

HACCP

Sara Mortimore • Carol Wallace

HACCP

A Practical Approach

Third Edition

Revisited with a view of food safety risk reduction

Foreword by William H. Sperber



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For Harriet, Elspeth, and Christina

Foreword

The 1994 and 1998 editions of *HACCP: A Practical Approach* found a ready audience, particularly among food companies and corporations that were engaged in global commerce and wanted to comply with the recommended codes of practice for food safety management as first published by Codex Alimentarius in 1992. Those particular codes were based upon the Hazard Analysis and Critical Control Point (HACCP) system and Good Hygienic Practices (GHP). As discussed below, the latter is one example of a prerequisite program (PRP) that is a necessary part of the foundation for a successful food safety management system. Because HACCP had emerged and evolved as a voluntary effort of the food industry in the United States beginning in 1971, it seemed natural for food companies to independently acquire knowledge about food safety management from authoritative sources, such as the earlier editions of this book.

Considering the global authority of the Codex codes of practice, as empowered through the World Trade Organization, it is disappointing that more than one decade into the twenty-first century the management of food safety is not better incorporated into the mechanics of the global food supply chain. Given the breadth and complexity of the supply chain, which handles vast quantities of food commodities, ingredients, and products, everyone must understand that the success of international food safety efforts depends upon the development and implementation of:

- Effective food safety practices,
- Sound food safety regulations, and
- Effective governmental and intergovernmental food safety organizations.

Only the first of these points—effective food safety practices—has received sufficient and effective attention at this time. The remaining two points have not been effectively addressed by the responsible parties. Therefore, direct participants in the global supply chain must shoulder the responsibility for food safety as described briefly below. It is reasonable to expect that such action can be effective because most of the knowledge of food safety hazards and the means for their

control resides with the scientists, engineers, and managers in the global food industry.

This third edition of *HACCP: A Practical Approach* is an excellent resource to teach and reinforce effective food safety practices. The authors are highly experienced teachers, researchers, and practitioners of the subject matter; they have extensively updated their original material. The content on prerequisite programs has been considerably increased. These include good agricultural practices (GAP), GHPs, good manufacturing practices (GMP), and a newly proposed PRP—good consumer practices (GCP). GAPs and GCPs in particular make the points that food safety is a “farm-to-table” effort and that everyone has a role in food safety. These are especially important considerations in the case of foods that are typically distributed and consumed raw or undercooked.

The matter of food safety regulations is somewhat beyond the direct scope of this book, but it must be mentioned here because it sometimes affects the ability of the food industry to fulfill its responsibilities to produce safe food. Over the course of the past century a number of effective food safety regulations have been implemented worldwide; these greatly assisted the food industry and improved public health. Prominent examples include regulations for the pasteurization of fluid milk and liquid eggs, the sterilization of canned foods, and the chlorination of drinking water. More recent regulations deal with raw meat and poultry products, fresh seafood, juice products, and produce. Although some of these in the USA are purportedly HACCP regulations, they are actually ineffective and hinder the food industry in its efforts to produce safe food. The cause of food safety was well served in 1972 when industry and government scientists in the USA collaborated to write canned foods regulations, which were based upon HACCP principles. In stark contrast, some recent food safety regulations have been drafted and enacted with the principal input of various politicians, lawyers, lobbyists, think tanks, or consumer advocates; persons inexperienced with food production and food safety management. These regulations have further hindered food safety management and public health education by creating the false expectation that foods typically distributed and consumed raw or undercooked can always be pathogen-free. Sometimes we are confronted with an impractical clamor to declare pathogens in raw foods to be treated as adulterants.

A brief consideration of the matter of effective governmental and intergovernmental food safety organizations demonstrates the necessity for the food industry to take direct control of all aspects of the safety of its products and to not wait for more effective governmental actions or regulations. While we must continue to work to have effective governmental organizations for food safety, progress will come with difficulty. There are about 200 countries in the world. It can accurately be claimed that even some developed countries have dysfunctional food safety organizations. While some countries have effective single food safety agencies, many do not. There is also no effective intergovernmental food safety organization; therefore, coordination at the international level has been defaulted to the global food supply chain, particularly to food corporations, which have a global interest in maintaining a supply of safe food. Should an effective intergovernmental food

safety organization be formed, say in the United Nations, it could ideally coordinate its global activities through the single food safety agencies of each member country.

There is room for optimism that effective actions will eventually be taken to provide effective food safety regulations and organizations. In the meantime the food industry must assume the mantle of food safety leadership. HACCP and effective food safety management procedures began more than 40 years ago as independent food industry efforts. To a very large extent, if they are to continue to produce safe food, members of the global food supply chain must maintain this independent mindset that they bear the principal responsibility for food safety. Food producers, processors, distributors, handlers, and consumers must collectively understand and exercise their shared responsibility for food safety. This third edition of *HACCP: A Practical Approach* will be an excellent tool to assist their efforts.

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Finally, we remain grateful to the contributors to the first and second editions of *HACCP: A Practical Approach*, many of which remain in this third edition.

About this book

HACCP: A Practical Approach, third edition has been updated to take into account current best practice and new developments in HACCP application since the last edition was published in 1998. This book is intended to be a compendium of up-to-date thinking and best practice approaches to the development, implementation, and maintenance of HACCP programs for food safety management.

Introductory chapters set the scene and update the reader on developments on HACCP over the last 15 years. As with the previous editions, we cover the preliminary stages of HACCP including preparation and planning and system design before moving on to consider food safety hazards and their control. Prerequisite program (PRP) coverage has been significantly expanded in this new edition reflecting their development as key support systems for HACCP. The HACCP plan development and verification and maintenance chapters have also been substantially updated to reflect current practice and a completely new chapter on application within the food supply chain has been added. Appendices provide a new set of case studies of practical HACCP application plus two completely new case studies looking at lessons learned through food safety incident investigation. Pathogen profiles have also been updated by experts to provide an up-to-date summary of pathogen growth and survival characteristics that will be useful to HACCP teams.

Whilst some readers may wish to read the book from cover to cover, we anticipate that many readers will dip into the specific sections, chapters, and appendices at different parts of their food safety journey. The book is written both for those who are developing HACCP systems for the first time and for those who need to update, refresh, and strengthen their existing systems. New materials and new tools to assist the HACCP team have been provided and we have included the current situation on issues that are still undergoing international debate, such as operational PRPs. All tools such as decision trees and record-keeping formats are provided to be of assistance and are not obligatory to successful HACCP. Readers are guided to choose those that are relevant to their situations and which they find are helpful in their HACCP endeavors.

