elimination of *Salmonella* in the product is 72 °C. To ensure that, the *centre* of each unit reaches this temperature the product is cooked at 140 °C for 55 min.

Validation: Literature confirms that vegetative pathogens will be destroyed by cooking the product at the baking step to a 72 °C critical limit. Validation studies would confirm that cooking to 140 °C for 55 min ensures that the product centre temperature reaches 72 °C throughout the oven.

Statistical techniques can be used during validation to establish the capability of maintaining the process within specified limits. Too often, equipment capability is not known, and this means that its inherent variability could lead to product being produced that is out of specification (the critical or operating limits).

When the HACCP team is satisfied that the all the control measures will effectively control the identified hazards of concern, the HACCP plan can be implemented.

Verification

Verification is the confirmation that the control measure parameters have been met during the process, i.e. usually once the HACCP plan has been implemented.

For example:
Records confirm that the cheesecake was baked for 55 min at 140 °C.

Verification activities include auditing the HACCP system and the review and analysis of data such as CCP records to confirm compliance, microbiological and chemical product sampling and testing, review of customer complaint records and calibration of equipment. Verification is an ongoing activity.

Regular auditing

Auditing is a key verification activity and should include inspection of production records, deviations, actions taken and reviewing the practices and procedures used to control CCPs. Internal auditing will be done by

the business itself, and it is important that the audits are carried out by personnel who have not been involved in this particular HACCP study or in the day-to-day management of the HACCP plans so that they are independent, i.e. detached from the process and likely to be more objective in their approach. External auditing is also a verification activity and is likely to be carried out by customers, government inspectors or third parties, e.g. certification bodies, used either by customers or the business itself. Both ISO22000 and the GFSI benchmarked scheme audits use HACCP as the basis of the standards. Any of these audits will be a useful and independent verification component, particularly as the auditors for these certification standards tend to be well trained and have a lot of experience.

It can be said that regular auditing provides evidence that the HACCP plan continues to be effective. The benefits of a HACCP system audit are as follows:

- Continuing confidence in the effectiveness of the system and heightened awareness of food safety management.
- The opportunity to improve the system through the identification of the weaker areas.
- Providing documented evidence that food safety is managed.

Data analysis

As already indicated, the records generated by the HACCP system must be reviewed on a regular basis as part of the verification process. This confirms that the HACCP plan is properly implemented, trends can be analysed and corrective actions put into place. Given the requirement for prerequisite good hygiene practice, these records should also be reviewed where they exist.

The types of data that need regular reviews are varied, and they might include the following:

HACCP:

CCP log sheets
Test results
Process control charts
HACCP audit reports
Customer complaints

Prerequisites:

Pest control records
Glass register
Housekeeping or hygiene audit reports
Cleaning and sanitation-related records
Environmental microbiological monitoring data

The frequency of reviewing these records will depend on their nature and importance, and it may be daily, weekly, monthly, quarterly or annual. Analysis and reporting is best handled electronically wherever possible, and through the use of graphs and charts, it should indicate trends and provide a visual record. Statistical techniques can also be utilised to great advantage.

Table 3.7 summarises the likely activities when validating and verifying that each of the seven HACCP principles has been applied correctly. In confirming the effectiveness of the broader food safety management system, verification, including validation, should be carried out on the PRPs in addition to the HACCP activities.

3.2.7 Principle 7: Establish appropriate documentation concerning all procedures and records appropriate to those principles and their application – How can you demonstrate (if challenged) that the system works?

KEY POINTS

- Appropriate documentation and records are needed to demonstrate the effectiveness of the HACCP system.
- Records must be kept for a length of time as defined by legislation and the shelf life of the product.

The HACCP system must be documented and records maintained to demonstrate that it is both properly established and working correctly, i.e. principle 7 really applies across all of the other six principles. This will support 'due diligence' (as required by UK legislation) or any other litigation proceedings. In having legal status in many countries, it is important that the documents and records are of good standard, i.e. legible, with no crossing out or correcting fluid. All documents should be signed and dated. Records are essential in analysing trends that will be needed when reviewing and improving the system.

Table 3.7 Examples of validation and conformity verification

HACCP principle	Validation *Evidence to demonstrate the following:*	Verification *Evidence to demonstrate the following:*
1. Hazard analysis	The correct skills were in the HACCP team. The flow diagram is suitable for the purposes of the HACCP study, and all the significant hazards were identified.	Validation was carried out correctly. Product safety implications of process changes are being actively considered through hazard analysis.
2. Determination of the CCPs required to control identified hazards.	All significant hazards were considered during CCP identification. There are CCPs to control all significant hazards. The CCPs are at the appropriate stages in the process.	Validation was carried out correctly. CCPs are in place in the operation. Control measures are working in practice at each CCP.
3. Specification of critical limits to assure that an operation is under control at a particular CCP.	The critical limits control the identified hazards.	Validation was carried out correctly. Operating limits are or continue to be set at appropriate levels.
4. Establishment and implementation of systems to monitor and control CCPs	The monitoring system will ensure that the control measures at the CCP will be effective. Procedures for the necessary calibration of testing equipment are included.	Records of monitoring exist and confirm control. Statistical process control is used where appropriate. Review of monitoring records by designated person. Records of calibration exist and confirm compliance.
5. Establishment of the corrective action to be taken when monitoring indicates that a particular CCP is not under control	Corrective actions will prevent non-conforming product from reaching the consumer. Authority for corrective actions has been assigned.	In cases of non-conformity, control is regained and appropriate steps are taken to prevent unsafe product reaching the consumer. Corrective actions are recorded and actions taken by designated persons.

Table 3.7 (*Continued*)

HACCP principle	Validation *Evidence to demonstrate the following:*	Verification *Evidence to demonstrate the following:*
6. Establishment of procedures for verification to confirm that the HACCP system is working effectively	Procedures for information gathering and compliance verification of the HACCP system have been established	All verification procedures are defined and carried out.
7. Establishment of documentation concerning all procedures and records appropriate to these principles and their application	Documentation covering the entire HACCP system has been established.	Documentation and record-keeping covering the entire HACCP system is complete, in the correct format, properly filled out and up to date.
HACCP training	The training materials and delivery meet the objectives, i.e. that the HACCP team understood how to apply the principles of HACCP.	The appropriate people were trained correctly.

Source: Adapted from ILSI (1999).

Document control will be easier if well organised:

- Each HACCP plan can be allocated a unique reference number that is cross-referenced on all documentation relating to it. This makes it easier to track records during implementation.
- Records must be archived and kept for an adequate length of time, which may reflect legislative requirements of the country where the product is manufactured or sold and the shelf life of the product. As a general rule, records should be kept for at least a year after the end of product shelf-life, though a certified quality management system may require this period extended to 3 years.
- Documents should be readily accessible. In some countries, they are truly legal documents that the regulator can demand to see.
- Updates or revisions to any documents should be done in a controlled way, i.e. dated and authorised. Many companies keep a 'history of amendments' in order to track the development of the system.

- Electronic records must be subject to the same level of security and control as paper records.

The types of records that will be retained are the following:

- The HACCP plan that will include as a minimum the process flow diagram and HACCP control chart together with support information (e.g. the hazard analysis, HACCP team details, product description)
- History of amendments to the HACCP plan that will demonstrate any changes carried out
- CCP monitoring records
- Hold/trace/recall records generated in handling deviations
- Training records proving that personnel involved in implementing the HACCP system have been trained to do so
- Audit records
- Calibration records

In smaller businesses, there is often a concern about the large amount of paperwork inevitably needed for HACCP. It is possible that these types of concerns have arisen because HACCP is not properly understood and more specifically, because the relationship between HACCP and hygiene prerequisite programmes is not understood. Records and documents are needed to confirm that that the CCPs are properly identified and are under control. If the CCPs have not been identified correctly (and sometimes this means that they have been identified but are hidden amongst many other CPs that have also been classed as CCPs), then there will be a lot of monitoring and hence record-keeping. If the few true CCPs have been identified, then this should not really be a burden and, in fact, should help the business to track process performance.

3.3 Implementation of the HACCP plan

KEY POINTS

- The full benefits of the HACCP plan will only be realised when it has been properly implemented.
- Implementation is carried out through personnel training, setting up of monitoring systems and completion of support activities.
- Once the HACCP plan is implemented, it becomes part of the day-to-day operations.

The completion and validation of the HACCP plan is often such a relief that it is very tempting to assume that HACCP is complete. However, unless the HACCP system is in place and operating, i.e. the HACCP plan is properly implemented, there will be no real benefit from all the work carried out thus far. To make HACCP work in practice, it is necessary to ensure that it becomes part of the everyday operating procedures.

'Implementation' is not a HACCP principle. It is not even proprietary to HACCP in that it is an activity requiring many of the business management practices associated with implementing any system.

Time and money are usually the main restricting factors in every organisation whenever a new system has to be implemented, and HACCP is no exception. Costs of implementation should therefore be considered in addition to those of the HACCP study itself (see also Section 1, Frequently asked questions). Sufficient resources must be made available to ensure that the CCPs are effectively implemented and monitoring records are kept.

The implementation process at key stage 3 of HACCP application is best achieved by breaking it down into key steps as shown in Figure 3.3. Responsibility for implementation of the HACCP plan should be allocated to relevant personnel by the management team in discussion with the HACCP team. Relevant disciplines must be included to assist with training, production, engineering and technical issues. A timetable should then be put into place to organise and carry out training and confirm that monitoring systems, facilities and equipment are in place.

Step 1: Determine the approach to implementation

There are two main approaches to implementing the HACCP system, and these are either doing it all at once or in phases. The first method involves implementing everything in one go on a certain date, whereas the second allows each section (e.g. a HACCP plan module or even a single CCP) to be implemented independently when the previous section has been completed. There are advantages and disadvantages in both the methods, but the phased method is likely to be more practical for most businesses.

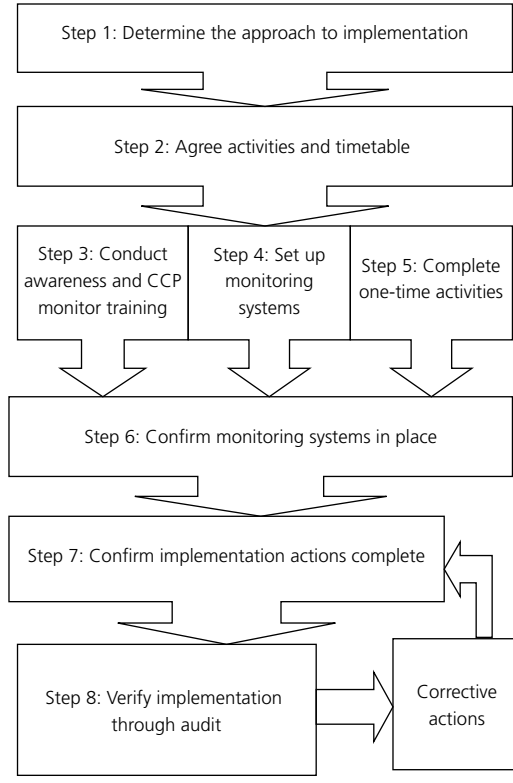


Figure 3.3 Key Stage 3: Example of implementation of HACCP plan. Source: Adapted from Mortimore and Wallace (2013).

Step 2: Agree activity list and timetable

As implementation will require the involvement of a large number of people and may take some time to complete, it is useful to construct a detailed activity list and timetable. This should include details of each activity, who is involved and/or responsible for making it happen as well as the deadline for completion. The activity list and timetable can be constructed in the form of a Gantt chart (Figure 2.10); and since some activities may require others to have been completed, a dependency listing may be helpful.

The main activities are likely to include training and setting up of monitoring systems. However, other activities may have been identified during the HACCP study, which need to be completed in support of the HACCP plan.

These will often be issues that came through the decision tree loop at Q1a (Figure 3.2) and require a modification to the process or product, or the development of a new procedure. It may be that these modifications are directly involved with the identified CCPs, or they may have caused hazards to drop out of the decision tree at Q3 by designing them out of the process. These modifications may be considered 'one-time activities' because they need to be done once either to build in control systems or to design out hazards. Examples of one-time activities include engineering work on plant and equipment.

A requirement to strengthen PRPs may also have been identified as part of HACCP development, and issues highlighted should also be included on the activity list if not already completed.

Step 3: Conduct awareness and CCP monitor training

It is important that all personnel involved in CCP monitoring receive the necessary training and, most importantly, understand their role in the running of the system. As working practices may be changing, it is beneficial for all personnel within the organisation to have a basic understanding of what HACCP is, how it works and how it affects their particular working environment. Revisiting the need for compliance with programmes such as good hygiene practices will help personnel understand how their commitment to such programmes links to HACCP and food safety management.

Training is essential, but it does not have to be costly. HACCP team members, after appropriate trainer training, should be able to provide in-house training to other personnel and conduct briefing sessions. Training resource materials such as video clips and materials developed from this book may be helpful, along with examples from the facility's own HACCP plan(s).

More in-depth HACCP training will be needed for CCP monitors, their deputies, supervisors and managerial staff. This type of training is most likely to be gained through a combination of classroom and on-the-job teaching. They will need to understand what they are expected to do and also why they are doing it and how it fits in with the rest of the system. They will need to have a clear understanding of the requirements for CCP monitoring and the corrective actions required when a deviation occurs, as well as how they are expected to record their results or actions. The CCP monitors should understand exactly what a deviation is, when to report it and to whom it

needs to be reported. It is helpful if this information is specified on the monitoring log sheets or in separate work instructions. In turn, the organisation needs to be sure that the individuals chosen are responsible and are capable of carrying out such important tasks.

Step 4: Set up monitoring systems

Setting up of monitoring systems requires the development of monitoring work instructions, preparation of relevant equipment and recording datasheets for use by the trained CCP monitors. The validated HACCP plan will already detail the monitoring requirements; now these requirements need to be translated into everyday practical activities that can be carried out during production. It is not necessary to reinvent paperwork and record-keeping systems if existing monitoring sheets can be adapted, e.g. by adding additional columns for CCP data and signing off.

Consideration should also be given to additional requirements such as the need for extra facilities, e.g. test areas, log sheet storage, computer work stations and work instruction displays where necessary.

Step 5: Complete one-time activities

This requires the personnel responsible for each activity to complete their individual actions so that they can be checked off from the list. This will often include the completion of a diverse range of activities such as engineering work, procedure writing, prerequisite development and additional training. As this may take some time, it is useful for the HACCP team to review progress on a regular basis.

Step 6: Confirm monitoring systems are in place

This is the final check that everything is ready and that the documented work instructions are in place along with all equipment necessary to complete the tasks.

Step 7: Confirm implementation actions are complete

Once the training and setting up of monitoring systems is confirmed and one-time activities have been completed, the HACCP plan can be transferred into everyday practice through

- monitoring CCPs
- taking the required actions
- recording the results

This is where HACCP can be said to be implemented and management of the CCPs becomes the responsibility of personnel within the day-to-day operation.

It is a requirement of HACCP that monitoring records are reviewed by a responsible reviewing official. This will most frequently be a supervisor or manager, and this is a good opportunity to check that the implementation actions are adequate in the early days of the implemented HACCP plan.

Step 8: Verify implementation through audit

Once the system is implemented and a period of records – e.g. 6 months – is available, a verification audit can be carried out. This may be performed by internal personnel not directly involved with the day-to-day running of the HACCP plan or by external HACCP consultants as stated earlier.

3.4 Maintenance of the HACCP system

KEY POINTS

- The effectiveness of a HACCP system in managing food safety is dependent on continuous maintenance.
- The HACCP plan should be updated and amended at least once annually.
- Ongoing training is important to ensure that HACCP awareness is maintained.