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GrandMet Foods Europe and in retail at Sainsbury's. She then moved to the consultancy, training, and audit organization, Reading Scientific Services Ltd, where she was General Manager of the Food Safety Consultancy, Training and Assessment Services, including RSSL's *Select QA*, one of the first certification bodies providing audits under the BRC Scheme. These positions allowed her to gain 20 years practical experience of food safety management systems in practice in the UK and international food industry prior to joining academia in 2004. She gained a PhD for her study of factors impacting HACCP effectiveness and continues to work closely with international food companies and organizations for the ongoing improvement of food safety standards.

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Prologue

When we wrote the first edition of *HACCP: A practical approach*, we did not dream that it would be so successful. Its popularity related mainly to the easy-to-read style and step-by-step approach to planning, developing, implementing, and maintaining an effective HACCP system. The second edition was built on this straightforward formula to update and extend our practical advice on the use of HACCP systems.

There have been a number of changes in the HACCP field in the past 10 years, which this new edition of the book takes into account. The Codex *HACCP system and guidelines*, the international HACCP “standard,” and the recommended International Code of Practice General Principles of Food Hygiene, the international prerequisite program “standard” have both been updated and republished more than once (Latest editions: Codex, 2009a, b), and increased experience in the practicalities of HACCP has led to changes in the way it is applied. Specifically, this has led to the use of more modular HACCP systems and even generic HACCP being favored in some sectors. There has been much focus in parts of the world on the use of prerequisite programs (PRPs) to control cross contamination, minimize growth of microbiological hazards and allow the HACCP plan to control those hazards that are specific to the process. All of these issues (and more) will be discussed.

Food safety is as much a topic of debate now as it was when HACCP was first being developed, maybe even more so. There are signs of transformation on a global scale—significant change in the US regulatory framework and the continued evolution of the Global Food Safety Initiative (GFSI). To us it also feels as though there is an increased spirit of open communication and a willingness to collaborate more than ever before. This may be due to the size of some of the more recent failures in the food safety system or the greater media interest. It may be that with increased globalization of the industry and general concerns regarding food security and bio (terrorism) security, we feel a need to work together like never before. Whatever the catalyst for change, food safety discussions continue feverishly at many levels, and with this, comes increased sharing of knowledge.

Knowledge is the key. Knowledge has always been the key in any sector, but with hundreds of thousands of food companies and millions of mouths to feed,

knowledge in the food industry must be shared. Food safety is not a competitive advantage. We share the same objective, whether working as regulators, academics, or industrialists, and we need to work together to have a greater chance of success in meeting our goals. Food safety zero risk is unattainable but we need to use all the tools available to help us do the best we can and drive down risk as far as possible. HACCP really does help to anticipate and manage risk through identification of hazards and implementation of preventative control measures. It is sad that so few companies have used HACCP properly. It is such a simple concept and yet many have overcomplicated its use and added to the misunderstanding by pronouncing it to be burdensome and difficult. With more open debate it is hoped that this mindset will gradually change. The time has come to stop looking for reasons why HACCP is difficult and get on with building practical and effective systems.

The Changing Context

Before we leave you to your task, we wanted to share some of our thoughts on food safety management in the future.

First, let us briefly consider what the main drivers of change in the food industry have been over the past 50 years or so, and what may develop in the future. By doing so we can explore what we may need to put in place to ensure a safe food supply for the future. We will consider the key drivers of legislative, environmental, and social change, in addition to developments in food processing and technology, and distribution networks.

(a) Legislative

In general terms, regulatory requirements in many countries have significantly contributed to the change in food industry practices over the years. In the USA, the Food Safety Modernization Act (2011) and the pending food safety regulation that will follow is, no doubt, acting as a catalyst for transformational change in many US food companies through review and update of existing HACCP systems (though some companies are only just starting to implement) development of Food Defense Plans and upgraded PRPs. In the UK, it could be argued, that the Food Safety Act (1990) and its obligation for food business proprietors to take all reasonable precautions in the manufacture and supply of safe food was also a catalyst for change. It was largely responsible for the surge in supplier auditing, and this led first to the development of the British Retail Consortium (BRC) standard and then to the Global Food Safety Initiative (GFSI). The challenge for governments worldwide is to impose reasonable frameworks within which the issues of food safety can be managed. These frameworks must encompass

education and training, both for industry practitioners and regulatory personnel, and include support systems and resources as well as standards.

(b) Environmental Change

This encompasses not just the physical world but also the microbiological world which allows mutagenesis of new strains of organisms. Fifty years ago there were only four recognized foodborne pathogens; *Staphylococcus aureus*, *Salmonella*, *Clostridium botulinum*, and *Clostridium perfringens*. Emergence of new pathogens in recent years (now close on 30 recognized food pathogens) has led to the review of existing control measures (Wallace, Sperber & Mortimore 2011). For example, the methods for limitation of cross-contamination with *E. coli* O157, or the prevention of the likely BSE causative agents from entering the human food chain, are areas still relatively new. And understanding of organisms such as *Salmonella* continues to be researched. The mutagenicity of microorganisms will become of increasing concern with the appearance of more antibiotic-resistant strains of increasing virulence. Ultimately the approach to food safety will necessarily be based on prevention of contamination rather than preservation or destruction. If we have robust HACCP systems and strong PRPs in place, then this will surely contribute to prevention of, as yet unknown, hazards. However, we will need to constantly review the continued effectiveness of existing control measures. The world is changing and the speed of change is accelerating. Climate change continues to impact on agricultural practices and water availability—both have an impact on food production. There have been increased outputs in some countries and decreased outputs in others—basically a shift which requires new skills and knowledge. Scarcity of water will also have an impact on the ability to produce an adequate food supply to feed a growing population.

(c) Sociological Change

Internationally, consumers have now had the opportunity, through travel and media, to experience a wider culinary culture (Fig. 1).

In addition, people have increasingly migrated from country to country, taking their food cultures with them. Food influences from around the world can be observed in many domestic households and television cooking programs are constantly urging people to expand their horizons even more. In today's mobile society, people eat out routinely and there is a decline in the family meal occasion where the family cook prepares a meal for the whole family to eat together. Individuals in the household are now far more likely to prepare a meal just for themselves. This means that the knowledge of how to handle and prepare food has declined and the preparation instructions on packaging are needed by people, who may have

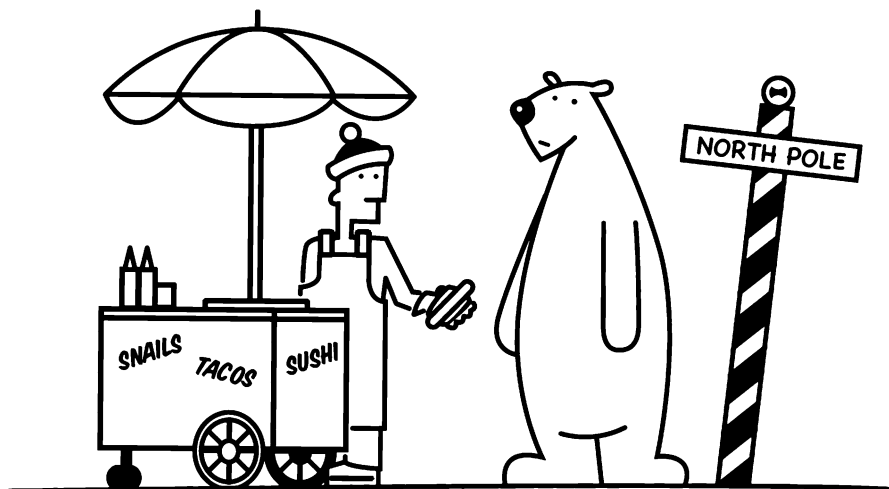


Fig. 1 Expansion of international cuisine

differing literacy and numeracy skills as well as diverse food preparation abilities. The provision of food out of home has also moved away from traditional restaurants, where cooks would learn their skills under a hierarchy from the head chef. Much of the food eaten outside of the home is through preprepared fast food and on-the-move fast-food outlets. These require a larger number of people to be involved in the preparation of food in less knowledge-based structures. Turnover of staff can be high in many food businesses, so the use of HACCP to identify Critical Control Points will continue to offer a focused and practical way forward.

Social change has also occurred in the form of population growth and it is well known that we have to meet the challenge of feeding nine billion people by 2050. And then what? We have to embrace technology in order to meet the growing demand and that may lead to new food safety issues as yet unheard of.

(d) Food Distribution

The way that food reaches consumers through a now global supply chain, has altered the approach to food sourcing and distribution considerably over the last few years and this has brought new hazards with it. The alternative trend for locally sourced food (with fewer “food miles”) does little to offset the vast amount of food that is shipped round the world and, of course, is not necessarily any safer.

The food retailing model has changed dramatically; in some countries, notably the UK, but also Western Europe, North America, and Australia, the growth of major grocery retailers has been phenomenal. In the UK, approximately 80 % of the value of all grocery purchases is vested in only five retailers, each of which has

several hundred stores across the country. Similar scenarios continue to develop elsewhere. This poses a number of issues. The food supply chain has become so prepackaged and sanitized that very few people in these stores actually handle food; they are essentially involved in merchandising. The number of people in retailing at store level who are skilled at food handling and preparation, with the exception of a few people on service counters and in-store processing, has decreased. The primary food safety issues at large here are generally ones of temperature control and shelf-life.

The ability of retailers to source globally and to offer a wide choice of ethnic foods has succeeded in making consumers' tastes more eclectic and consumers now demand year round produce. For the retailers and manufacturers who also globally source raw materials, the contact with a global supply base provides a unique opportunity to further the use of HACCP and PRPs in a consistent way. The challenge with global sourcing is in having the resources to visit such a wide base of suppliers as frequently as they would if they were in the same geographical region. Therefore, there is increased reliance on third party auditors to evaluate that systems such as HACCP and supporting prerequisites are understood and managed in the same way by suppliers based in Minnesota in the USA or Manchester in England. The GFSI is also providing an opportunity to promote the knowledge and understanding of food safety best practice on a global basis.

(e) Food Processing and Technology

Producers and processors have not been insulated from change during this time. Primary producers have seen the advent of intensive agriculture and factory farming and have not escaped unscathed from the mass use of chemicals and intensive agricultural practices, which has in turn enabled greater yields. The resurgence of organic farming poses its own challenges and a number of food safety incidents have resulted through environmental cross contamination. The structure of manufacturing organizations has been affected by merger and rationalization. Large companies frequently source their raw materials on a global basis for reasons of economy and supply through logistically controlled distribution systems to fewer bigger customers. The control of food safety in these companies is now vested in the hands of a few experts. The challenge is to create the right amount of awareness and skills at the critical food contact points through education and training, and then to maintain this at adequate levels. Throughout all this change the food industry has introduced new controls, though perhaps in some instances these were perceived by consumers as coming too late—a good example here is the need for Salmonella control in low-moisture foods such as chocolate and peanut butter.

What next, then, for the future? How might our HACCP and food safety management systems be improved to ensure that new developments, whether technological, sociological, or whatever, are managed properly such that food

safety incidents are prevented? Two main themes occurred to us as we started to write this prologue. Firstly, more effective training and education, and secondly, a more closely integrated food safety system across the supply chain.

We will look at each of these areas in turn and consider how HACCP may be used to make a positive contribution.

Education and Training

The increased regulation of HACCP, global sourcing and world trade agreements will continue to have a major impact on the training and education needs across the food supply chain.

In the past few years there has been a surge in the demand for HACCP and food safety training. Unfortunately, to date, although some training has been delivered by experienced trainers, there remains considerable variability in the standards of training available, given the lack of regulation or standardization in this area. In many instances HACCP training is being offered by consultant training providers as a range extension to their hygiene based training courses, yet many still fail to make the conceptual leap from hygiene management to hazard analysis, risk assessment and preventative controls (Mortimore and Smith, 1998). This is a problem largely facing the industry at present: many HACCP experts are skilled presenters yet few have a true education in learning theory and training skills; on the other hand, training experts are rarely HACCP practitioners. Training in HACCP, then, can often end up leaving the trainees confused and with a superficial theoretical knowledge. In the UK, the RIPHH (now the RSPH) facilitated the development of a HACCP training standard (1995b), and almost more important than this went on to register HACCP training providers running courses against that standard, offer examinations as verification of learning, and to register training centers and trainers. Trainers had to demonstrate both HACCP experience and training skills. This was a good model and helped to focus both the trainer and trainee towards their joint objective of successful knowledge transfer during the training event. This initiative has since evolved and expanded to other awarding organizations and sector skills councils, and has progressed to the development of agreed specifications for HACCP training at various levels (agreed levels of qualification registered as units of learning by OFQUAL (UK Government Office of Qualifications and Registration—see <http://register.ofqual.gov.uk/> for further information)). There is a real opportunity for a global body such as GFSI to take this idea forward and develop an **international** benchmarked scheme for food safety training and education.