A HACCP plan will only achieve its purpose in managing food safety if it is kept up to date, i.e. through continuous maintenance. It needs periodic review and update if it is to remain current and, therefore, effective. Operations change all the time as new raw materials are introduced, new recipes and products are proposed, improved processes or test methods become available, updated equipment and structural changes occur in the kitchen or factory. New scientific information on hazards or new foodborne illness events may increase the knowledge of the HACCP team. All of these factors will lead to a review of identified hazards and existing controls to

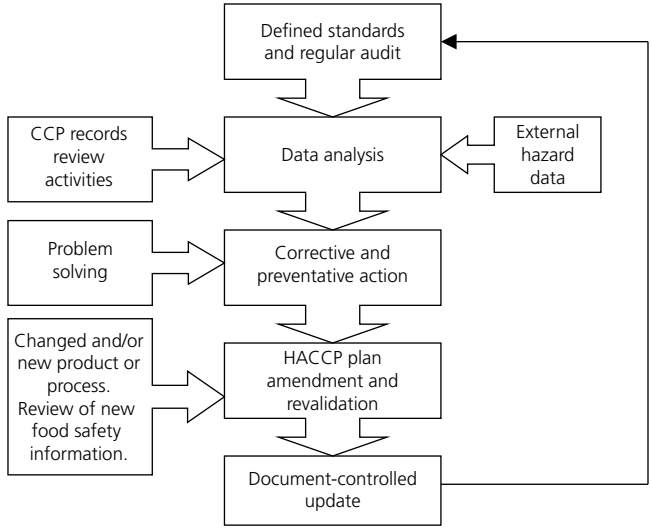


Figure 3.4 Key stage 4: Example of verification and maintenance of the HACCP plan. Source: Adapted from Mortimore and Wallace (2013).

determine what changes are needed. The team is then able to update and amend the HACCP plan. In the absence of any known changes, the plan should be reviewed and revalidated as effective at least annually.

'HACCP maintenance' is not a HACCP principle, but it is so vitally important that many practitioners would like to see it directly included in the principles. If the HACCP study was carried out on a product or process that no longer exists, then it will be of little value in controlling food safety for the current activities of the business.

Maintenance of the HACCP system will include the steps shown in Figure 3.4. The activities considered include regular auditing, hazard data analysis, updating and amending the HACCP plan, all of which should be supported by on-going training and educational requirements.

Refresher training should be carried out regularly to ensure that all personnel involved in the HACCP system are kept aware of changes to the system and the emergence of new food safety information, particularly with regard to hazards and their control. New staff members also need to be trained so that they have the same level of understanding as their colleagues. Doing this will ensure that the HACCP system is dynamic and really helping to

reduce food safety risk as opposed to just being an exercise that was required for regulatory compliance or for a customer audit i.e. still not part of the company's operating culture.

3.5 Third-party certification of food safety management systems

KEY POINTS

- Once fully implemented, HACCP systems can be independently certified.
- ISO22000 or a GFSI benchmarked scheme are the most commonly used approaches.

Once the HACCP system is operating effectively, the HACCP team can decide whether they feel ready to get it independently certified if that is the goal. The most likely options will be ISO22000 (2005) or one of the GFSI benchmarked schemes as discussed earlier. Normal practice is to have a gap assessment with the selected certification body. This is not necessary however if it was done earlier and the team feels confident that all gaps have been closed. At this point, a certification body will be selected and the audit can be scheduled. Typically, at least 6 months of records are required to demonstrate that the system is working.

3.6 Conclusion

This concludes Section 3. In following all of the steps outlined, a business should have a robust HACCP system. It will have been thoroughly researched during its development, be based on sound science and will be kept up to date through proactive maintenance. Food safety is not negotiable. As food business operators, whether in catering, foodservice, manufacturing, food distribution, retail or enforcement, we owe it to the consumer to do the best we can to ensure that the food we provide is safe rather than a danger to the public health and well being. There is no such thing as zero risk, but we can anticipate and manage the potential hazards to an acceptable level. It is our responsibility to do this whether we work in a large or a small business.

Epilogue

KEY POINTS

- HACCP will only succeed if it is backed by a management team that fully understands the concept and operates in an environment that has a strong food safety culture.
- To avoid failure, a HACCP system must be planned, executed and implemented correctly. Once implemented, it must be reviewed regularly.
- The people who develop a HACCP system must have the appropriate education, experience and skills.
- Good communications within the supply chain will result in shared knowledge of potential hazards, better controls and safer food production.

To those of you who have read the entire book before beginning on the Epilogue, have we achieved our objective as set out in the Preface? Have you gained a working knowledge of HACCP? We hope so.

You should also have an appreciation that the topic of HACCP is not exactly black and white. The HACCP approach is really a way of thinking and working. Learning about HACCP is not like learning about hygiene that is more fact-based. HACCP is evolving all the time and despite having been around for more than 50 years, it is still the subject of much discussion and debate amongst professionals, enforcers and academics. In closing the book, it seems appropriate to do several things:

- Provide a quick reminder of what we have told you thus far.
- Indicate some of the typical problem areas or pitfalls encountered by businesses starting to use HACCP.

HACCP: A Food Industry Briefing, Second Edition. Sara E. Mortimore and Carol A. Wallace.

- Look at some of the current issues causing debate or controversy.
- Indicate what might come next in terms of businesses wanting to manage food safety.

What we have told you – i.e. HACCP in a nutshell

HACCP is an acronym for the Hazard Analysis and Critical Control Point system. HACCP is recognised by WHO as being the most effective way of preventing foodborne illness. It is a preventative approach to food safety (not quality) management and works by:

- breaking a process down into individual process steps;
- analysing each step to find out whether a significant hazard might be introduced – a hazard analysis;
- deciding what control measures would prevent or eliminate the potential hazards or reduce them to an acceptable level;
- establishing where it is absolutely *essential* to control the safety of the food, i.e. the CCPs at which the control measures are working;
- establishing what the critical operating specification is for the critical control points – the critical limits;
- determining how to monitor the CCPs and what corrective actions are needed in the event of deviation;
- establishing procedures to verify that the whole system is working, i.e. it will control food safety and is working in practice;
- documenting all of the above (a HACCP plan) and keeping records.

All of the above is set out in a set of 7 HACCP principles as published by Codex (2009b) and NACMCF (1997).

Effective food safety management requires additional skills and activities than HACCP alone. These can be grouped under the headings:

- Prerequisite programmes or (PRPs)
- Business management practices
- Quality management systems

A HACCP system must be planned, developed, implemented and maintained by people who have the right skills and a clear understanding of their roles. It also requires real management commitment to a level that a food safety culture is championed.

Typical problems in using HACCP – i.e. potential pitfalls or why HACCP may fail

Just because a business uses the HACCP principles and has a HACCP plan, it does not mean that it has a safe food process. Why is this?

Lack of real management commitment and absence of a food safety culture

This is essential if time and money is to be made available to do a thorough job. Much more time is needed to develop and implement HACCP than many managers imagine, and they need to know that it will take months rather than weeks in most cases in order to manage expectations.

The attitude and behaviour of employees could be a barrier to the implementation of HACCP. Attitudinal problems can include resistance to change but also resistance to authority in general. This could be one of the causes of behavioral problems. In addition to HACCP monitors, the prerequisite hygiene controls, which are an essential foundation, demand a certain behavior. Yet, operatives with an attitude problem will often only operate the required procedures when a manager or supervisor is standing over them. This can include PRPs such as basic hand-washing or personal hygiene as well CCP control activities. It needs real management commitment to proactively identify these behaviors and deal with them. Developing a real culture of food safety is a task not to be underestimated. It starts with the senior management team but percolates through the entire organization, not just manufacturing and quality, but sales, marketing, sourcing, logistics, human resources and so on. Each function and individual understands how they contribute to the overall programme. If HACCP is to be a successful element of an effective food safety programme, all the employees must wholeheartedly understand the concept and believe in the benefits that it will bring to the business.

Low skill level of the food business operator and HACCP team

A HACCP system will only be as good as the people who developed it and the support it receives. Unless it is properly planned, implemented and maintained, it will not serve its purpose of managing food safety and will only give a false sense of security.

Some of the main reasons why a HACCP system may fail to meet its objectives are the team not fully understanding its principles or not having the technical knowledge to understand and control the relevant hazards. It is important that the appropriate educated, experienced and trained people are available when a HACCP system is developed. *Education* and *experience* is particularly important in being able to analyse hazards correctly and set critical limits for the control measures. Whilst everyone should be able to understand the concept of HACCP, the application of sound science is needed to be able to use it in practice. *Training* is important for the understanding of the concept in the first place. Sometimes, and probably fairly often, a business will see training as a single intervention, i.e. 'we'll send someone on a course and they'll be our expert'. However, very few training organisations would claim this as an outcome of their introductory level courses. To be able to take on such a complex project as HACCP, an ongoing series of training interventions, combined with expert coaching and support, provides a better grounding. This might include additional courses on food safety, employing experienced practitioners as HACCP study facilitators, reading books, using the Internet to look at generic HACCP plans and to seek out and learn from other companies' failures, attendance at symposia and conferences, further academic study and, very importantly, networking with others who have done it before.

Lack of management or project skills

This is perhaps another noteworthy reason for failure. HACCP development and implementation can be quite a big project in any business regardless of size. Basic administrative and organisational skills can help keep documentation to a minimum and ensure that time and money are spent wisely.

Over-documentation and complexity

This leads on from the above. Failing to keep the system simple and focussed on what is really critical can create burdens on any business, regardless of size. There are numerous examples of systems being unnecessarily over complex. This has a major impact not just during the development of the system but more significantly in trying to maintain it.

Cost

Financial constraints are sometimes responsible for food safety failure and for the inability of HACCP to be effective. When a gap analysis of PRPs identifies the need for investment (which it frequently will), it is

important to invest properly and on a prioritised basis as a HACCP system needs the support of these programmes to be effective at reducing food safety risk.

It is important also that any additional equipment and resources requirements are considered carefully and all alternatives are evaluated. These can be significant investments, particularly if data analysis software is needed.

Education and training are also expensive whether achieved through the recruitment of more highly qualified staff (where none of them were previously available), using educated, experienced consultants or the running of training courses. It all costs money, but failures are much more costly – recalls, lost customers, bad publicity, loss of trust and damaged reputation. These cost a lot more than the cost of prevention, and unfortunately there are countless (well-publicised) examples of the consequences of failure – if there is any doubt regarding this.

Inadequate prerequisite programmes

Many businesses believe that they already have adequate PRPs in place. However, to support HACCP, it is important that they are confirmed to be effective systems that have been planned, developed, monitored and verified in the same way as HACCP itself. In looking at reasons for many of the twenty-first-century failures in food safety, it is clear that many relate to a breakdown in PRPs. Upgrading PRPs is often found to be required once the HACCP team starts looking at the facility with a hazard analysis mindset.

Failure to implement and maintain the HACCP plan

A paper HACCP plan will not be very helpful if left on the office shelf. It has to direct management to implement the identified controls and to continuously review, challenge and strengthen them. Lack of maintenance will mean that potential hazards resulting from changes in products, procedures or equipment are missed.

These pitfalls can only be avoided through good planning, training, the use of the required skills and, most of all, real management commitment to the HACCP concept.

Current issues and controversies

There are so many that this subject could easily form the basis of another book – however, just to provide a feel for some of the current issues.

HACCP and Small and Medium-Sized Enterprises

There is some considerable debate over whether HACCP can be used by small and medium-sized enterprises (SMEs). The basic issue is actually the skill base. Product safety is *not* negotiable according to the size and location of the business, and a food business with just one employee will be perfectly capable of putting in a HACCP system provided that the person is a good manager and is well educated, experienced and trained in PRPs, HACCP and other quality management systems. Unfortunately, people without this level of education, experience and training run many SMEs, but training and guidance developed specifically for SMEs can help provide the necessary capability.

Lack of international food safety standards and no global regulatory agency

Currently national governments legislate for food safety and do not always have the same standards. With ISO22000 and the emergence of GFSI we have a better means of facilitating food safety for global trade in food. Governments are more and more communicating on food safety matters, trying to establish equivalence and memoranda of understanding where possible but we've a long way to go. This does continue to cause problems for multinationals and for export/import businesses.

Use of Operational Prerequisite programmes

The term *operational prerequisite programmes* or OPRPs is relatively new. It was introduced by ISO (2005) within the ISO22000 standard. They are described within the standard as a 'PRP identified by the hazard analysis as essential in order to control the likelihood of introducing food safety hazards to and/or the contamination or proliferation of food safety hazards in the products(s) or process environment'. Some companies find this additional term and categorisation to be very helpful for communicating which practices or programmes, whilst not a CCP at a process step, are nonetheless *essential* for ongoing food safety assurance. Typically, they are likely to

be utilised in a manufacturing process once a product is deemed to be safe for consumption, i.e. where protection from recontamination is necessary for food safety.

Some people are concerned that the use of such an approach might mean that issues that could be CCPs are missed out from HACCP plans. PRPs have, actually, been around for longer than HACCP – it is just that the OPRP term and the formalisation of its relationship with HACCP is new. This approach could help make the identification of true CCPs a lot easier and food a lot safer.

Economically motivated food adulteration – food fraud

This is an emerging area of discussion, and awareness has been raised largely as a result of a number of high-profile issues – horsemeat in Europe, Sudan Red in spices, melamine in pet food and infant formula. In reality, economic adulteration has been around as long as the food industry. Watering down of milk and beer was an early challenge that is still found in some of the developing countries. Education and awareness of associated risk can be helpful as can a vulnerability assessment of your supply chain. High-value, short-supply raw materials and finished products are the most at risk.

Bioterrorism

It is acknowledged that the food supply chain could be a vehicle for terrorist attack. We are not going to go into details here except to suggest that using a HACCP system to assess areas of vulnerability could be a useful exercise – this evaluation should go beyond the typical building security assessment to include, for example, the screening of personnel, assessment of unsupervised work areas, and evaluation of the raw materials and finished product distribution network.

Risk assessment and quantified HACCP

Formal risk assessment is carried out at government level. Codex has published a guidance document on microbiological risk analysis (1999). Yet some confusion remains, partly because of using the term *risk assessment*. Hazard analysis requires that the risk is assessed, i.e. the likelihood of occurrence and the severity of effect. This is usually done by

HACCP teams and in that sense is a qualitative risk assessment. Formal government-level risk assessment is a quantitative process, usually involving large groups of scientists, sometimes lengthy research work and usually a high investment. The determination of the acceptable level of risk is rightly a government decision in many situations – acrylamide is a good recent example of this. Quantified HACCP is being discussed in some circles, mainly in large organisations and academia. This centres around a numerical risk rating at the hazard analysis stage of HACCP. It is too early to say whether this will be widely adopted, but adding levels of complexity to HACCP may not be beneficial in the long term, particularly with respect to widening the effective application of HACCP to smaller businesses.

Food Safety Objectives (FSOs), Performance Objectives (POs) and the Appropriate Level of Protection (ALOP) concept

Food safety objectives (FSOs) and performance objectives (POs) are distinct levels of foodborne hazards (e.g. specific micro-organism numbers) that cannot be exceeded if products are to be safe for consumption. FSOs are end product targets at the point of consumption and POs are targets to be met earlier in the food chain, and both can be achieved through the application of PRPs and HACCP. According to the International Commission on Microbiological Specifications for Foods (ICMSF 2006), FSOs should only be developed if a need for this has been specifically identified, e.g. when it is anticipated that the FSO will improve food safety.

FSOs and POs are linked to the appropriate level of protection (ALOP) concept. This is a population-level measure – the level of risk that a society is willing to tolerate – and it is normally set by governments for a range of health conditions. ALOPs may vary between countries and, since societies generally wish to improve health of their citizens and lower the incidence of disease, ALOP targets may be tightened over time.

Government public health goals regarding health conditions and the incidence of disease need to be translated into parameters that can be assessed by government agencies and used by food producers. This is where the concepts of FSOs and POs come into national health protection plans. FSOs are defined as ‘the maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the ALOP (ICMSF, 2006).

POs are intended to be used in product sectors where the product is intended to be cooked by the consumer before consumption. In these cases, a point of consumption target for specific micro-organisms would not be helpful, and therefore a target is set for the product further up the supply chain, e.g. when it leaves the processing facility. Because foods that need to be cooked before consumption may contain harmful bacteria, there is a risk that these organisms may be transferred through cross-contamination to surfaces and utensils within the kitchen, and may also contaminate other ready-to-eat foods. Thus, although the original 'raw' food can be made safe by cooking, the pathogens that contaminated it in its raw state may still cause illness due to cross-contamination. POs are intended to specify the levels of contamination that should not be exceeded in these types of products to reduce the likelihood of cross contamination. A useful example from ICMSF (2006) helps illustrate this concept:

> A raw chicken may be contaminated with *Salmonella*. Although thorough cooking will make the chicken safe (absence of *Salmonella* in a serving), the raw chicken may contaminate other foods during preparation of a meal. A PO of 'no more than a specified number of raw chicken carcases may contain *Salmonella* may reduce the likelihood that *Salmonella* will contaminate other foods'.
>
> *(ICMSF, 2006)*

Some years ago, it was thought that FSOs and POs would gain more traction than they have since the approach has a lot of merit.

However current discussions about diverse food safety topics such as consumer food handling behaviour and hygiene capability, and the perceived need for absence of pathogens in traditional 'raw' products such as ground beef (sometimes called zero tolerance) on one hand and the 'just cook it' argument that zero tolerance is not possible and thorough cooking is always essential on the other could mean that now is a good time to revisit these topics in more detail. Adding to this the potential for unintended use of food products demonstrates the complexity of the situation. Therefore the shared responsibility between the designer, manufacturer, regulator, retailer and consumer needs to be further explored and communicated and FSOs, POs and the ALOP may have a role to play.

Consumer safety concerns and trends

Food has probably never been safer, yet concerns over food safety appear to be increasing. Consumer perceptions of food safety (real or not), as well as what constitutes a healthy diet have to be managed alongside the real food safety issues in order to remain in business. The rise in the desire for organic, gluten free, GMO free, artisan and locally sourced foods continues although currently the science does not confirm that these foods are any safer or any better for us.

Social change

Consumers are rightly concerned about broader issues such as food security (will there be enough to eat) and environmental sustainability (including climate change and scarcity of water). The population is set to increase to over 9 billion by 2015. This will put a strain on food production (and food safety) systems; more intensive farming, new technologies, increased global trade, and with climate change, potentially less water. Add to this, the increase in immune compromised consumers (ageing population), and we feel the pressure to do all that we can to prevent food waste through food safety failure.

What next in terms of food safety management?

A more integrated approach and on a global scale

HACCP can be used by all sectors of the supply chain; but in reality, it has largely been used by the processing industry. We foresee greater acceptance for the need to use an integrated approach, a fully operational matrix of activity across the global supply chain (Mortimore and Wallace 2013), with shared hazard analysis between primary producers and their processing industry customers and between them and their retail and foodservice customers, all working towards identifying the areas where hazards may arise in the food chain and, therefore, where the preventative controls can be put in place. Without good communications, each segment of the supply chain is ignorant of the matters arising later on. Encouragingly, what is increasing is the level of open dialogue and collaboration within the industry. This is not restricted to manufacturers; our sense is that governments too are more open, and this in turn leads to

memorandums of understanding and facilitates global trade. We are not quite there in terms of equivalency, e.g. in the content of regulations and testing protocols; but we are closer which is very positive and should be set to continue.

Oversight of education and training

Only just starting to be recognised within government and industry is the need for more oversight of the approach taken to ensuring effective food industry education and training. What was recognised as a problem a number of years ago (Mortimore and Smith 1998) was the fact that many so-called HACCP trainers were more experienced in fact-based training (e.g. sanitation, hygiene and pest control), but had extended their portfolio as the need for training in HACCP evolved without the necessary skills and experience in HACCP. Conversely, many HACCP experts may have been good at HACCP and presenting, but they were not effective trainers. This is still a problem. Whilst a few countries have national standards (e.g. United Kingdom), most do not. There are no global standards for training in the food industry, which means that training standards are highly variable as is the resulting knowledge – the two go together. Companies who buy in training have no way of assessing the competency of the trainers and no real way of knowing whether their employees learned the right things or even if they learned anything at all. It is evident that the still traditional single intervention of HACCP training (a two- or three-day course) will not create sufficient expertise and skills. Much more enlightenment, collaboration and evaluation are needed in this area to make the much needed changes.

Inspection and auditing

There is still considerable variability in HACCP and food safety knowledge and skills amongst inspectors and auditors across the globe. Some are excellent, but a number of them have limited personal experience of actually applying HACCP and therefore struggle with auditing a HACCP system. Currently, some businesses find themselves in the position of having to defend their HACCP plans because the auditors or assessors have less of an understanding of how to do HACCP than does the HACCP team that developed it. This can be very difficult, and it is not unknown for companies to have to put in extra ‘CCPs’ because their customers told them to do so (Mayes and Mortimore 2000). GFSI has been working on auditor competency models, but this issue will continue to evolve, hopefully to include a

food safety certified auditor program that could be adopted through both the public and private sector, as well as across national borders. That has to be a good thing for food safety worldwide.

Food safety culture

This is being discussed more and more, yet many would argue that we are in the very early stages of understanding, development and adoption. Some seasoned food safety experts struggle with this concept, and yet it makes perfect sense. Food safety is a science, yet the management of food safety requires people. Bringing together food scientists and behavioural scientists is very exciting, and a perfect example of how food safety management is done best by having a cross-functional input. No doubt that there will rightly be a lot more discussion on this topic over the coming years, and key guidance on how to implement and measure the effectiveness of food safety culture will be essential.

These are probably not the only debates, controversies and emerging issues, but hopefully by including some of them we have managed to convey the fact that this is an evolving area that offers an outstanding opportunity to be truly efficient, effective and above all practical in the management of food safety across all sectors, technologies and national boundaries.

What more can we say… We hope that you have enjoyed this book and that your appetite has been whetted for more in-depth discussions and training on this dynamic topic. The journey continues!

APPENDIX A

Case study: Chilled and frozen cheesecake production

1 Introduction

This case study is provided to illustrate the application of the HACCP principles as discussed in the main text (Sections 2 and 3). It is laid out in the format of a HACCP study, initially giving general information such as HACCP team details, terms of reference and product description and then progresses through the process flow diagrams, hazard analysis and CCP determination to the hazard control chart.

This case study is a fictional example and is not intended as a generic HACCP plan. It is provided without any liability whatsoever in its application and use.

Whilst the case study follows the steps of HACCP principle application and uses both typical data formats that might be seen in food operations and a level of detail often provided by HACCP teams, it should be realised that it is fictional and will therefore not be as comprehensive as a true, in plant HACCP study. It should also be noted that it was prepared at a point in time – most companies will continue to refine over and over once they have the initial work completed. As stated at the beginning of the book, HACCP is a journey where we continue to learn and readers are encouraged to look for where they would make improvements when applying HACCP to their own operations.

2 The company

The company is a medium-sized privately owned dairy company producing a range of pasteurised milk products, cream, soft cheese and desserts. There are several factory buildings on a large, purpose built site, and the dairy

HACCP: A Food Industry Briefing, Second Edition. Sara E. Mortimore and Carol A. Wallace.

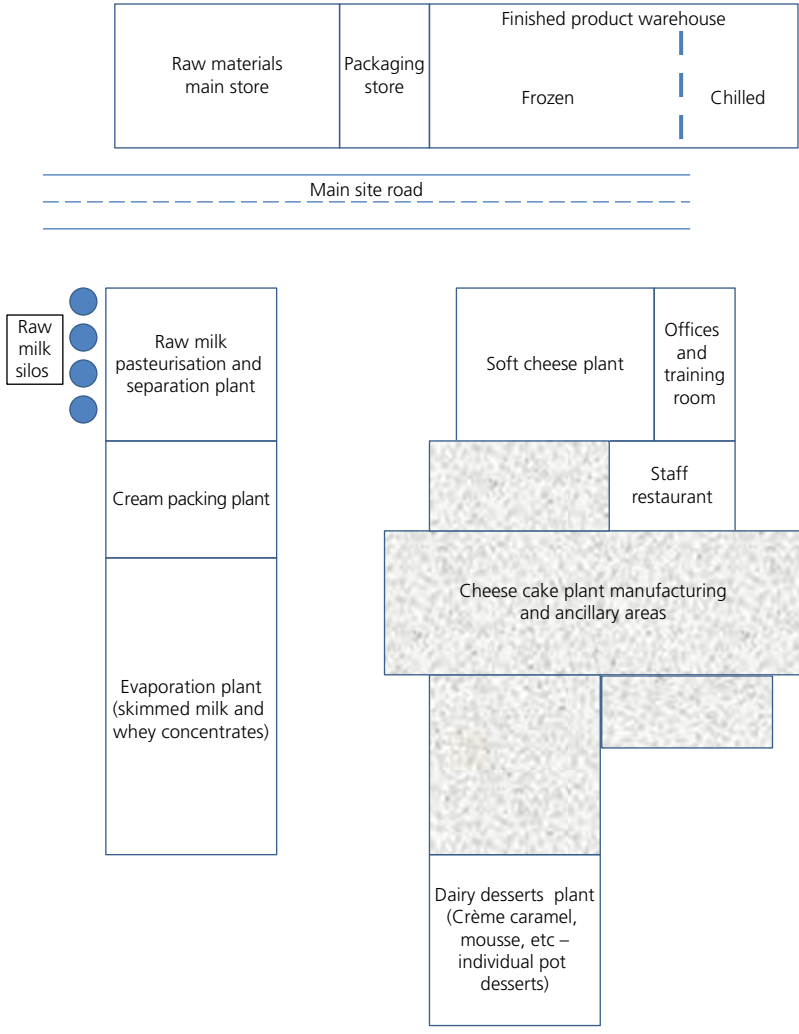


Figure CS.1 Case study company – Factory layout plan.

desserts are manufactured in their own separate building. The site plan is shown in Figure CS.1 and the cheesecakes area in Figure CS.2. These are provided for visualisation of the site only and, whilst it is not possible to show on such a small figure within the book, these layouts have been analysed for traffic patterns, movements and so on to identify any cross-contamination potential for inclusion in the hazard analysis. As you can see from Figure CS.1 there is added complexity because of the separation between buildings on

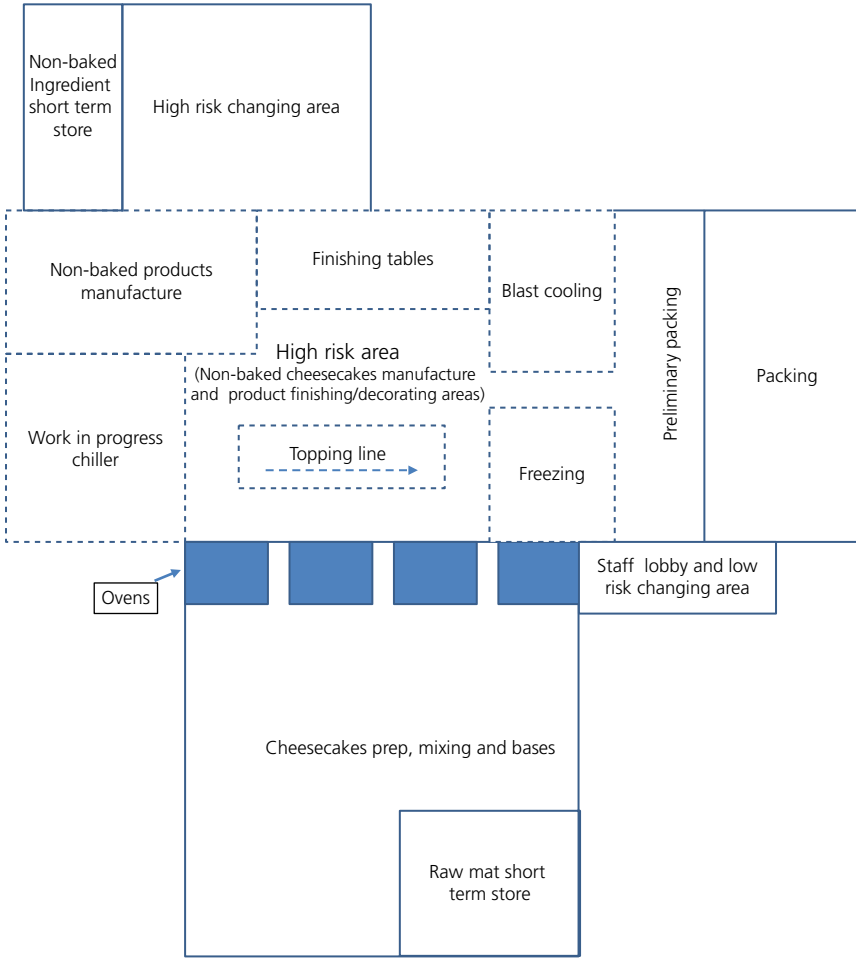


Figure CS.2 Case study company – Cheesecakes area layout plan.

the same site and this means that products from one department being used as ingredients in another must be fully risk-assessed in terms of the potential for cross contamination during transit. Effectively this means that these materials must be packed and contained in vessels that are suitable for external transit and must be treated in the same way as all external ingredients on receipt to the cheesecakes department. Full and detailed prerequisite programmes (PRPs) have been developed to minimise these cross-contamination risks and the materials concerned (cream and soft cheese) are packed in the same containers as they would be for external sale before being

transferred across the site in enclosed vehicles. Please be aware that there is much more discussion and expert evaluation needed to identify and control the food safety risks associated with potential contamination from handling and the environment around production in this type of operation than we are able to show in the pages available for this HACCP plan case study.

Production of desserts is mainly automated, but manual processes are used for decorating/finishing of products. Finished cheesecakes are boxed and are either stored and distributed chilled or go through a blast-freezing process for frozen storage/distribution.

3 HACCP team members

- Technical/quality assurance manager
- Production manager
- Line supervisor
- Quality assurance supervisor
- Maintenance manager

4 Terms of reference

- The HACCP plan covers all types of food safety hazards: biological, chemical and physical.
- The HACCP system is supported by PRPs throughout the factory. This includes a high risk area for post-baking activities in the cooked range and all production activities of the unbaked ready-to-eat range, where different colour clothing is worn and tight hygiene controls are practised. The PRP programme manual includes the following elements:
  - Raw materials and supplier assurance
  - Cleaning and disinfection
  - Allergen control plan
  - Personal hygiene – staff and visitors
  - Pest management
  - Facility buildings and temperature control
  - High risk area – special food hygiene practices
  - Equipment maintenance and calibration
  - Product and customer information
  - Warehousing and distribution
  - Traceability, recall and incident management

All PRP elements are subject to monitoring at appropriate frequencies, with weekly housekeeping inspections and formal verification via 3-monthly audit.

- This study covers a range of fresh and frozen cheesecakes, which may be baked or non-baked.
- In this study, the entire process is divided into eight modules.
- **Note:** Although this modular HACCP plan covers the modules involved in processing the above product groups, all new flavours/varieties need to be assessed for food safety to make sure all hazards are controlled by this HACCP plan, or the HACCP plan can be updated with any additional necessary control measures, before manufacture.

5 Product description

5.1 General

- Chilled and frozen ready-to-eat products are to be consumed straight from the refrigerator (chilled) or after thawing at ambient temperature for 4 h or in a refrigerator overnight (frozen).
- After thawing, the product must be kept chilled and consumed within 48 h; therefore temperature and/or time abuse is potentially high.
- The product is targeted at the general public and may be consumed by high risk individuals, e.g. children and elderly people.
- The cheesecakes come in a number of serving sizes from individually packed portions to family size. The frozen product is also made in a large foodservice size.
- The range includes a variety of speciality biscuit bases (digestive, chocolate, amaretto) and comprises the following flavour groups:
  - **Baked cheesecake**
    - Simple flavours, e.g. vanilla, lemon, chocolate
    - Inclusions, e.g. blueberry and vanilla bean, cherry and white chocolate
  - **Non-baked cheesecake**
    - Flavoured ‘cheese’ layer, e.g. vanilla, lemon, chocolate
    - Fruit/nut/choc layer topped, e.g. strawberry, blackcurrant, orange, etc. over vanilla layer; amaretto crunch, flaked almonds, hazelnuts or chocolate flakes over chocolate base, etc.
    - Hand-decorated, e.g. piped cream with nuts or fruit pieces over base cheese layer

5.2 Raw materials

All raw materials used are bought to agree detailed technical specifications and come from approved third-party-certified suppliers. Suppliers of higher risk ingredients (e.g. dairy, egg, nuts and chocolate) are audited by the company's own technical staff in addition. All ingredients are subject to incoming goods checks as defined in the prerequisite supplier assurance programme. The raw materials used are as follows:

Chilled

- Dairy ingredients: both soft cheese and cream are produced in one of the other factory buildings on site (see Figure CS.1) and are delivered to the cheesecakes building in stainless steel, mobile and lidded bins.
- Egg – whole, liquid, pasteurised – in blue-coloured plastic bags inside buckets.
- Butter in blue plastic-lined cardboard boxes.
- Freshly prepared fruits, e.g. washed blueberries, raspberries, strawberries, stoned cherries, etc – all received in blue plastic bags in returnable plastic trays.

Ambient

- Chocolate (chips and flakes) and biscuit crumb (digestive, chocolate and amaretti biscuit crumbs) in blue plastic-lined cardboard boxes, delivered ambient but stored chilled to protect quality and prevent temperature rise of product during production.
- Chopped hazelnuts, flaked almonds and pecans, all received in plastic-lined cardboard boxes, stored in separate designated nut allergen area to minimise the risk of cross-contamination.
- Dry powders, sugar, flour, gelatine powder and modified starch, in poly-lined paper sacks.
- Fruit toppings, in plastic buckets, aseptically packed, low pH, e.g. black-currant, strawberry, orange, etc. Although these are ambient stable products and are not susceptible to microbial hazards due to the Ph and a_w of the recipes, they are stored under chilled conditions on site to prevent temperature rise of the finished product during production.
- Various liquid flavourings, in plastic containers.
- Vegetable oil in plastic drums.