Training in HACCP, past and present, tends to be just that—fairly narrow in scope—when you consider all the other aspects that are part of food safety management. While the demand for food safety training is likely to increase, hopefully it will expand to include a deeper examination of all the elements of food safety PRPs. This will then look more like an integrated food safety management program with HACCP as the core element.

The Future of Food Safety Oversight

What we continue to see for the future is the need for a fully operational matrix of activity across the supply chain overseen by a global organization. Sperber (2008) called for the creation of a global organization of food protection and has renewed this call in the foreword to this edition. It is possible that with the support from nongovernmental organizations such as the World Health Organization and the Food and Agriculture Organization, GFSI could make a significant contribution to this. Shared goals through a mutual desire to improve food safety management should be a common theme since in many cases the drivers for a primary producer will be the same as for a processor, food service provider, caterer, or retailer. In some instances one may be a driver of the other, for example, retailers driving improvements through their suppliers in the processing sector and processors demanding improvements of their raw material suppliers. Supplier Quality Assurance systems clearly affect the entire supply chain. Therefore the opportunity for shared hazard analysis, problem solving, quality systems linkages, and continuous improvement activities should be sought out rather than each segment working in isolation (Fig. 2).

A commonality of approach for the implementation and support of HACCP can serve as a vehicle for the integration of the associated prerequisite and other Quality Management Systems. This will provide the foundation for knowledge transfer and will allow, for example, hazards to be jointly identified by different parts of the supply chain. Where they arise in one part of the supply chain they may actually be controlled in another part. Some industry schemes have built this into their requirements, e.g., the animal feed schemes in the UK with Universal Feed Assurance Scheme (UFAS) from Agricultural Industries Federation (AIC) for compound feed manufacturers requiring that the inputs are certified through the sister FEMAS (Feed Materials Assurance Scheme). Such integration of systems must occur in order to enable effective control to be imposed, and whilst we are a long way off from this being a reality, the topic is getting more discussion.

In the future we could envisage a knowledge transfer system, perhaps electronic, which spans the supply chain. Use of a product safety assessment, as outlined in Chap. 5, could facilitate the handing on of the essential hazard analysis information from one area of the supply chain to the next—a sort of “passport” system—enabling the sharing of information that doesn’t stay confidential within each company.

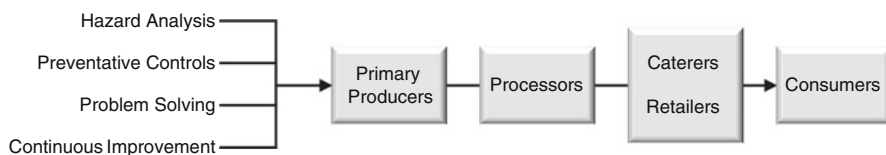


Fig. 2 Joint food safety programs: Crossing supply chain barriers

With developing and more readily accessible technology, use of electronic data transfer will increase; perhaps, also to the consumer who will be able to use a scanner in the retail outlet not only for identity and price information but also to read product safety information. Some retailers are already beginning to offer this scanning facility in-store so that consumers can access a database of nutritional information and details of potential allergens.

For those of you who have read and enjoyed the first and second editions, we hope that the third edition will not only bring you up to date but also provide food for thought and stimulate your ideas on HACCP as a major part of global food control. For those who are new to HACCP and this book, we trust that it will help you find your way to developing a successful HACCP system.

Sara Mortimore and Carol Wallace

Chapter 1

An Introduction to HACCP and Its Role in Food Safety Control

HACCP is the well-known acronym for the Hazard Analysis and Critical Control Point system. It has been frequently written about and talked about at conferences and within companies over the last 50 years but is still often misunderstood and poorly applied in real situations.

Since we last updated this book there have continued to be many failures in the food supply chain. Some of these are world renowned (e.g., melamine in milk powder from China), many were significant national failures (e.g., Salmonella in peanut butter in the USA, Salmonella in chocolate in the UK, *E. coli* in sprouted seeds in Germany), and many, many more were small, isolated, and sometimes tragic events occurring in countries all around the world. So what has gone wrong? Is HACCP not working? Sadly, the answer to this question is that it hasn't had a chance to work. Far from being "done," HACCP has been poorly implemented and under-utilized in probably the majority of food companies.

The HACCP concept has been around in the food industry for a long time, yet food safety control continues to be debated rigorously at the international level and there continues to be calls for new committees, new agencies, and new laws to fix the problem. Twenty years ago developments in HACCP were fairly major, and some governments saw its implementation as a remedy for all of their country's food safety issues. In reality, use of the HACCP approach does offer a practical and major contribution to the way forward, but **only** if the people charged with its implementation have the proper knowledge and expertise to apply it effectively. Foodborne illness continues to be a major problem that must be addressed. We cannot go another 20 years and still be searching for solutions. **Consumers have a right to expect that each product produced and sold will be safe for consumption.**

HACCP is a tool that can be used to reduce the risk of a food safety failure. However, the food industry has failed to use it effectively to do that, often by spending time in writing and updating the documents, as opposed to recognizing that the thought and application process is the key to food safety assurance. Many companies think they have a HACCP system because they have a written HACCP plan, yet frequently the content of the plan is poor and adds little value in terms of

food safety risk reduction. In these cases HACCP needs to be revisited, upgraded, and properly implemented before it can have an impact on food safety risk reduction.

In this chapter, we will consider some of the most common questions asked not only by those who are new to HACCP but also by those who want to take a fresh look and upgrade their food safety systems. We will endeavor to explore some of the reasons for using the system—for the management of product safety, to meet government and customers' expectations and, perhaps less obviously, because it makes good business sense.

1.1 HACCP: The Basic Questions Answered

1.1.1 *What Is HACCP?*

HACCP is a logical system of food control based on prevention. In identifying where the hazards are likely to occur in the process, we have the opportunity to put in place the measures needed to **prevent** those hazards from affecting the consumer. This facilitates the move towards a preventative quality assurance approach within a food business and reduces the traditional reliance on end-product inspection and testing.

In brief, HACCP is applied by taking a number of straightforward steps:

- Understand **your** product—what is making it safe?
- Look at your production process from start to finish—understand your operating environment and process activities.
- Identify potential hazards and decide where they could occur in the process.
- Put in preventative control measures with defined safety limits.
- Monitor the controls.
- Write it all down and keep records as evidence that you've done it.
- Ensure that it continues to work effectively.

All types of food safety hazards are considered as part of the HACCP system—biological, chemical, and physical. Effective implementation of a HACCP-based food safety system should, therefore, give the growers, manufacturers, food service operators, and retailers' confidence that the food they provide is safe. This can and should involve everyone in the company as each employee has a role to play. This is a fundamental requirement that is often forgotten: the systems element is not just about documentation, it is also a "people system." The people who use it own it—they maintain it and keep it current. Our first edition of this book was published in 1994, nowadays there are few people in the industry who haven't heard of HACCP but there are many who have lost sight of the fact that you need people who know how to get it done and who are accountable. The culture that evolves through this systems/people approach not only makes it more likely to succeed but makes it

much simpler to progress to additional programs such as quality improvement, productivity, and cost reduction.

1.1.2 What Are the Principles of HACCP?

The HACCP system consists of seven principles which outline how to establish a HACCP plan for each operation under study. The HACCP principles have international acceptance and details of this approach have been published by the Codex Alimentarius Commission (1993, 1997, 2003, 2009b) and the National Advisory Committee on Microbiological Criteria for Foods (NACMCF, 1992, 1997).

We are now going to introduce a number of terms which may be unfamiliar to you if you are just starting out. There is a glossary in Appendix C and an abbreviations list in Appendix D, and we will be discussing these again in full in Chap. 6 when we look at applying the principles.

Principle 1. Conduct a hazard analysis. Prepare a list of steps in the process, identify where significant hazards could occur, and describe the control measures.

Principle 1 describes where the HACCP team should start. A Process Flow Diagram is put together detailing all the steps in the process, from incoming raw materials to finished product. When complete, the HACCP team identifies all the hazards that could occur at each step, considers the likelihood of their occurrence, and considers the severity of effect to the consumer. This determines the significant hazards and enables the team to go on to describe preventative measures for their control. These may be existing or new control measures.

Principle 2. Determine the Critical Control Points (CCPs). When all the significant hazards and control measures have been described, the HACCP team establishes the points where control is **critical** to assuring the safety of the product. These are the Critical Control Points or CCPs.

Principle 3. Establish Critical limits for control measures associated with each identified CCP. The critical limits describe the difference between safe and potentially unsafe product at the CCPs. They must involve a measurable parameter and may also be known as the absolute tolerance or safety limit for the CCP.

Principle 4. Establish a system to monitor control of the CCP. The HACCP team should specify monitoring requirements for management of the CCP within its critical limits. This will involve specifying monitoring actions along with monitoring frequency and responsibility.

Principle 5. Establish the corrective actions to be taken when monitoring indicates that a particular CCP is not under control. Corrective action procedures and responsibilities for their implementation need to be specified. This will include action **both** to bring the process back under control and to deal with potentially unsafe product manufactured while the process was out of control.

Principle 6. Establish procedures for verification to confirm that the HACCP system is working correctly. Procedures must be put in place to both **validate** that the CCPs will control the hazards of concern and **verify** that the system is working day-to-day as planned.

Principle 7. Establish documentation concerning all procedures and records appropriate to these principles and their application. Records must be kept to demonstrate that the HACCP system is operating under control and that appropriate corrective action has been taken for any deviations from the critical limits. This will provide evidence of safe product manufacture.

1.1.3 Where Did HACCP Come from?

HACCP was developed originally as a microbiological safety system in the early days of the US manned space program. It was vital to ensure the safety of food for the astronauts—imagine suffering foodborne illness in a zero gravity environment! At that time, most food safety and quality systems were based on end-product testing, but it was realized that this could only fully assure safe products through testing 100 % of the product, a method which obviously could not have worked as all product would have been used up! Instead it became clear that a preventative system was required which would give a high level of food safety assurance, and the HACCP system was born (Fig. 1.1).

The original system was pioneered by The Pillsbury Company working alongside NASA and the US Army Laboratories at Natick. It was based on the engineering system, Failure, Mode and Effect Analysis (FMEA), which looks at what could potentially go wrong at each stage in an operation together with possible causes and the likely effect. Effective control mechanisms are then put in place to ensure that the potential failures are prevented from occurring.

Like FMEA, HACCP looks for hazards, or what could go wrong, but in the product safety sense. Preventative control measures are then implemented to ensure that the product is safe and cannot cause harm to the consumer.

1.1.4 So, Why Should You Use HACCP?

A simple answer to this question is “because product safety cannot be tested in.” HACCP is a proven system which, if properly applied, will give confidence that food safety is being managed effectively. Implemented properly, it will enable you to focus on product safety as the highest priority always and allow for forward planning to prevent things going wrong, rather than waiting for problems to occur before deciding how to control them.

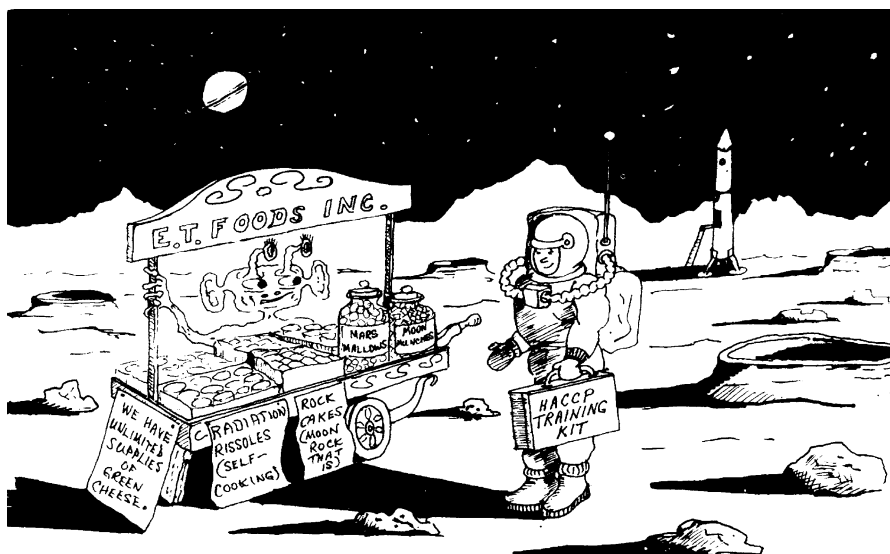


Fig. 1.1 Origins of HACCP

HACCP was developed as a straightforward method of helping manufacturers assure the provision of safe food to the consumer, but many companies have not fully realized the full potential of the system. By not committing to full and detailed implementation of the HACCP system we risk not achieving the benefits (Sect. 1.1.6), and of seeing HACCP as an on-cost to business rather than a fundamental element that is core to food business practice.