5.3 Intrinsic factors

- pH of cheese layer =4.6–4.8
- Water activity (a_w) of cheesecake layer = >0.90
- No chemical preservatives are used.

The cheesecake products are chilled or frozen and do not rely on intrinsic factors for stability. Frozen products are not intended to be stored refrigerated for long periods after defrosting and will carry instructions to store chilled and consume within 48 h of defrosting. Chilled products have a maximum shelf life of 10 days and are labelled with 'use by' dates plus additional instructions to use within 48 h of opening.

5.4 Key processes

- Mixing – automated and manual
- Assembly – automated
- Baking – in double-entry rack ovens
- Cooling – on racks in blast chiller
- Decorating – by hand
- Batch freezing – on racks
- Packing – automated and manual

5.5 Main hazards to be considered

- Microbial pathogens, e.g. the presence of specific pathogens in raw materials, particularly those added after baking, although the nature of the product range (baked/unbaked) and the factory layout mean that the majority of raw materials have to be ready to eat on receipt at the facility. This will include consideration of vegetative organisms of concern, e.g. *Salmonella* spp., *Listeria monocytogenes*, *Staphylococcus aureus*, *Escherichia coli*, and the potential for survival and growth of spore formers, such as *Bacillus cereus* and *Clostridium perfringens.*
- Allergen control for allergenic/allergen-containing ingredients. This will include nuts (e.g. hazelnuts, pecan, almonds and amaretti biscuits), egg, wheat and dairy (cream and soft cheese). Allergen handling on site is controlled through the allergen control plan PRPs including labelling requirements. However, significance of allergens as chemical hazards is considered as part of the hazard analysis and CCPs identified accordingly.
- Hazardous foreign material, e.g. metal contaminants from plant and equipment. The possibility of physical hazard presence in all raw materials is also considered but of significant concern are cherry stones that

could be a choking hazard in children <3 years of age. Here, labelling was also seen as a preventative control measure.

5.6 Main control measures

- Supplier control and raw material certification
- Temperature control (cooking and chilling)
- Cross-contamination prevention
- Allergen controls programme
- Sieving and metal detection
- Labelling – allergens and cherry stones

6 Process flow diagram

The overall process is shown on Figure CS.3 (modular system structure) and divided into eight modules that are shown in detail in Figures CS.4, CS.5, CS.6, CS.7, CS.8, CS.9, CS.10 and CS.11.

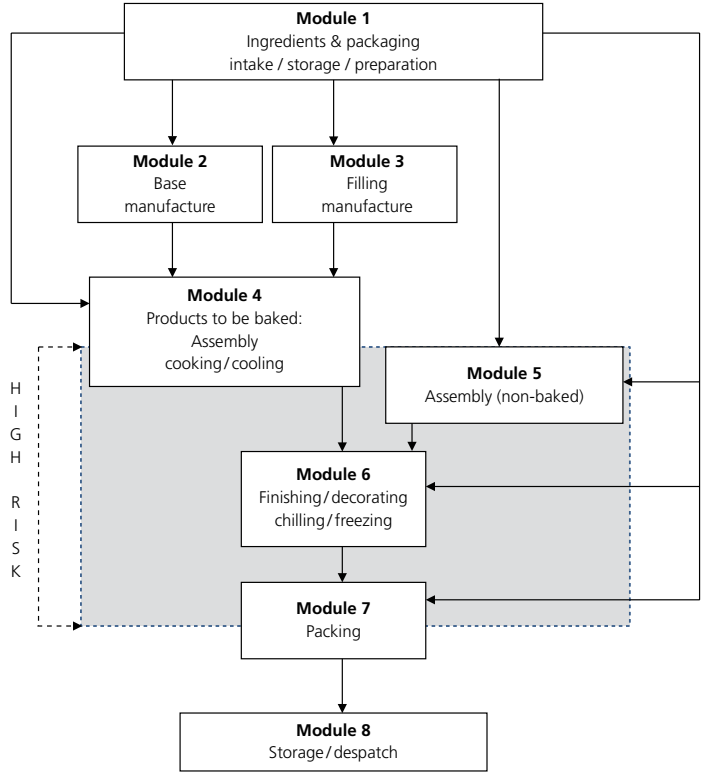


Figure CS.3 Frozen cheesecake: Modular system structure.

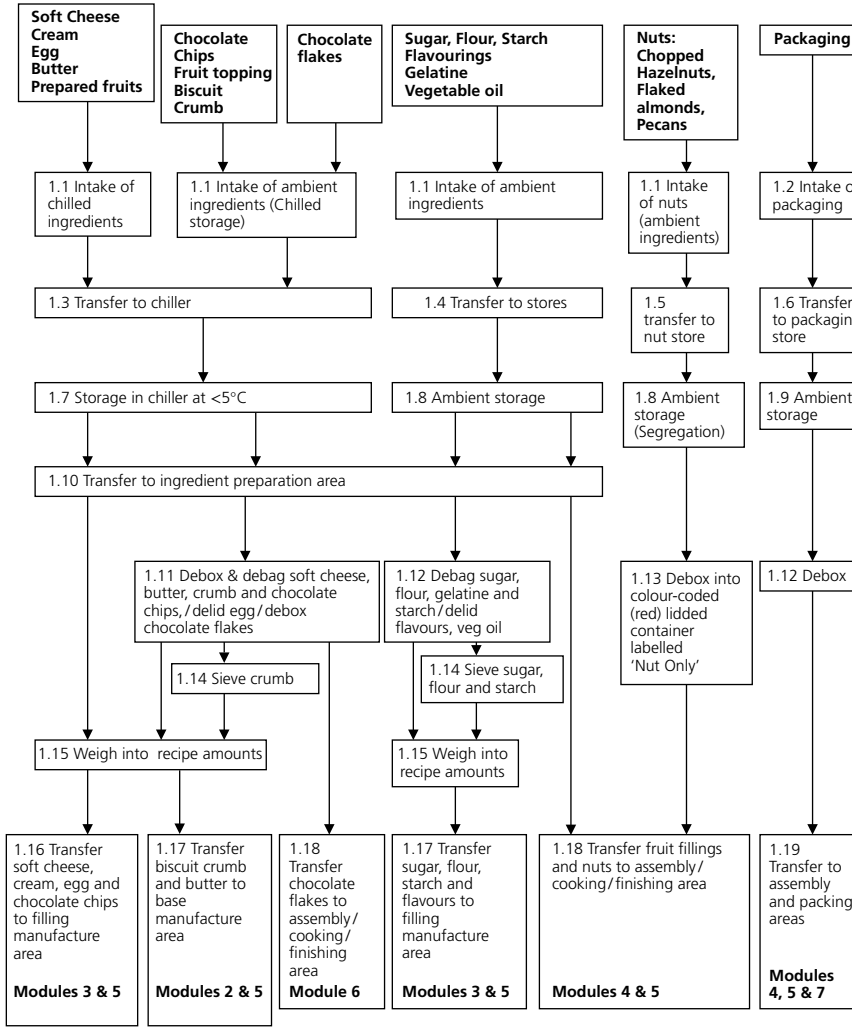


Figure CS.4 Module 1: Ingredients and Packaging intake/storage/preparation.

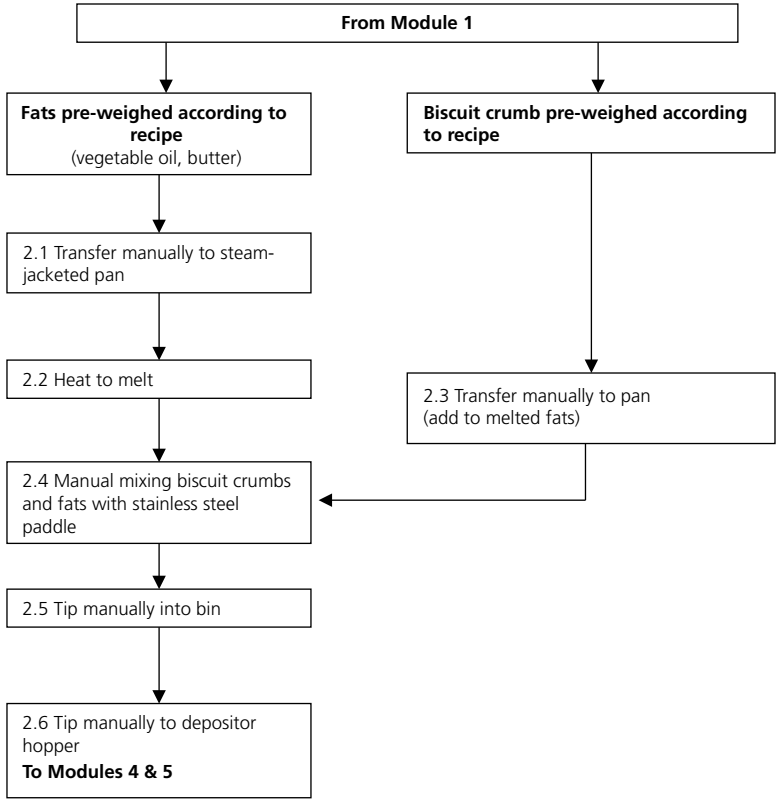


Figure CS.5 Module 2: Base manufacture.

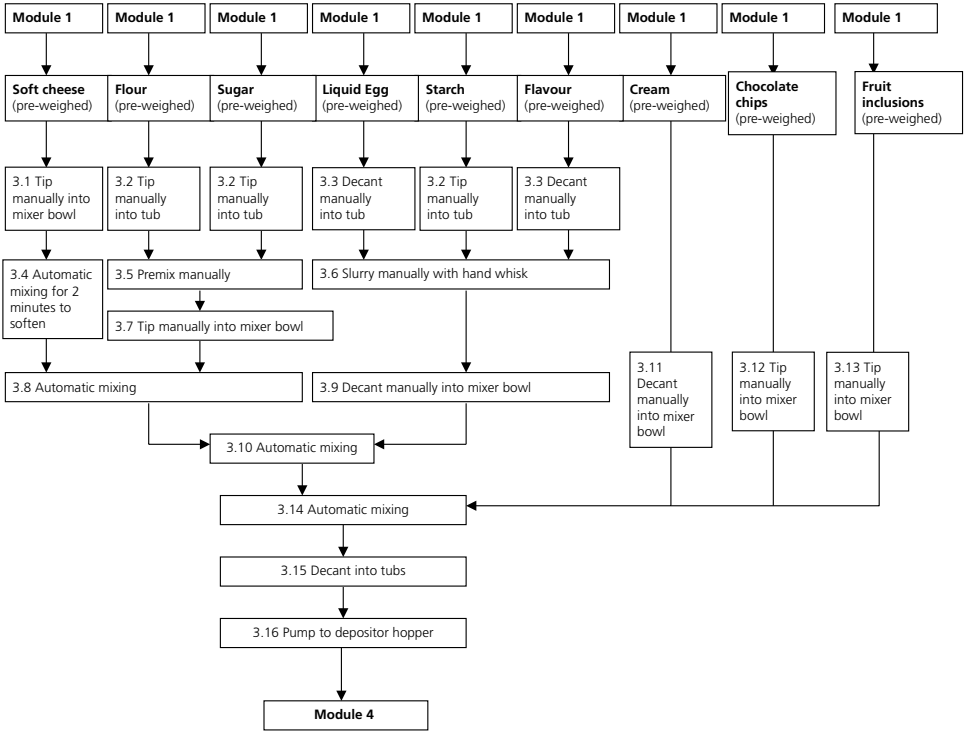


Figure CS.6 Module 3: Filling manufacture (products to be baked).

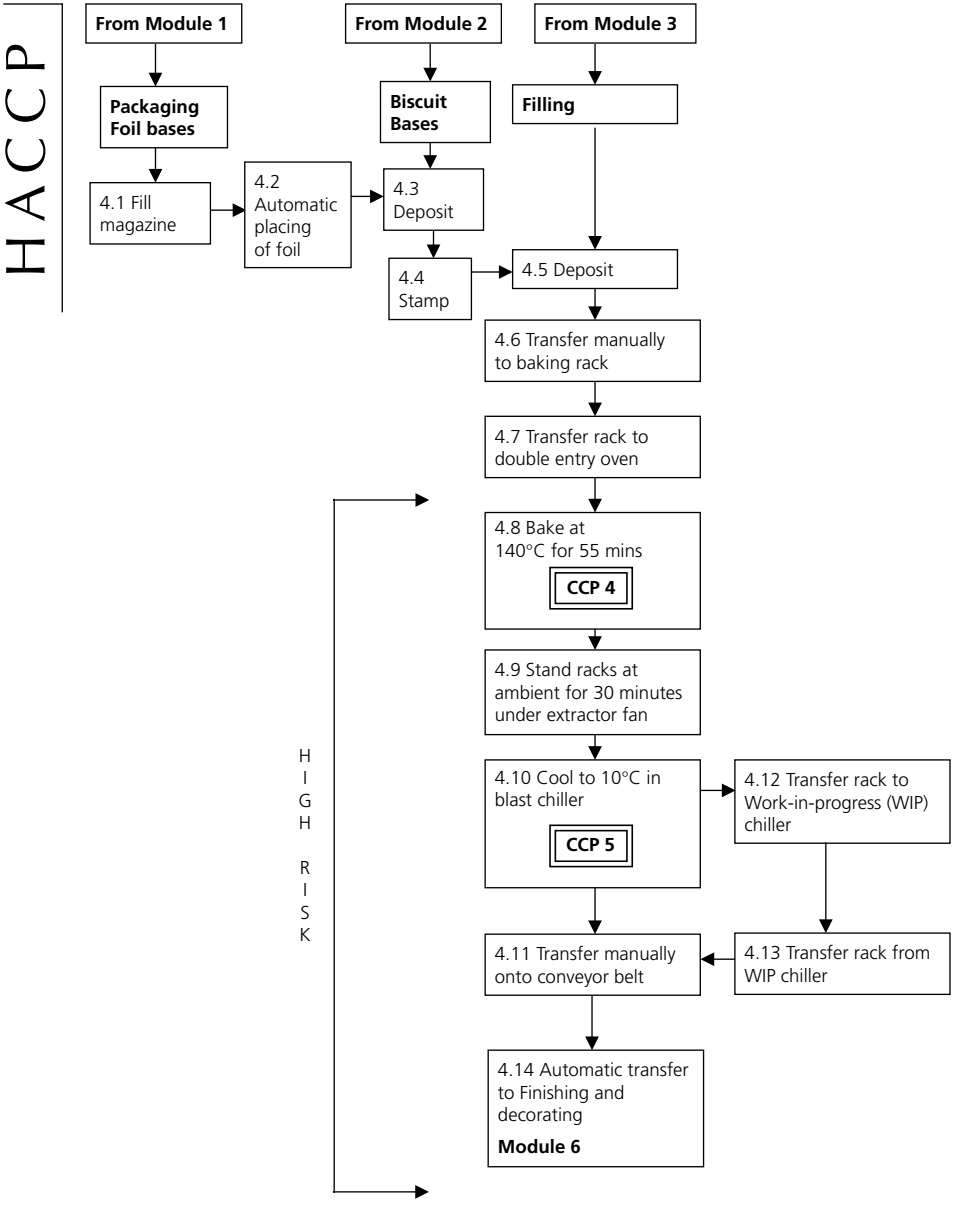


Figure CS.7 Module 4: Assembly, cooking/cooling (baked products).