Despite progress, foodborne disease continues to be one of the largest public health problems worldwide. There are a number of reasons for this including:

1. The proportion of the population who have increased susceptibility to foodborne illness is increasing, for example, the elderly community in many parts of the world (including Japan and many western countries), the number of immuno-compromised consumers (for example, AIDs, cancer patients), and the malnourished, not just in less developed countries but also surprisingly in many developed countries due to the economic challenges in recent years.
2. Changing lifestyles have resulted in a number of changes to our eating habits:
 - (a) More people now regularly eat out or snack on the move, which has led to an increased demand for food service establishments of varying standards.
 - (b) Many people work outside the home and rely on processed foods for fast meal preparation; this has meant that knowledge of how to handle and prepare foods has decreased in recent years.
 - (c) Increased mass production of foods has increased the potential for larger numbers of consumers to be affected in the event of an outbreak of foodborne disease.

- (d) Increased tourism has meant that people are exposed to foodborne hazards from other areas.
3. Emerging pathogens (such as *Cronobacter sakazakii*) and increased awareness of the persistence and survival of pathogens in low moisture foods.
 4. Global sourcing of finished products and ingredients has increased the complexity of the supply chain and made it more difficult to trace and recall in the event of a failure.
 5. Increased testing capabilities combined with improved laboratory communication schemes mean that previously unidentified issues can both be detected and also linked together across states and countries to reveal an outbreak that would otherwise have gone unrecognized.
 6. Whilst new technologies, processing methods, and work practices are generally intended as improvements to provide better food products, we must not lose sight of the fact that, without careful safety evaluation, changes could also result in unsafe practices that might contribute to foodborne disease.

The importance of the HACCP approach as the most effective means of preventing foodborne illness has long been recognized by the World Health Organization and many governments worldwide (WHO, 2007). Despite this, many companies are not using the concept to identify and manage food safety risk—they may have HACCP systems, perhaps due to customer or legal requirements, but are not really using HACCP to its best effect.

Consumer awareness of the right to purchase food that is safe has increased significantly over the past few years. Similarly their awareness is raised of quality failures or wholesomeness, for example, the presence of unwanted harmless physical contaminants, such as extraneous vegetable matter. Here the controls used to prevent the presence of a harmful contaminant, such as glass, are often likely to prevent the occurrence of less harmful contaminants, therefore providing brand quality protection as well as consumer protection.

1.1.5 Why Can't We Rely on Inspection and Testing?

So, what is wrong with what we continue to do—inspecting and testing? From a consumer perspective, 100 % inspection, where every single product manufactured is inspected would seem to be the ultimate approach to product safety, or would it? We often rely on visual inspection, particularly for finished products going down the production line, or ingredients during the weighing-up stage. Fruit and vegetables are good examples, where we look for physical contamination such as stalks, stones, leaves, insects, etc. Reasons why the technique is not as effective as we would like include the following: employees get distracted in the workplace by other activities going on around them, such as the noise of the production line or field environment, fellow workers talking about their holiday plans, or what was on television the night before. The human attention span when carrying out tedious

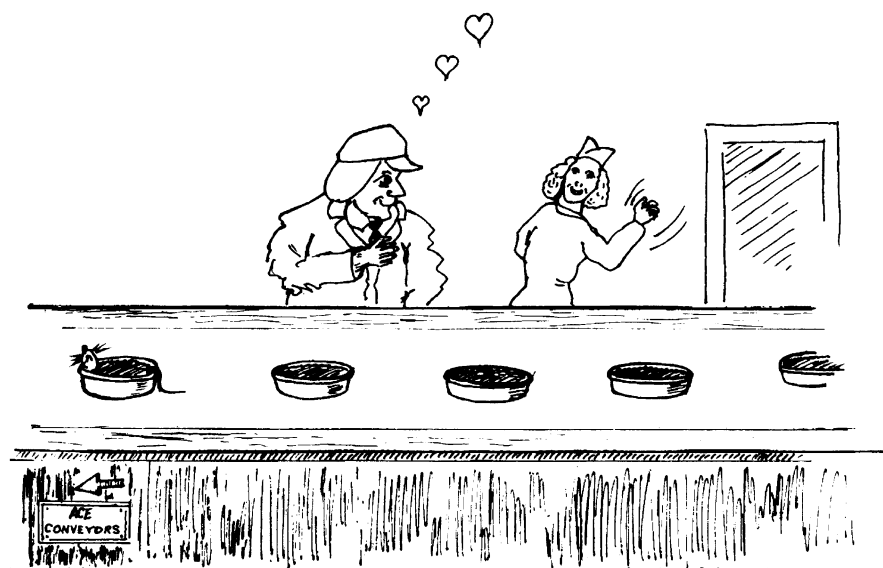


Fig. 1.2 The limitations of inspection and testing

activities is short (generally recognized to be 10–20 min) and “hazards” could be easily missed during visual inspection (Fig. 1.2). Because of this, people are often moved from task to task, in order to give some variety. However, this in itself brings problems along with line changes or shift changes; different personnel may be more aware of one hazard than another. Increasingly, electronic sensing techniques are being used to replace human input. These systems are more reliable but are still not widely used except in large, more developed food plants and need to be accurately calibrated to be effective.

Of course, the main difficulty with a 100 % inspection when it is applied to biological and chemical hazards is that it is impractical because biological and chemical testing is nearly always destructive. This leads us on to the use of sampling plans.

Many businesses “randomly” take a sample(s) from the production line. This can be daily, by batch, or even annually in the case of a seasonal vegetable, fruit, or grain crop. Statistically the chance of finding a hazard is usually very low based on typical practice. Sampling products to detect a hazard relies on two key factors:

1. The ability to detect the hazard reliably with an appropriate analytical technique.
2. The ability to capture the hazard in the sample chosen for analysis.

Analytical methods for the detection of hazards vary in their sensitivity, specificity, reliability, and reproducibility. The ability to trap a hazard in a sample is, in itself, dependent on a number of factors, including:

1. The distribution of the hazard in the batch.
2. The frequency at which the hazard occurs in the batch.

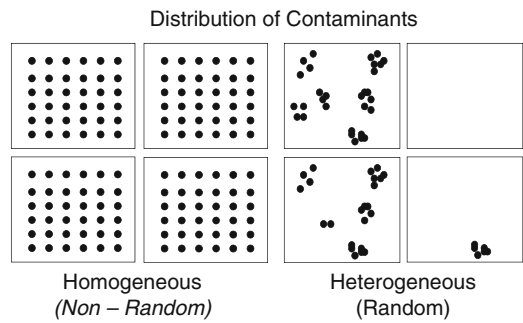


Fig. 1.3 Distribution of contaminants

Hazards distributed homogeneously within a batch at a high frequency are naturally more readily detectable than heterogeneously distributed hazards occurring at low frequencies (Fig. 1.3).

It is easy to come up with examples which might follow the distribution patterns shown in the diagram—some chemical contaminants such as heavy metals coming in with ingredients might be homogeneously distributed through a batch. More often, contaminants such as allergens (particularly in the particulate form), foreign material, or microorganisms are heterogeneously distributed which means that it is difficult to trap the contaminants within a sample.

For example, as illustrated in Table 1.1, in a batch of milk powder contaminated with *Salmonella* distributed evenly at a level of 5 cells/kg, a sampling plan involving testing ten randomly selected samples, each of 25 g, would have a probability of detection of 71 %. For powder contaminated at 1 cell/kg, the probability of detection using the same sampling plan would be only 22 %.

This naturally assumes that the detection method is capable of recovering the *Salmonella* serotype contaminating the batch. Few of the traditional testing methods for *Salmonella* detection would claim an ability to detect in excess of 90 % of the >2,500 serotypes, and most of the methods probably have a success rate of less than 75 %. Therefore the low probability of 22 % will be further reduced. Now that we have the availability of polymerase chain reaction (PCR) methods the testing capability has improved somewhat since targeting common DNA is quite

Table 1.1 Detection probabilities—end product testing, milk powder contaminated with *Salmonella*

Contamination rate		Number of random samples	Probability of detection (%) ^a
Homogeneously contaminated	5 cells/kg	10	71
	1 cell/kg	10	22
Heterogeneously contaminated	5 cells/kg in 1 % of batch	10	<2
	10,000 cells/kg in 1 % of batch	10	<15

^aAssuming detection test is 100 % effective (most are <90 %)

specific and accurate—more accurate than biochemical reactions. For method validation work, the Association of Analytical Communities (AOAC) methods must test at least 100 strains for *Salmonella*—this will be at least as good and probably better than traditional culture techniques, but still not 100 %.

The probability of detecting a hazard distributed homogeneously in a batch is improved quite simply by increasing the overall quantity of the sample taken and is relatively unaffected by the number of samples taken. Therefore, ten samples of 25 g would have the same probability of detection as one sample of 250 g.

However, as stated earlier, in the majority of cases, hazards, particularly microbiological hazards, are distributed heterogeneously, often present in small clusters in a relatively small proportion of a batch. The probability of detecting a hazard distributed in this way is extremely low if low numbers of samples are taken. Using the example above (*Salmonella* at 5 cells/kg), and assuming that the contamination is restricted to 1 % of the batch, the probability of detecting the hazard by taking ten samples of 25 g would be lower than 2 %. Interestingly, even if the hazard occurred at high levels within 1 % of the batch (10,000 *Salmonella* cells per kg), the probability of detection would still be lower than 15 %.

Such a situation cannot be rectified without recourse to a higher number of samples. In fact the probability of detecting the hazard in this scenario is greatly improved by merely taking more frequent samples from a batch, using a continuous sampling device. For example, if 100 g of the milk powder was removed from every ton by a continuous sampler and a well-mixed subsample was tested (5 g from each ton), the probability of detecting *Salmonella* heterogeneously distributed at 5 cells/kg would increase from 2 % to greater than 90 %. However, even with exhaustive statistical based sampling techniques, detection can never be absolute unless the entire batch is analyzed, and in most cases few manufacturers understand or can afford to operate rigorous statistical sampling procedures.

In summary, if you look for hazards just by taking random samples, there is a high probability that they will go undetected and you will have a false sense of security about the safety of your product.

1.1.6 What Are the Benefits?

The real benefit is that HACCP is a very effective method of reducing risk of failure and maximizing product safety. Traditionally the benefits are described as follows:

- HACCP helps with prioritization in making informed judgments on food safety matters and removes bias, ensuring that the right personnel with the right training and experience are making the decisions.
- HACCP will also help to demonstrate effective food safety management through documented evidence which can be used in the event of litigation.
- HACCP can, after the initial setting up of the system, be extremely cost effective.

- First, by building the controls into the process, failure can be identified at an early stage and therefore less finished product will be rejected at the end of the production line.
- Secondly, by identifying the CCPs, a limited technical resource can be focused on their management.
- HACCP enables food companies to meet their legal obligations to produce safe, wholesome food.
- The disciplines of applying HACCP are such that there is almost always going to be an improvement in product quality. This is primarily due to the increased awareness of hazards in general and the participation of people from all areas of the operation.
- Finally, food safety failure is very costly. HACCP and food safety systems are a sound business investment.

1.1.7 Is HACCP All I Need to Do for Food Safety?

HACCP alone will not assure the production of safe food. In your overall food safety program you need management commitment first and foremost and to be operating within the boundaries of good manufacturing practices (GMPs) although these are nowadays referred to as prerequisite programs (PRPs) for HACCP implementation, or PRPs to use the acronym. PRPs are described as the:

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 22000: 2005, section 3.8)

PRPs and more will be covered in detail in Chap. 4 but basically, HACCP needs the support of all the programs and practices that are needed to operate in a safe and hygienic environment.

In terms of management commitment, ISO 2000 (2005) describes this as “management responsibility” which includes provision of appropriate human resources and suitable infrastructure, as well as the ability to plan for and realize safe products.