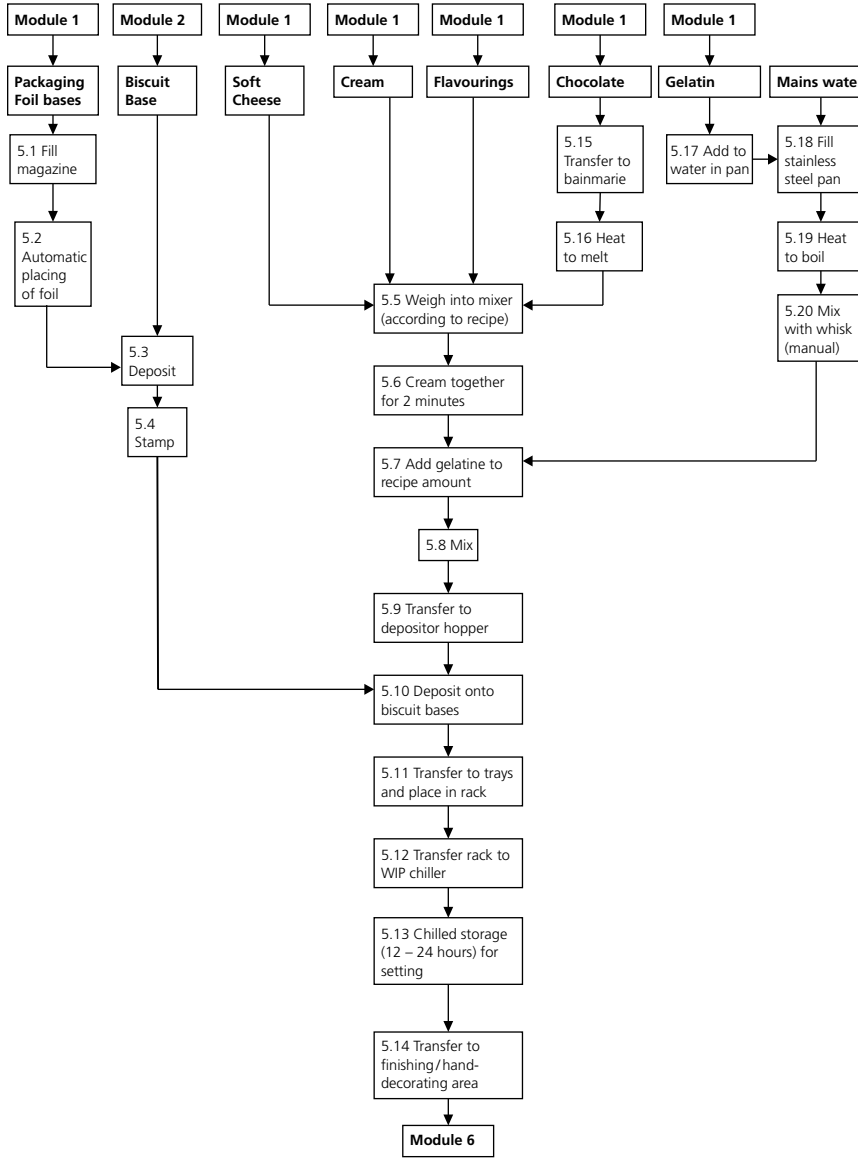


Figure CS.8 Module 5: Assembly (non-baked). *Note:* Complete module is in high risk area.

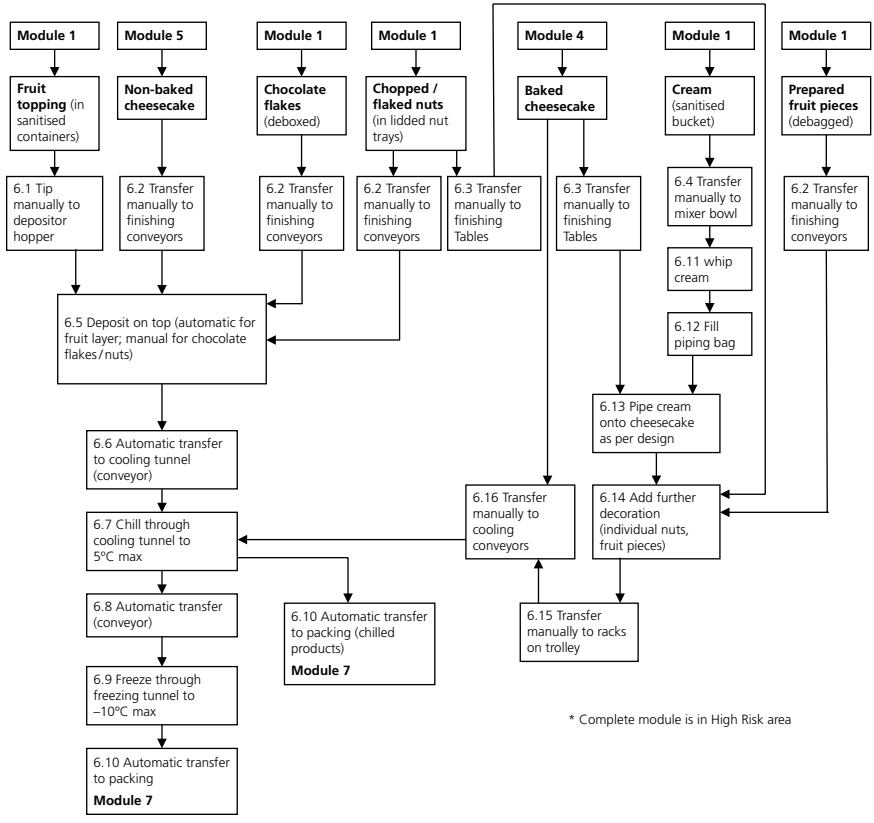


Figure CS.9 Module 6: Finishing/decorating, chilling/freezing.

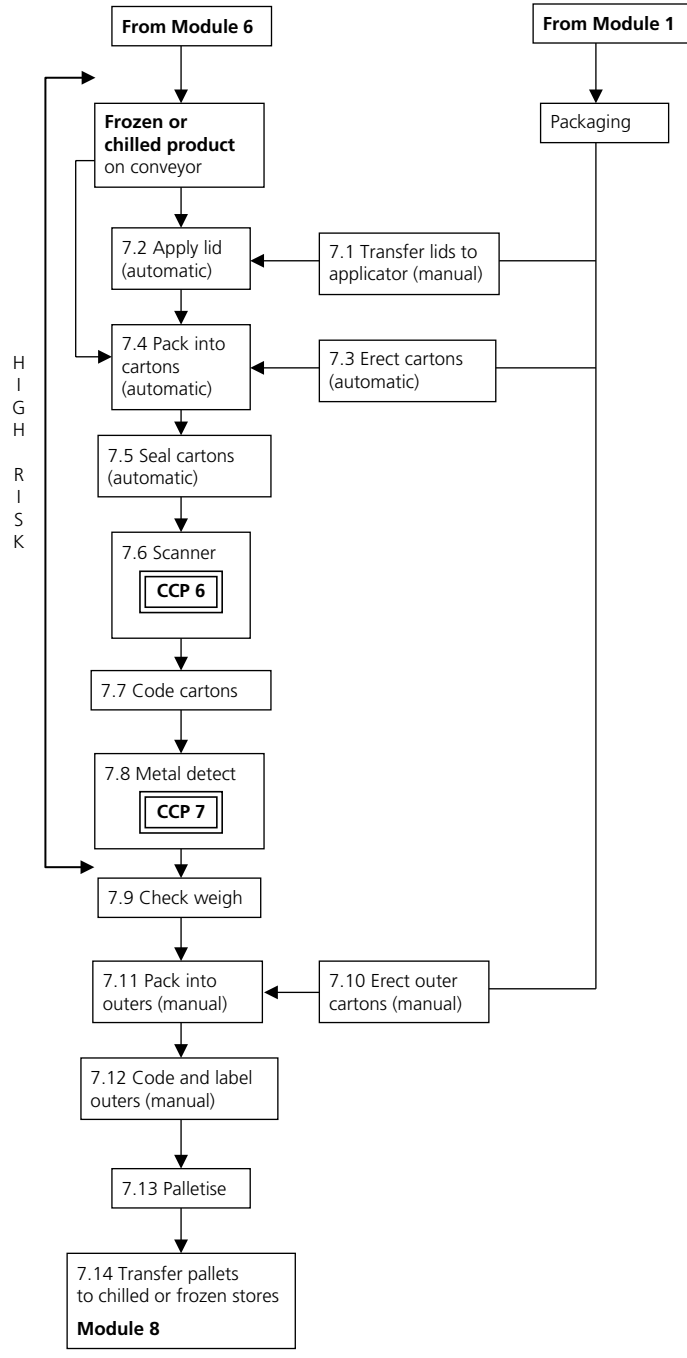


Figure CS.10 Module 7: Packing.

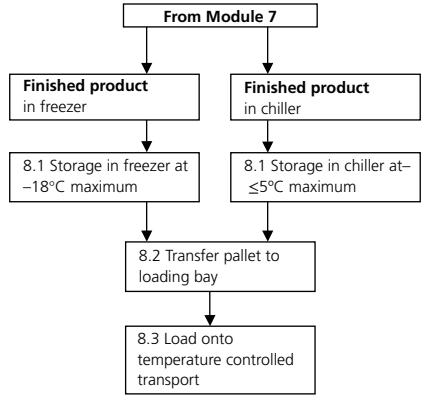


Figure CS.11 Module 8: Storage and despatch.

7 Hazard analysis and CCP identification

The HACCP team's decisions on hazard analysis and CCP identification can be followed in the hazard analysis chart (Form CS.1), which also gives some brief justification notes of the decisions taken. Because this is a complex operation, both in terms of the manufacture of a range of products on site and because both baked and non-baked cheesecakes are produced, it is necessary to have a detailed understanding of the control mechanisms in place throughout the food safety management system (i.e. PRPs, HACCP, product and facility design constraints) to fully understand how and why the HACCP team has made these decisions. This can only really be achieved with specific manufacturing site experience and sector expertise, but this expanded discussion aims to cover some of the key food safety considerations that were understood and debated by the team. However, as noted at the beginning of this case study, there is much more discussion, expert evaluation and judgement needed to identify and control the food safety risks associated with this type of operation than we are able to show in the pages available for this HACCP plan case study. Readers should therefore be aware that this does not form a complete solution and that PRPs to control potential contamination from handling and the environment around production, as well as to control the normal facility and raw material considerations in any operation, will be very important in this operation. These are not shown here although they would clearly need to be in place and verified as effective in practice (see Section 2.2.2).

Note: The team is planning on having their system certified to FSSC22000, and therefore has utilised the concept of Operational PRPs, i.e. where a specific PRP activity is deemed to be *essential* for food safety.

7.1 Product designs

All new product and recipe designs go through an individual formal product safety evaluation and have to be signed off by the HACCP team and product development before they can be brought into manufacture. This process is to ensure that the new designs can be made safely within the constraints of the existing manufacturing systems and that any new hazard issues associated with ingredients can be controlled effectively. The paperwork is reviewed and authorised by the site technical and operations managers to complete this process.

7.2 Special ingredient considerations

Whilst all ingredients are important and the supplier approval procedures (PRP) ensure that all ingredients are bought to specification from approved suppliers, there are special considerations for certain ingredients that could affect the safety of the products. The HACCP team considered the likely microbiological, chemical and physical hazards associated with all ingredients and packaging materials (Form CS.1) and key issues were identified with respect to potential allergen contamination of certain ingredients – cross-contamination of nuts with other non-specified nuts – and potential pathogen contamination of ingredients added after baking or to the non-baked products.

- Dairy ingredients – soft cheese and cream.
  - Both of these ingredients are manufactured elsewhere on the same manufacturing site. Because of this, the manufacturing conditions are very well understood, and the same PRPs are followed as in the cheesecakes area. There is also information sharing regarding HACCP, CCP and PRPs monitoring and verification, which helps to provide additional confidence in the ingredients.
- Chocolate flakes.
  - The HACCP team decided that pathogen contamination (*Salmonella* spp.) was a concern because of historical evidence of *Salmonella* in chocolate and, since the chocolate flakes are used for decoration post baking, that this was a sensitive ingredient that required priority (critical) control as part of supplier assurance. This is in contrast to the chocolate chips which, although they could potentially have the same contamination hazard as ingredients, will be baked within the product and will be handled separately from the chocolate flakes.
- Nuts – hazelnuts, almonds and pecans all added post baking.
  - Nuts are a raw agricultural commodity and are known to be susceptible to pathogen contamination due to the growing and harvesting conditions. Like the risks in cocoa beans, the precursor to chocolate, an effective

control measure for pathogens such as *Salmonella* spp. and *E. coli* O157:H7 exists in the nut-roasting process that all of these ingredients receive at the supplier. However, also like the issues raised for chocolate flakes earlier, there is historical evidence of poor hygienic practices and *Salmonella* spp. presence in processed nut products, and the HACCP team decided that these were all sensitive ingredients for pathogen contamination that required priority (critical) control as part of supplier assurance. Alflatoxin was identified as a further hazard that needed to be investigated for significance as was further allergen contamination – it was recognised that the nuts are all allergens in their own right, which need managing and effective labelling, but the team was also concerned about potential cross-contamination with other nuts since it is known that individuals can be allergic to some nuts but not others.

- Freshly prepared fruits, specifically strawberries and raspberries.
  - Some of the hand-finished products include a fresh fruit garnish with either strawberries or raspberries. Because of the potential for pathogen contamination of the raw fruits, e.g. *Salmonella* spp., *L. Monocytogenes*, *E. coli* O157:H7 and viruses, e.g. norovirus, the supply of strawberries and raspberries was investigated as part of a special development project to improve the safety management of these products. This entailed working closely with one specific fruit supplier to ensure a safe and consistent ingredient. Product purchased is grown in enclosed poly-tunnels in sterile compost. Fruit is picked, washed and packed under hygienic conditions and does not come into contact with field fruit. Because of the heated poly-tunnel set up the fruits are available for most of the year round, and the enclosed system means that the likelihood of contamination from animals and pests is minimal.

7.3 High risk area management

The high risk area is a key part of food safety management for all the cheesecake products. It handles all activities post oven for the baked products and all manufacturing steps, with the exception of some basic ingredient preparation steps (e.g. removal of outer packaging), for the non-baked products. In both the cases, the product remains in the high risk area until sealed in primary cartons, when it passes via automatic conveyor through the wall into the outer packing room.

The high risk area has been designed using the principles of good hygienic practices to minimise the risk of product cross-contamination. These

design considerations are essential for the safety of the cheesecake products, and it must be stressed that the range of products made requires the high risk area to be tightly managed at all times. Specific controls and considerations include the following:

- Segregation of the high risk area.
  - The high risk area is designed to be completely segregated from the rest of the facility with respect to access, personnel and materials movement, air control and sanitation and waste management. There is only one entry point for staff, and this is designed with a hygiene entry/exit juncture (Holah and Lelieveld 2011), including a bench barrier system.
- Controls on personnel entering the high risk area.
  - All personnel entering the high risk area go through a complete change of protective clothing, including footwear. High risk area clothing and footwear is captive to the area and laundered separately under a specific contract. Changing routines and training cover the proper use of the bench-barrier system, as well as the order for putting on protective clothing items and hand-washing routines.
- Controls on raw materials and part-produced product entering the high risk area.
  - Part-produced product enters the high risk area by conveyors at the end of the post oven cooling process. All other ingredients are transferred through the materials hatch where containers are sprayed with sanitizer on entry.
- Control of air quality within the high risk area.
  - The high risk area is under a positive pressure air system using HEPA filtered air to prevent microbiological contamination from the air supply.
- Hygiene and sanitation controls within the high risk area.
  - All hygiene and sanitation controls are designed specifically for the high risk area and use dedicated equipment and materials. Bagged waste is removed through the hatch at the secondary packing room end. All drains flow away from the high risk area and are subject to *L. monocytogenes* control and monitoring procedures.

With the high risk area controls in place, the likelihood of pathogen contamination of products is low. Nevertheless, this is identified by the HACCP team as a recurring significant hazard throughout Module 5 which highlights the importance of the high hygiene practice PRPs. In addition, all chilled products have their shelf-life limited to 10 days maximum to prevent the growth of listeria to hazardous levels within the product shelf-life at chilled temperatures, and all products have instructions to consume within 48 h of opening.

Form CS.1 Cheesecake manufacture: hazard analysis and CCP identification for raw materials and process steps

Raw material	Hazard	Control measures	Significant hazard?	Q1	Q1a	Q2	Q3	Q4	CCP	Justification
Ingredients										
Low fat soft cheese (pasteurised)	Presence of vegetative pathogens, e.g. *Salmonella, Listeria*	In-house approved supplier, operates to agreed specification, pH 4.4, effective cooking (baked products only)	Y	Y		N	N	–	N	Low fat soft cheese is manufactured in-house on the same site. The soft cheese product will not support the growth of the pathogens concerned due to the low pH. Additional control measure for baked products in that they will be cooked, but this is not available for non-baked, and therefore the soft cheese must be consumable in its current state – which it is. The decision at Q3 was taken because the HACCP and hygiene controls in the cheese department were considered sufficient to prevent contamination in excess of acceptable levels. Cheese and cheesecake department supervisors both sit on site HACCP strategy team and results for both departments reviewed on a daily basis.
	Presence of dairy allergens	Labelling	Y	Y		N	Y	Y	N	Labelling control at later step is designed to ensure all allergen-containing products are adequately labelled

Double cream (pasteurised)	Presence of vegetative pathogens, e.g. *Salmonella*, *Listeria*	In-house approved supplier, operates to agreed specification, effective cooking (baked products only)	Y	Y	N	N	–	N	The same comment as for soft cheese – this is a ready to consume ingredient made on the same site under a HACCP programme within the cream department.
	Presence of dairy allergens	Labelling	Y	Y	N	Y	Y	N	Labelling control at later step is designed to ensure all allergen-containing products are adequately labelled.
Whole egg (liquid pasteurised) contains sugar 10%)	Presence of *Salmonella*	Approved supplier, agreed specification, effective cooking	Y	Y	N	Y	Y	N	Supplier audited on a regular basis and pasteurization step verified at the supplier. Vegetative pathogens destroyed by cooking.
	Presence of egg allergens	Labelling	Y	Y	N	Y	Y	N	Labelling control at later step is designed to ensure all allergen-containing products are adequately labelled.
Chocolate chips	Presence of *Salmonella*	Approved supplier, agreed specification, effective cooking	Y	Y	N	Y	Y	N	Supplier audited on a regular basis. Product will be cooked.
	Presence of dairy and soy (lecithin) allergens	Labelling	Y	Y	N	Y	Y	N	Labelling control at later step is designed to ensure all allergen-containing products are adequately labelled.

Q1. Do control measures exist? / Q1a. Is control at this step necessary for safety?
Q2. Is the step specifically designed to eliminate or reduce the likely occurrence of a hazard to an unacceptable level?
Q3. Could contamination with identified hazard(s) occur in excess of acceptable level(s) or could these increase to unacceptable levels?
Q4. Will a subsequent step eliminate identified hazards or reduce the likely occurrence of a hazard to acceptable level(s)?

(*Continued*)

Form CS.1 (*Continued*)

Raw material	Hazard	Control measures	Significant hazard?	Q1	Q1a	Q2	Q3	Q4	CCP	Justification
Chocolate flakes	Presence of *Salmonella*	Approved supplier, agreed specification	Y	Y		N	Y	N	**Y**	Although the chance of *Salmonella* contamination in chocolate flakes is considered to be low the team was aware of historical evidence of *Salmonella* in chocolate, and therefore decided that it was a significant hazard since the flakes are added after cooking.
	Presence of dairy and soy (lecithin) allergens	Labelling	Y	Y		N	Y	Y	N	Labelling control at later step is designed to ensure all allergen-containing products are adequately labelled.
Nut ingredients* Chopped hazelnuts, Flaked almonds, pecan halves *Would normally be considered individually; but to save space (in this case study example), they have been grouped together here because the same hazards applied in each case for this operation.	Presence of Aflatoxin	Approved supplier, agreed specification, Certificate of Analysis	N						N	Low likelihood of occurrence based on national surveillance data. Controlled by supplier. Supplier management per the PRP

Presence of vegetative pathogens, e.g. *Salmonella* spp., Escherichia coli O157:H7	Approved supplier, agreed specification, certificate of analysis	Y	Y	N	Y	N	**Y**	Controlled by supplier. Supplier management is critical for this ingredient. Nut ingredients do not receive a heat kill step.
Presence of allergens from other nuts at supplier's premises	Supplier control, supplier audit	Y	Y	N	Y	N	**Y**	Controlled by supplier Note: Each nut ingredient is also a known allergen in its own right and will be subject to allergen control on site – nut handling procedures.
Presence of nut allergens	Labelling	Y	Y	N	Y	Y	N	Labelling control at later step is designed to ensure all allergen-containing products are adequately labelled. No free from products are manufactured on site.
Choking hazard in children <3 years old – pecans only	Label warning on the pecan variety that the product contains pecans	Y	Y	N	Y	Y	N	Labelling at a later step.

Q1. Do control measures exist? / Q1a. Is control at this step necessary for safety?
Q2. Is the step specifically designed to eliminate or reduce the likely occurrence of a hazard to an unacceptable level?
Q3. Could contamination with identified hazard(s) occur in excess of acceptable level(s) or could these increase to unacceptable levels?
Q4. Will a subsequent step eliminate identified hazards or reduce the likely occurrence of a hazard to acceptable level(s)?

(*Continued*)

Form CS.1 (*Continued*)

Raw material	Hazard	Control measures	Significant hazard?	Q1	Q1a	Q2	Q3	Q4	CCP	Justification
	Presence of shell fragments	Supplier control, supplier audit Visual check on debagging and depositing	N						N	The team decided that this was not a significant hazard due to historical data on shell fragment absence combined with an assessment of the likely harm to the consumer from shell fragment, which was considered to be negligible.
Biscuit crumb – digestive	Presence of wheat gluten – potential to cause allergic or intolerant reaction	Labelling	Y	Y		N	Y	Y	N	Labelling control at later step is designed to ensure all allergen-containing products are adequately labelled. Supplier control, supplier audit, visual check on debagging and sieving.
Biscuit crumb – chocolate	Presence of wheat gluten – potential to cause allergic or intolerant reaction. Also soy lecithin	Labelling	Y	Y		N	Y	Y	N	Labelling control at later step is designed to ensure all allergen-containing products are adequately labelled. Supplier control, supplier audit, visual check on debagging and sieving.
Biscuit crumb – amaretti	Presence of nut allergens	Labelling	Y	Y		N	Y	Y	N	Labelling control at later step is designed to ensure all allergen-containing products are adequately labelled

Butter	Presence of dairy allergens	Labelling	Y	Y	N	Y	Y	N	Labelling control at later step is designed to ensure all allergen-containing products are adequately labelled. High fat content, salt. Material does not easily support growth of pathogens. Therefore, the team did not identify a microbiological pathogen hazard.
Sugar	No hazard identified							N	Supplier control, supplier audit, visual check on debagging and sieving.
Flour	Presence of wheat gluten – potential to cause allergic or intolerant reaction	Labelling	Y	Y	N	Y	Y	N	Labelling control at later step is designed to ensure all allergen-containing products are adequately labelled
Gelatine powder	No hazard identified		–					N	Supplier control, supplier audit, visual check on debagging and sieving.
Modified starch	No hazard identified		–					N	The modified starch used does not contain wheat or other grains containing gluten, therefore, it is not highlighted as an allergen risk. This would need to be reviewed if the supplier/specific ingredient is changed. Supplier control, supplier audit, visual check on debagging and sieving.

Q1. Do control measures exist? / Q1a. Is control at this step necessary for safety?
Q2. Is the step specifically designed to eliminate or reduce the likely occurrence of a hazard to an unacceptable level?
Q3. Could contamination with identified hazard(s) occur in excess of acceptable level(s) or could these increase to unacceptable levels?
Q4. Will a subsequent step eliminate identified hazards or reduce the likely occurrence of a hazard to acceptable level(s)?

(*Continued*)

Form CS.1 (*Continued*)

Raw material	Hazard	Control measures	Significant hazard?	Q1	Q1a	Q2	Q3	Q4	CCP	Justification
Flavours	No hazard identified								N	Material does not support growth of pathogens.
Fruit toppings	Foreign material, stalks, leaves, stones/pips. Choking hazard discussed by the team but no large stones/pips likely in the type of fruit purchased.		N						N	Supplier control, supplier audit, visual check on debagging. This is a low pH ingredient (pH < 4.0) which does not support the growth of pathogens. Therefore, the team has not identified a pathogen hazard in this case.
Freshly prepared fruits (washed blueberries, raspberries, strawberries, and stoned cherries)	Presence of pathogens, e.g. *Salmonella* spp., L. Monocytogenes, *E. coli* O157:H7, viruses, e.g. norovirus.	Products are washed by supplier using chlorine washing system.	Y	Y		N	Y	N	**Y**	Supplier assurance is critical. Product purchased is grown in enclosed poly-tunnels in sterile compost. Fruit is picked, washed and packed under hygienic conditions and does not come into contact with field fruit.
		Additional control measure of cooking in some cases (blueberries and cherries).	Y	Y		N	Y	Y	N	Due to the cooking process, the blueberries and cherries are lower risk as ingredients and do not require the same level of supplier assurance as the strawberries and raspberries added after cooking.

	Choking hazard discussed by the team for all freshly prepared fruits, but only cherries are seen to contain a significant hazard, i.e. cherry stones.	Label warnings that the product could contain cherry stones	Y	Y		N	Y	Y	N	Labelling at a later step. Supplier washing and inspection procedures minimise the risk – supplier assurance prerequisite programme.
Vegetable oil	No hazard identified								N	Material does not support growth of pathogens.
Packaging										
Foil bases	No hazard identified								N	Food grade material
Waxed cardboard lids	No hazard identified								N	Food grade material
Boxes, outers	No hazard identified								N	No contact with product.

Q1. Do control measures exist? / Q1a. Is control at this step necessary for safety?
Q2. Is the step specifically designed to eliminate or reduce the likely occurrence of a hazard to an unacceptable level?
Q3. Could contamination with identified hazard(s) occur in excess of acceptable level(s) or could these increase to unacceptable levels?
Q4. Will a subsequent step eliminate identified hazards or reduce the likely occurrence of a hazard to acceptable level(s)?

(*Continued*)

Form CS.1 (*Continued*)

Process step	Hazard	Control measures	Significant hazard?	Q1	Q1a	Q2	Q3	Q4	CCP	Justification
Module 1										
1.1 Intake of ingredients	Microbiological growth (chilled ingredients)	Temperature control	N						N	Temperature of delivery must be <5°C. Reject if above. This would be a control point in the quality management system. The team noted that there is no subsequent step for chilled ingredients. This could be managed as an OPRP in it being a PRP but an essential element.
	Physical contamination	Intact packaging	N						N	Packaging standards specified. Visual check before acceptance – prerequisite programmes.
1.2 Intake of packaging	No hazard identified								N	
1.3 Transfer to chiller	Microbiological growth	Time/ temperature control	N						N	Speed of transit means growth is highly unlikely.
1.4 Transfer to ambient store	No hazard identified								N	Food hygiene practices are observed – prerequisite programme.
1.5 Transfer to nut storage area	Cross-contamination to other materials	Intact packaging	N						N	Food hygiene practices are observed – prerequisite programme. Nut packaging intact. *This too could be operated as an OPRP in that it is an essential element of the allergen control program.*

1.6 Transfer to packaging store	No hazard identified								N	Food hygiene practices are observed – prerequisite programme.
1.7 Chilled storage	Microbiological growth	Temperature control Use within shelf life	N						N	Not a *significant* hazard, but the control is essential as part of the prerequisite programme – *another OPRP could be put in place. For the chilled products, there is no additional control.*
1.8 Ambient storage	Physical contamination Pest infestation	Clean, dry store	N						N	No significant contamination risk – GMP and pest control in place.
1.9 Storage of packaging	No hazard identified								N	
1.10 Transfer to ingredient preparation area	Physical contamination	Covered containers	N						N	Food hygiene practices are observed – prerequisite programme.
	Microbiological growth within chilled ingredients	Time/ temperature control	Y	Y		N	Y	Y	N	Prerequisite programme. Some products will be cooked, storage time insufficient for toxin formation.
1.11 Debox and debag (chilled and chilled storage ingredients)	Microbiological contamination from outer packaging if not properly controlled	Hygienic handling – prerequisite programmes.	N						N	Prerequisite programme – the team identified this as an OPRP, which would be strongly recommended for these chilled products, particularly since there is no cooking for some products.

Q1. Do control measures exist? / Q1a. Is control at this step necessary for safety?
Q2. Is the step specifically designed to eliminate or reduce the likely occurrence of a hazard to an unacceptable level?
Q3. Could contamination with identified hazard(s) occur in excess of acceptable level(s) or could these increase to unacceptable levels?
Q4. Will a subsequent step eliminate identified hazards or reduce the likely occurrence of a hazard to acceptable level(s)?

(*Continued*)

Form CS.1 (*Continued*)

Process step	Hazard	Control measures	Significant hazard?	Q1	Q1a	Q2	Q3	Q4	CCP	Justification
1.12 Debox/debag/ Delid	No hazard identified cross-contamination with packaging as a physical hazard was discussed by the team but discounted.								N	Food hygiene practices are observed – prerequisite programme.
1.13 Debox nuts	No hazard identified Cross-contamination with packaging as a physical hazard was discussed by the team but discounted.								N	Prerequisite programme. Deboxing done in segregated nut room with colour-coded containers only used for specific nuts. Identified as an OPRP by the team.
1.14 Sieving	No hazard identified. This is a control measure.								N	Food hygiene and equipment maintenance in place – prerequisite programmes.
1.15 Weighing	Microbiological contamination if cream tank nozzles not adequately cleaned	Validated effective cleaning programme	N						N	Effective food hygiene practices are observed – prerequisite programme. Identified as an OPRP by the HACCP team.
1.16 Transfer to filling manufacture areas	Microbiological growth within chilled ingredients	Time/ temperature control	N						N	Storage time insufficient for toxin formation.
1.17 Transfer to base manufacture areas	No hazard identified								N	

1.18 Transfer to finishing (high care) area	Microbiological contamination to other ingredients	Debox in low risk Spray containers with sanitiser.	N	N	Effective food hygiene practices are observed – prerequisite programme. Identified as an OPRP by the HACCP team.
	Nut contamination to other ingredients/process	Use lidded 'nut only' colour-coded plastic containers (specific colour for each nut type). At this stage, nuts are still in sealed bags.	N	N	Food hygiene practices are observed – prerequisite programme
1.18 Transfer of packaging to packing area	No hazard identified			N	
Module 2					
Steps 2.1 – 2.6	No hazard identified at any of these process steps			N	Food hygiene practices are observed – prerequisite programme.

Q1. Do control measures exist? / Q1a. Is control at this step necessary for safety?
Q2. Is the step specifically designed to eliminate or reduce the likely occurrence of a hazard to an unacceptable level?
Q3. Could contamination with identified hazard(s) occur in excess of acceptable level(s) or could these increase to unacceptable levels?
Q4. Will a subsequent step eliminate identified hazards or reduce the likely occurrence of a hazard to acceptable level(s)?

(*Continued*)

Form CS.1 (*Continued*)

Process step	Hazard	Control measures	Significant hazard?	Q1	Q1a	Q2	Q3	Q4	CCP	Justification
Module 3										
3.1 Manual tipping of soft cheese to mixing bowl	No hazard identified								N	Food hygiene practices are observed – prerequisite programme.
3.2 Manual tipping of dry ingredients	No hazard identified								N	Food hygiene practices are observed
3.3 Manual decanting of liquid ingredients	Microbiological growth in the egg component	Time/ Temperature control. Cooking at later stage.	Y	Y		N	Y	Y	N	Decanting time not long enough to allow outgrowth of spores or toxin formation. Food hygiene practices are observed – prerequisite programme.
3.4 Mixing of soft cheese to soften	Microbiological growth	Time/ temperature control. Cooking at later stage.	Y	Y		N	Y	Y	N	Mixing time not long enough to allow spore outgrowth or toxin formation.
3.5 Manual premixing of sugar and flour	No hazard identified								N	Food hygiene practices are observed – prerequisite programme.
3.6 Manual slurrying of egg, starch and flavour	Microbiological growth	Time/ Temperature control. Cooking at later stage.	Y	Y		N	Y	Y	N	Slurry time not long enough to allow spore outgrowth or toxin formation. Food hygiene practices are observed – prerequisite programme.

Steps 3.7–3.16	No hazards identified at any of these process steps.							N	Food hygiene practices are observed – prerequisite programme.
Module 4									
Steps 4.1–4.7	No hazard identified at any of these process steps							N	Food hygiene practices are observed – prerequisite programme.
4.8 Baking	Survival of vegetative pathogens	Correct heat process	Y	Y	Y			**Y**	No subsequent step to remove hazard
4.9 Standing of racks under extractor (30 min)	No hazard identified	Racks need to be moved through quickly to the blast chiller						N	Food hygiene practices are observed to avoid cross-contamination. Time would not allow micro-hazard to develop. This step allows initial heat loss and prevents condensation problems in the blast chiller.
4.10 Cooling in blast chiller	Growth of surviving spore formers	Time/ temperature control	Y	Y	N	Y	N	**Y**	Cooling trials demonstrate reduction to 10°C in 90 min, therefore spore germination not likely if properly controlled, i.e. through the cooling curve. This is critical.
Steps 4.11–4.14	No hazard identified at any of these process steps	Needs to be moved through these transfer steps quickly						N	Food hygiene practices are observed – prerequisite programme.

Q1. Do control measures exist? / Q1a. Is control at this step necessary for safety?
Q2. Is the step specifically designed to eliminate or reduce the likely occurrence of a hazard to an unacceptable level?
Q3. Could contamination with identified hazard(s) occur in excess of acceptable level(s) or could these increase to unacceptable levels?
Q4. Will a subsequent step eliminate identified hazards or reduce the likely occurrence of a hazard to acceptable level(s)?

(*Continued*)

Note: Modules 5 and 6 take place entirely in the high risk area. High risk area special food hygiene practices are observed throughout this area – see discussion in text for more detail. This is a prerequisite programme and may be considered an operational prerequisite in ISO22000 systems. Cross-contamination with microbial pathogens was considered for all steps in this area; however, the combination of ingredient controls, high risk area design and operation routines, including control of personnel, equipment and practices, means that the likelihood of contamination is low. Nevertheless, this is identified as a recurring significant hazard throughout the module; and although it is not possible to develop a process-based CCP for this hazard, the special food hygiene practices of the high risk area are prioritised. In addition, all chilled products have their shelf life limited to 10 days maximum to prevent the growth of listeria to hazardous levels within the product shelf life at chilled temperatures and all products have instructions to consume within 48 h of opening.

Form CS.1 (*Continued*)

Process step	Hazard	Control measures	Significant hazard?	Q1	Q1a	Q2	Q3	Q4	CCP	Justification
Module 5										
5.1 Transfer of foil bases to magazine	No hazard identified								N	
5.2 Placing of foil bases onto line	No hazard identified								N	
5.3 Depositing of biscuit base	Cross contamination with microbial pathogens, e.g. *Listeria*	High risk area special food hygiene practices.	Y	Y		Y	N		N	Hygiene procedures mean that it is unlikely that contamination is possible within the high risk area.
5.4 Blocking of biscuit base	Cross-contamination with microbial pathogens, e.g. *Listeria*	High risk area special food hygiene practices.	Y	Y		Y	N		N	Hygiene procedures mean that it is unlikely that contamination is possible within the high risk area.

5.5 Weigh into mixer according to recipe (soft cheese, cream, flavourings, melted chocolate)	Cross-contamination with microbial pathogens, e.g. *Listeria*	High risk area special food hygiene practices.	Y	Y	Y	N	N	Hygiene procedures mean that it is unlikely that contamination is possible within the high risk area.
5.6 Cream together for 2 min	No hazard identified						N	Food hygiene practices are observed – prerequisite programme.
5.7 Add gelatine to recipe amount	Cross contamination with microbial pathogens, e.g. *Listeria*	High risk area special food hygiene practices.	Y	Y	Y	N	N	Hygiene procedures mean that it is unlikely that contamination is possible within the high risk area.
5.8 Automatic mixing	No hazard identified						N	Food hygiene practices are observed – prerequisite programme.
5.9 Transfer to depositor hopper	Cross-contamination with microbial pathogens, e.g. *Listeria*	High risk area special food hygiene practices.	Y	Y	Y	N	N	Hygiene procedures mean that it is unlikely that contamination is possible within the high risk area.
5.10 Depositing of filling	Cross-contamination with microbial pathogens, e.g. *Listeria*	High risk area special food hygiene practices.	Y	Y	Y	N	N	Hygiene procedures mean that it is unlikely that contamination is possible within the high risk area.
5.11 Transfer to trays and place in rack	Cross-contamination with microbial pathogens, e.g. *Listeria*	High risk area special food hygiene practices.	Y	Y	Y	N	N	Hygiene procedures mean that it is unlikely that contamination is possible within the high risk area.

Q1. Do control measures exist? / Q1a. Is control at this step necessary for safety?
Q2. Is the step specifically designed to eliminate or reduce the likely occurrence of a hazard to an unacceptable level?
Q3. Could contamination with identified hazard(s) occur in excess of acceptable level(s) or could these increase to unacceptable levels?
Q4. Will a subsequent step eliminate identified hazards or reduce the likely occurrence of a hazard to acceptable level(s)?

(*Continued*)

Form CS.1 (*Continued*)

Process step	Hazard	Control measures	Significant hazard?	Q1	Q1a	Q2	Q3	Q4	CCP	Justification
5.12 Transfer rack to WIP chiller	Cross-contamination with microbial pathogens, e.g. *Listeria*	High risk area special food hygiene practices.	Y	Y		Y	N		N	Hygiene procedures mean that it is unlikely that contamination is possible within the high risk area.
5.13 Chilled storage for setting (12–24 h maximum)	Growth of pathogenic microorganisms	Limitation of time in chilled storage, temperature <2°C	Y	Y		Y	N		N	With the lower pH and chilled storage the team determined that the likelihood was no more than medium. Temperature and time controlled as a CP and OPRP.
5.14 Transfer to finishing/ hand-decorating area	Cross-contamination with microbial pathogens, e.g. *Listeria*	High risk area special food hygiene practices.	Y	Y		Y	N		N	Hygiene procedures mean that it is unlikely that contamination is possible within the high risk area.
5.15 Transfer to bain-marie	Cross-contamination with microbial pathogens, e.g. *Listeria*	High risk area special food hygiene practices.	Y	Y		Y	N		N	Hygiene procedures mean that it is unlikely that contamination is possible within the high risk area.
5.16 Heat to melt	No hazard identified								N	Chocolate is enclosed and not subject to cross-contamination risk
5.17 Add to water in pan	No hazard identified								N	Mains water with UV treatment on site.
5.18 Fill stainless steel pan	No hazard identified								N	Food hygiene practices are observed – prerequisite programme.

5.19 Heat to boil	No hazard identified						N	Boiling temperature makes microbiological hazards unlikely
5.20 Mix with whisk (manual)	Cross-contamination with microbial pathogens, e.g. *Listeria*	High risk area special food hygiene practices.	Y	Y	Y	N	N	Hygiene procedures mean that it is unlikely that contamination is possible within the high risk area.
Module 6								
6.1 Tipping of fruit topping to depositor hopper	Cross-contamination with microbial pathogens	High risk area special food hygiene practices.	Y	Y	Y	N	N	Hygiene procedures mean that it is unlikely that contamination is possible within the high risk area.
	Cross-contamination with potential physical contaminants		N				N	Choking hazards from physical contaminants discussed because all products are exposed, and there is high degree of manual handling in this area. The team concluded this was unlikely to be significant due to the existing prerequisite programmes.

Q1. Do control measures exist? / Q1a. Is control at this step necessary for safety?
Q2. Is the step specifically designed to eliminate or reduce the likely occurrence of a hazard to an unacceptable level?
Q3. Could contamination with identified hazard(s) occur in excess of acceptable level(s) or could these increase to unacceptable levels?
Q4. Will a subsequent step eliminate identified hazards or reduce the likely occurrence of a hazard to acceptable level(s)?

(*Continued*)

Form CS.1 (*Continued*)

Process step	Hazard	Control measures	Significant hazard?	Q1	Q1a	Q2	Q3	Q4	CCP	Justification
6.2 Transfer manually to finishing conveyors (non-baked cheesecakes, chocolate flakes, nuts – in lidded nut trays, prepared fruit pieces)	Cross-contamination with microbial pathogens	High risk area special food hygiene practices.	Y	Y		Y	N		N	Hygiene procedures mean that it is unlikely that contamination is possible within the high risk area.
	Cross-contamination with potential physical contaminants		N						N	Choking hazards from physical contaminants discussed because all products have exposed, and there is high degree of manual handling in this area. The team concluded this was unlikely to be significant due to the existing prerequisite programmes.

6.3 Transfer manually to finishing tables (baked cheesecakes, nuts – in lidded nut trays)	Cross-contamination with microbial pathogens	High risk area special food hygiene practices.	Y	Y	Y	N	N	Hygiene procedures mean that it is unlikely that contamination is possible within the high risk area.
	Cross-contamination with potential physical contaminants		N				N	Choking hazards from physical contaminants discussed because all products are exposed, and there is high degree of manual handling in this area. The team concluded this was unlikely to be significant due to the existing prerequisite programmes.
6.4 Decant cream into mixer bowl	Cross-contamination with microbial pathogens	High risk area special food hygiene practices.	Y	Y	Y	N	N	Hygiene procedures mean that it is unlikely that contamination is possible within the high risk area.
6.5 Deposit layer on top of cheesecake – manual for chocolate flakes/ nuts, automatic for fruit layer	Cross contamination with microbial pathogens	High risk area special food hygiene practices.	Y	Y	Y	N	N	Hygiene procedures mean that it is unlikely that contamination is possible within the high risk area.
	Cross-contamination with potential physical contaminants		N				N	Choking hazards from physical contaminants discussed because all products are exposed, and there is high degree of manual handling in this area. The team concluded this was unlikely to be significant due to the existing prerequisite programmes.

Q1. Do control measures exist? / Q1a. Is control at this step necessary for safety?
Q2. Is the step specifically designed to eliminate or reduce the likely occurrence of a hazard to an unacceptable level?
Q3. Could contamination with identified hazard(s) occur in excess of acceptable level(s) or could these increase to unacceptable levels?
Q4. Will a subsequent step eliminate identified hazards or reduce the likely occurrence of a hazard to acceptable level(s)?

(*Continued*)

Form CS.1 (*Continued*)

Process step	Hazard	Control measures	Significant hazard?	Q1	Q1a	Q2	Q3	Q4	CCP	Justification
6.6 Automatic transfer to cooling tunnel (conveyor)	Cross contamination with microbial pathogens	High risk area special food hygiene practices.	Y	Y		Y	N		N	Hygiene procedures mean that it is unlikely that contamination is possible within the high risk area.
6.7 Chill through cooling tunnel (to 5°C maximum)	Cross-contamination with microbial pathogens	High risk area special food hygiene practices.	Y	Y		Y	N		N	Hygiene procedures mean that it is unlikely that contamination is possible within the high risk area.
6.8 Automatic transfer (conveyor)	Cross-contamination with microbial pathogens	High risk area special food hygiene practices.	Y	Y		Y	N		N	Hygiene procedures mean that it is unlikely that contamination is possible within the high risk area.
6.9 Freeze through freezing tunnel to – 15°C maximum	Pathogen growth	Temperature control	N						N	Growth unlikely in a freezing process
6.10 Automatic transfer to packing (conveyor)	Cross contamination with microbial pathogens	High risk area special food hygiene practices.	Y	Y		Y	N		N	Hygiene procedures mean that it is unlikely that contamination is possible within the high risk area.
6.11 Whip cream	Cross contamination with microbial pathogens	High risk area special food hygiene practices.	Y	Y		Y	N		N	Hygiene procedures mean that it is unlikely that contamination is possible within the high risk area.

6.12 Fill piping bag	Cross contamination with microbial pathogens	High risk area special food hygiene practices.	Y	Y	Y	N	N	Piping bags are single use blue polythene bags
6.13 Pipe cream onto cheesecake as per recipe design	Cross contamination with microbial pathogens	High risk area special food hygiene practices.	Y	Y	Y	N	N	Hygiene procedures mean that it is unlikely that contamination is possible within the high risk area.
6.14 Add further decoration as per recipe design (individual nuts, fruit pieces)	Allergen cross-contamination	Product containing nuts packed last Effective cleaning after packing Dedicated equipment	N				N	Allergen control essential. Nut products made at the end of the day. Special 'deep' cleaning procedure to be used for the line. Validated cleaning is part of prerequisite programmes.
	Cross-contamination with potential physical contaminants		N				N	Choking hazards from physical contaminants discussed because all products are exposed, and there is high degree of manual handling in this area. The team concluded this was unlikely to be significant due to the existing prerequisite programmes.
	Cross contamination with microbial pathogens	High risk area special food hygiene practices.	Y	Y	Y	N	N	Hygiene procedures mean that it is unlikely that contamination is possible within the high risk area.

Q1. Do control measures exist? / Q1a. Is control at this step necessary for safety?
Q2. Is the step specifically designed to eliminate or reduce the likely occurrence of a hazard to an unacceptable level?
Q3. Could contamination with identified hazard(s) occur in excess of acceptable level(s) or could these increase to unacceptable levels?
Q4. Will a subsequent step eliminate identified hazards or reduce the likely occurrence of a hazard to acceptable level(s)?

(*Continued*)

Form CS.1 (*Continued*)

Process step	Hazard	Control measures	Significant hazard?	Q1	Q1a	Q2	Q3	Q4	CCP	Justification
6.15 Transfer manually to racks on trolleys	Cross-contamination	High risk area special food hygiene practices.	Y	Y		Y	N		N	Hygiene procedures mean that it is unlikely that contamination is possible within the high risk area.
6.16 Transfer manually to cooling conveyors	Cross-contamination	High risk area special food hygiene practices.	Y	Y		Y	N		N	Hygiene procedures mean that it is unlikely that contamination is possible within the high risk area.
Module 7										
Steps 7.1–7.3	No hazard identified at any of these process steps								N	Food hygiene practices are observed – prerequisite programme
7.4 Packing into pre-formed labelled cartons	Allergen-containing product placed in wrong container where allergen unlabelled.	Correct cartons for each product with appropriate allergen warnings.	Y	Y		N	Y	Y	N	There is a scanner further down the line.
	Choking hazard: cherry stones and pecans	For cherry and pecan nut products, a warning label to indicate that the product is unsuitable for children of <3 years of age	Y	Y		N	Y	Y	N	There is a scanner further down the line.

7.5 Sealing of cartons	Subsequent microbiological and physical contamination	Adequate seal	N			N	Product is already lidded. GMP used.
7.6 Scanning of sealed cartons	Allergen-containing product placed in wrong container where allergen unlabelled. Choking hazard – cherry stones and pecans packed in wrong container, i.e. which does not have warning statement for children <3 years of age	All products pass through functioning scanner device.	Y	Y	Y	**Y**	Allergen control essential as is choking warning for small children. Scanner will pick up wrong cartons that may be received in stack from printer.
7.7 Coding of cartons	Loss of traceability	Correct coding	N			N	Legal control measure
7.8 Metal detection	Presence of metal not identified	All products pass through a functioning metal detector	Y	Y	Y	**Y**	No subsequent step to remove hazard
7.9 Check weighing	No hazard identified					N	Legal requirement, i.e. to meet declared weight and may be managed as a CP.
Steps 7.10–7.14	No hazard identified at any of these process steps					N	

Q1. Do control measures exist? / Q1a. Is control at this step necessary for safety?
Q2. Is the step specifically designed to eliminate or reduce the likely occurrence of a hazard to an unacceptable level?
Q3. Could contamination with identified hazard(s) occur in excess of acceptable level(s) or could these increase to unacceptable levels?
Q4. Will a subsequent step eliminate identified hazards or reduce the likely occurrence of a hazard to acceptable level(s)?

(*Continued*)

Form CS.1 (*Continued*)

Process step	Hazard	Control measures	Significant hazard?	Q1	Q1a	Q2	Q3	Q4	CCP	Justification
Module 8										
8.1 Storage in freezer	No hazard identified								N	
8.2 Storage in chilled store at 5°C maximum	Growth of pathogenic microorganisms	Chilled storage, temperature at the lower level 1–3°C	Y	Y		N	N		N	With the lower pH and chilled storage, the team determined that the likelihood was no more than medium. The product has a 10 day shelf life when stored correctly – temperature and time controlled as a CP
8.3 Transfer to loading bay	No hazard identified								N	
8.4 Load onto controlled temperature transport	No hazard identified								N	

Q1. Do control measures exist? / Q1a. Is control at this step necessary for safety?
Q2. Is the step specifically designed to eliminate or reduce the likely occurrence of a hazard to an unacceptable level?
Q3. Could contamination with identified hazard(s) occur in excess of acceptable level(s) or could these increase to unacceptable levels?
Q4. Will a subsequent step eliminate identified hazards or reduce the likely occurrence of a hazard to acceptable level(s)?

8 HACCP control chart

Form CS.1 shows not only the hazard analysis but also the CCP decision-making process, which was done using the questions of the Codex decision tree (Figure 3.2). The control and monitoring requirements for the identified CCPs can be seen in the HACCP control chart (Form CS.2). Several CCPs are identified to manage the ingredient supply chain – chocolate flakes, nuts and freshly prepared fruits. In these cases, it is the supplier management process that ensures the ingredients are produced in such a way to minimise contamination risks. This includes specifications, supplier approval and regular verification audits, microbiological and allergen-monitoring programmes performed by the suppliers and receipt of certificates of analysis. Several in process CCPs are also identified, and these are controlled and monitored as indicated (Form CS.2).

Important note: Normally, each process step is considered individually. For this case study example write up, where the hazard analysis indicated that the hazard, control measures and justification was the same for a number of steps occurring in sequence, they have been captured as one line of items to save space. Each step would be seen individually on a real HACCP plan.

Form CS.2 Cheesecake manufacture: HACCP control chart

Raw material/ process step	CCP No	Hazard to be controlled	Control measure	Critical limits	Monitoring			Corrective action	
					Procedure	Frequency	Responsibility	Procedure	Responsibility
Chocolate Flakes	1	Presence of *Salmonella* spp.	Approved supplier	Only buy from approved supplier	Check approved supplier list	Each delivery	Stores supervisor	Reject delivery	Stores supervisor
			Agreed specification	Absent/25 g	Check C of A for evidence of compliance	Each delivery	Stores supervisor	Reject delivery and notify HACCP team leader	Stores supervisor
Nuts	2	Presence of Pathogens, e.g. *Salmonella* spp.	Approved supplier	Only buy from approved supplier	Check approved supplier list	Each delivery	Stores supervisor	Reject delivery	Stores supervisor
			Agreed specification	Absent/25 g	Check C of A for evidence of compliance	Each delivery	Stores supervisor	Reject delivery and notify HACCP team leader	Stores supervisor
		Presence of Allergens from other nuts at supplier's premises	Approved supplier	Only buy from approved supplier	Check approved supplier list	Each delivery	Stores supervisor	Reject delivery	Stores supervisor

Freshly prepared fruits (washed blueberries, raspberries, strawberries, stoned cherries)	3	Presence of pathogens, e.g. *Salmonella* spp., *L. monocytogenes*, *Escherichia* coli O157:H7, viruses, e.g. norovirus.	Approved supplier Products are grown and handled under controlled conditions and are washed by supplier using chlorine washing system.	Only buy from approved supplier	Check approved supplier list	Each delivery	Stores supervisor	Reject delivery	Stores supervisor
Baking	4	Survival of vegetative pathogens	Correct heat process 140°C for 55 min	Core temperature 72°C minimum	Calibrated oven chart recorder visual check and sign off.	Each batch	Oven operator	Quarantine batch Inform line manager. Continue cooking or re-cook until 72°C is achieved	Production operator
Blast Cooling	5	Outgrowth of pathogenic spore forming micro-organism, e.g. *B. cereus*	Rapid cooling to < 10°C within 90 min	Core temperature <10°C within 120 min	Time in and time out recorded for all racks and checked by operator. Calibrated chiller chart recorder visual check and sign off.	Each batch	Production operator	Quarantine batch Inform line manager if exit from chiller is >10°C	Production operator/ supervisor

(*Continued*)

Form CS.2 (*Continued*)

Raw material/ process step	CCP No	Hazard to be controlled	Control measure	Critical limits	Monitoring			Corrective action	
					Procedure	Frequency	Responsibility	Procedure	Responsibility
								Risk-based decision depending on actual temperature, and this may include disposal of product or further blast chilling	Line manager/ HACCP team leader
Scanning of packed product	6	Allergen-containing product in unlabelled packaging Choking hazard (cherry stones and pecans) in <3 years	All products pass through suitable scanner	Scanner functioning at all times	Check with packaging samples	Start-up and end of run plus half-hourly on all product runs	Line operator	Re-check product since previous satisfactory check Notify HACCP team leader	Line manager

Raw material/ process step	CCP No	Hazard to be controlled	Control measure	Critical limits	Monitoring			Corrective action	
					Procedure	Frequency	Responsibility	Procedure	Responsibility
Metal detection	7	Ferrous metal contamination	Effective metal detection and rejection	Absence of all ferrous metal > 2.5 mm. Correctly calibrated metal detector working continuously.	Must reject 2.5 mm Ferrous test strip when placed at centre of product	Start up, every 60 min and end of production	Line operator	Re-check product since previous satisfactory check Notify HACCP team leader	Line manager

9 Implementation and maintenance

Validation of HACCP plan elements was carried out prior to implementation. Heat penetration studies were carried out on the batch oven to ensure that the required product centre temperature would be achieved and on the blast chill operation to confirm rapid cooling is sufficient to prevent spore outgrowth at the centre of the product after cooking. In addition, validation studies were carried out on the scanner and metal detectors to ensure that they were capable of operating at the line speed.

A phased implementation plan starting with Module 1 and following the process through to Module 8 was then carried out on a departmental basis. Now that the HACCP plan has been implemented, all CCP monitoring records are subject to review and sign off by the trained section supervisors at the end of each shift, and CCP performance is discussed at the weekly management meetings.

The maintenance plan typically includes monthly HACCP team meetings to discuss the following:

1. Verification activities such as deviations at a CCP, corrective and preventative actions, consumer complaints, audit results (internal and third party), microbiological test results – finished product and environmental monitoring. Particular emphasis will be paid to the review of the overall hygiene monitoring of the high risk area, which is typically done weekly by the technical manager and reported at the management meeting. Review of allergen swabbing results for verification of allergen clean out is also done weekly by the technical manager and reported at the management meeting.
2. Proposed changes to the system such as new ingredients/varieties/process changes that would result in alterations to the HACCP plan.
3. HACCP plan revalidation.
4. Training needs.
5. Emerging food safety trends and issues external to the company, especially those that relate to similar products or raw materials. The team will review likely root cause and use the information to strengthen their HACCP and overall food safety system.

APPENDIX B
Acronyms and glossary

Acronyms

ALOP	appropriate level of protection
CCP	critical control point
FAO	Food and Agriculture Organisation
FDA	Food and Drug Administration (USA)
FMEA	failure, mode and effect analysis
FSIS	Food Safety Inspection Service (USA)
FSO	food safety objective
GATT	General Agreement on Tariffs and Trade
GFSI	Global Food Safety Initiative
GHP	good hygiene practice
GMP	good manufacturing practice
HACCP	hazard analysis and critical control point
HARPC	Hazard Analysis and Risk-based Preventive Controls
HEPA	high-efficiency particulate air
IFST	Institute of Food Science and Technology (UK)
ILSI	International Life Sciences Institute
ISO	International Organisation for Standardisation
NACMCF	National Advisory Committee on Microbiological Criteria for Foods (USA)
NASA	National Aeronautics and Space Administration (USA)
PO	performance objective
SMEs	small and medium-sized enterprises
SPC	statistical process control
SQA	supplier quality assurance (also referred to as vendor assurance)
SSOP	sanitation standard operating procedure
USDA	United States Department of Agriculture
VA	vendor assurance (also referred to as SQA)
WHO	World Health Organisation
WTO	World Trade Organisation

HACCP: A Food Industry Briefing, Second Edition. Sara E. Mortimore and Carol A. Wallace.

Glossary

The sources of these definitions are indicated in brackets. Definitions that do not indicate their source have been developed by the authors.

Allergen: A compound capable of inducing a repeatable immune-mediated hypersensitivity response in sensitive individuals.

Appropriate level of protection: The level of protection deemed appropriate by a national government to protect human health within its territory (adapted from WTO 1995).

Audit: A systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled (ISO 2002).

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.

Contaminant: Any biological or chemical agent, foreign matter, or other substances not intentionally added to food which may compromise food safety or suitability (Codex 2009a).

Contamination: The introduction or occurrence of a contaminant in food or food environment (Codex 2009a).

Control (noun): The state wherein correct procedures are being followed and criteria are being met (Codex 2009b).

Control (verb): To take all necessary actions to ensure and maintain compliance with criteria established in the HACCP plan (Codex 2009b).

Control measure: Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level (Codex 2009b).

Corrective action: Any action to be taken when the results of monitoring at the CCP indicate a loss of control (Codex 2009b).

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 (Codex 2009b).

Critical limit: A criterion that separates acceptability from unacceptability (Codex 2009b).

Flow diagram: A systematic representation of the sequence of steps or operations used in the production or manufacture of a particular food item (Codex 2009b).

Food hygiene: All conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain (Codex 2009a).

Food poisoning: Illness associated with consumption of food which has been contaminated, particularly with harmful micro-organisms or their toxins (IFST 1998).

Food safety: Assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use (ILSI 2004).

Food safety objectives: The maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP) (ICMSF 2006).

Gantt chart: A project implementation timetable. The Gantt chart shows at a glance the timing and dependencies of each project phase.

Gap analysis: Assessment of the current situation to identify any missing items, e.g. specific gaps, from the required situation.

Global Food Safety Initiative (GFSI): Organized through the Consumer Goods Forum out of Paris, but with a global oversight from its board, which is drawn from industry.

Good manufacturing practice (GMP): The combination of manufacturing and quality control procedures aimed at ensuring that products are consistently manufactured to their specifications (IFST 1998).

HEPA filtration: Filters meeting the HEPA standard must satisfy certain criteria for particle size. They are typically used in areas that require cleaner air such as the high risk areas in the food industry and the medical profession.

HACCP (Acronym for Hazard Analysis Critical Control Point): A system which identifies, evaluates, and controls hazards which are significant for food safety (Codex 2009b).

HACCP control chart: Matrix or table detailing the control criteria (i.e. critical limits, monitoring procedures and corrective action procedures) for each CCP and preventative measure. Part of the HACCP plan.

HACCP plan: A document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety of the food chain under consideration (Codex 2009b).

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

HACCP system: The result of the implementation of the HACCP plan (ILSI 1999).

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: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect (Codex 2009b).

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 (Codex 2009b).

Hazard analysis chart: A working document which can be used by the HACCP team when applying HACCP principle 1, i.e. listing hazards and describing measures for their control.

Ingredients: All materials, including starting materials, processing aids, additives and compounded foods, which are included in the formulation of the product (IFST 1998).

Monitor (verb): The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control (Codex 2009b).

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

Operational prerequisite programme: PRP identified by the hazard analysis as essential in order to control the likelihood of introducing food safety hazards to and/or the contamination or proliferation of food safety hazards in the products(s) or process environment (ISO 2005).

Performance objectives: A specific microbiological criterion specifying the levels of contamination that should not be exceeded in raw of products to reduce the likelihood of cross-contamination in the consumer kitchen (adapted from ICMSF 2006).

Prerequisite programmes (1): Practices and conditions needed prior to and during the implementation of HACCP and which are essential for food safety (WHO 1999).

Prerequisite programmes (2): Procedures including good manufacturing practices that address operational conditions providing the foundation for the HACCP system (NACMCF 1997).

Primary production: Those steps in the food chain up to and including, for example, harvesting, slaughter, milking, fishing (Codex 2009a).

Quality management system: A structured system for the management of quality in all aspects of a company's business.

Raw materials: Any material, ingredient, starting material, semi-prepared or intermediate material, packaging material, etc., used by the manufacturer for the production of a product (IFST 1998).

Risk: A function of the probability of an adverse health effect and the severity of that effect consequential to a hazard(s) in food (Codex 1998a).

Significant hazards: Hazards that are of such a nature that their elimination or reduction to an acceptable level is essential to the production of safe foods (ILSI 1999).

Specification: A document giving a description of material, machinery, equipment, process or product in terms of its required properties or performance. Where quantitative requirements are stated, they are either in terms of limits or in terms of standards with permitted tolerances (IFST 1998).

Step: A point, procedure, operation or stage in the food chain including raw materials, from primary production to final consumption (Codex 2009b).

Supplier quality assurance: The programme of actions to ensure the quality of the raw material supply. Includes preparation of raw material and procedures to assess supplier competency, e.g. inspections, questionnaires.

Validation: Obtaining evidence that the elements of the HACCP are effective (Codex 2009b).

Verification: The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine compliance with the HACCP plan (Codex 2009b).

Water activity, a_w: A measure of the availability of water for the growth and metabolism of micro-organisms. It is expressed as the ratio of the water vapour pressure of a food or solution to that of pure water at the same temperature (IFST 1999).

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HACCP Resources

For those who will be going on to further education, training and practising in this field, we offer a few tips.

Further reading

This book is an introductory text and is not meant to be an in-depth practical guide to implementing HACCP, or broader food safety systems; there are other books for that. Below are a number of texts that are available. We have selected a few prominent titles that are in English unless otherwise stated:

Barach, J. and Dunaif, G.E. (eds) (2013) *A Systems Approach Using Preventative Controls for Safe Food Production. Part 1: Establishing a Food Safety System*, Grocery Manufacturers Association, Washington DC – A practical treatment of the preventative controls approach to food safety assurance.

British Standards Institute (2011) PAS 222:2011, *Prerequisite Programmes for Food Safety in the Manufacture of Food and Feed for Animals*, BSI, London, UK – A practical easy-to-read guide to basic conditions required for hygienic manufacture of food for animals.

Campden BRI (2000) *An Introduction to the Practice of Microbiological Risk Assessment for Food Industry Applications*, Guideline No. 28, Campden BRI, UK – Developed by a combined UK industry and government working party.

Campden BRI (2009) *HACCP – A Practical Guide*, 4th edn, Guideline No. 42, Campden BRI, Chipping Campden, UK – A high level overview similar to this one but with different case study examples.

Campden BRI (2010) *HACCP in Produce and Feed*, Guideline No. 64, Campden BRI, Chipping Campden, UK – A useful overview for anyone wanting to understand what the likely implementation will look like in these sectors.

Codex Alimentarius, 2009, *Food Hygiene Basic Texts*, 4th edn, www.fao.org/docrep/012/a1552e/a1552e00.htm – It contains the material used as the primary reference source for this book. The contents consist of the following:

- General principles of food hygiene
- HACCP system and guidelines for its application
- Principles for the establishment and application of microbiological criteria for foods

HACCP: A Food Industry Briefing, Second Edition. Sara E. Mortimore and Carol A. Wallace.

Holah, J. and Lelieveld, H.M.L. (2011) *Hygienic Design of Food Factories*, Woodhead Publishing, Cambridge, UK – Fairly detailed but a great reference for best practice in hygienically designed food processing facilities.

IFST (2013) *Food and Drink – Good Manufacturing Practice: A Guide to Its Responsible Management*, 6th edn, Institute of Food Science and Technology, Wiley-Blackwell, UK – A good general overview of the general elements that responsible mananufacturers will have in their food safety programme.

International Organization for Standardization (ISO) (2009) *Prerequisite Programmes on Food Safety: Part 1 Manufacturing*, ISO/TS 22002-1:2009 – A practical easy to read guide to basic conditions required for hygienic manufacture of food.

Mortimore, S.E. and Wallace, C.A. (2013) *HACCP: A Practical Approach*, 3rd edn, Springer, New York – This book does exactly what it says in providing a practical step-by-step guide to developing and implementing a HACCP system in a food plant.

Motarjemi, Y. and Lelieveld, H. (eds) (2014) *Food Safety Management, A Practical Guide for the Food Industry*, Elsevier, Oxford, UK – This is a very detailed reference book with chapter contributions from many experienced industry food safety managers.

Sprenger, R. (2009) *Hygiene for Management*, 15th edn, Highfield Publications, Rotherham, UK – The fact that this is in its 15th edition should tell the reader a lot.

Wallace, C.A. (2009) *Intermediate HACCP*, 3rd edn, Highfield.co.uk Ltd, Rotherham, UK – A short, introductory text designed as a course-book to accompany Level 3[1] HACCP courses but also useful in introducing the concepts to people who have not studied or been involved in HACCP previously.

Yiannas, F. (2009) *Food Safety Culture: Creating a Behaviour Based Food Safety Management System*, Springer, New York – A very interesting read, highlighting the importance of the human behavioural element in a food safety system.

Useful websites

Much information on HACCP is available on the Internet, although it is difficult to give a definitive list of suggested websites since this is a rapidly changing area. If you are using the Internet, remember it is important to check that the information is coming from reputable sources such as governments, universities and research associations.

HACCP training and consultancy providers

There are a huge number of organisations offering HACCP training and consultancy although it can be difficult to assess their level of competence. Many are excellent, but there are also a number who have never actually worked in a factory or catering

[1]Ofqual Register of Regulated Qualifications, UK.

establishment. It would be impossible to give a list of providers here as there are so many. However, here are a few pointers in finding a reliable supplier of training:

- They should be reputable – either through being a respected organisation or though the provenance of the actual trainer or consultant.
- For HACCP training, look for their trainer skills as well as evidence of their experience in implementing HACCP and food safety systems. They should be trained *trainers* not just experienced presenters, and they must be knowledgeable and experienced in HACCP principles and practice
- Some countries have registration schemes for training centres and courses. For example, UK Royal Society for Public health (RSPH) and Chartered Institute for Environmental Health (CIEH)
- Food Research Associations and academic institutions can be useful in suggesting a reliable source of training and library reference material

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