1.1.8 Can HACCP Be Used to Reduce Food Safety Risk in the Absence of Adequate PRPs?

What if I don’t have a well-developed food safety program or hygienic work environment—can I still use HACCP? Our advice would be not to wait until you think the factory is perfect, but start with Principle 1, conduct a Hazard Analysis. One of the main benefits in the early stages of implementation is its help in setting

priorities. Mistakenly, many people feel that HACCP can only be used by mature businesses who have well-developed PRPs and Quality Management Systems already in place. Whilst it is true that a certain level of maturity is needed to develop and implement a fully operational HACCP program, there are significant benefits to using a hazard analysis approach early on in a less mature business. Understanding where hazards may arise and how they may be controlled will help with developing preventative control measures, e.g., for cross-contamination control, where positive air pressure is needed, effective personnel traffic patterns, decisions on where to site hand washing sinks, and CCP monitoring stations. In this way, knowledge of food safety control and the hazard analysis technique can be used to prioritize areas for improvement and as an aid to understanding food safety issues. By systematically analyzing the hazards at each stage in any food production chain and determining at which points control is critical to food safety, you can see whether you already have these controls in place or not (see Chap. 6).

1.1.9 Is HACCP Applicable to Everyone?

Yes, absolutely. You may be a multinational food corporation who incorporates it within a sophisticated quality management system with documented procedures and well-defined practices. Or you may be a grower of salad crops, a small manufacturer of goat's cheese on the farm, a street vendor of ready-to-eat pizza slices, or a five star restaurant. No matter, the HACCP approach can be applied effectively to all food businesses. Those not familiar with hands on practical application of HACCP often hold the misconceived belief that it is a difficult, complicated system which must be left to the experts, and can only be done in large companies with plentiful resources. True, you do need a certain level of expertise to carry out a HACCP study, but this expertise includes a thorough understanding of your plant, kitchen, products, raw materials, and processes, along with an understanding of the factors (hazards) that could cause a health risk to the consumer. This latter point is the common weakness in small businesses and **this** is what needs to be addressed in initiatives geared toward improvement of food safety management in this sector. There is a sizeable lobby who think HACCP is not applicable to small businesses. We disagree. The key is flexibility in application and appropriateness of documentation, i.e., measuring and recording information that adds value as evidence of food safety control. The HACCP technique itself is a straightforward and logical system of control, based on the prevention of problems—a common-sense approach to food safety management. HACCP is a key element of all company product safety management systems and, with good training and education, everyone ought to be able to at least understand the concept.

HACCP is logical in its systematic assessment of all aspects of food safety from raw material sourcing through processing and distribution to final use by the consumer. Various terms are used to describe the scope of the HACCP system. “Farm to fork,” and “gate to plate” illustrate the fact that food safety control must

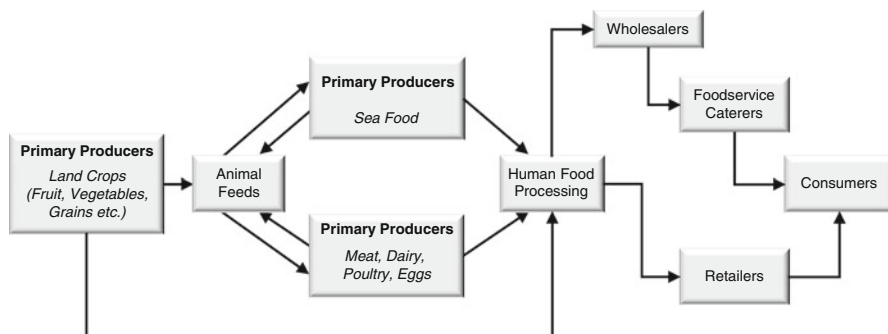


Fig. 1.4 Simplified supply chain model

encompass the entire food chain if you don't want to be in a "crop to court" situation!

If we consider a simple supply chain model (Fig. 1.4), we can see that there are various sectors within the food industry.

This book will largely deal with HACCP application within the processors sector, but it is essential that HACCP is applied to the whole of the supply chain if food safety is to be assured. We will now consider briefly how the Principles may be applied within the other areas and will discuss more detail, with the input of sector specialists, in Chap. 8.

Primary Producers

These are the fish producers and the land farmers, either raising livestock for the meat industry or the growers of the crops and vegetables that will be used by the processors in their conversion into finished products or sent direct to retail or food service. The individual steps within the on-farm process can be assessed systematically for the potential for hazards to occur, just as with any other area of the food-processing industry. Control measures can then be identified, and the control points that are critical to food safety established. Critical limits may be harder to identify, but here the farmer is often helped by legislative limits, for example, in the case of herbicide and pesticide application.

Monitoring the CCPs can sometimes require some ingenuity. Staying with our example of herbicide and pesticide application, this may be done through signing off application record sheets or, when using aerial application, through use of regularly placed pieces of test paper across the land being sprayed, in order to record the spread of the application.

For primary producers there may be added difficulty in understanding the impact of their actions further down the supply chain. Yet for the processors it is almost impossible to anticipate what potential new hazards may arise at their stage in the chain if they do not know what has occurred earlier on during primary production.

An issue that may not appear to be a hazard on the farm may well have an impact further down the chain and require control measures to be implemented at the stage of the earlier primary process. For example, presenting animals for slaughter in an unfit state may increase the likelihood of *E. coli* contamination of the meat. Application of hazard analysis at the primary-producer stage is useful to identify likely hazards and how they will be controlled either through prerequisite hygiene programs or specific control measures. This is probably best done by use of a team approach. This could involve both the primary producers themselves, but also their customers (i.e., the processors, retailers, and caterers).

For further specific information, the Campden BRI Produce and Feed HACCP guideline (Campden BRI, 2010) and sector certification schemes (e.g., Global Good Agricultural Practice—GAP) may be of value. For most producers there are very few CCPs in this sector as most of the food safety control is achieved through PRPs. However, that doesn't mean that the discipline of systematically carrying out a hazard analysis isn't helpful.

Food Service and Catering Operations

Food service and catering operators, large and small, usually have a vast number of raw materials and menu items, and a high turnover of staff. The principles of HACCP remain very relevant to this environment, however, the implementation may differ somewhat from a large food-processing establishment, as shown in the Chap. 8 example.

Although not all food service operators will have the in-depth technical knowledge to conduct what some might refer to as a “real HACCP study,” an attempt to understand and adopt the HACCP principles should make significant improvement to the level of food safety control possible. The output of the studies may look less technical, the critical limits may not have been established through in-depth testing or research, but with a certain degree of external support, a simple but effective HACCP plan can be put in place and will add value to the overall food safety program. This external support may include use of pre-developed generic models; however, it is essential that these are customized to the operation. Developers of models need to provide resources that assist in the hazard analysis and not just documentation templates which are of little value by themselves. They also need to appreciate that pre-prepared hazard analyses may not cover all options within specific businesses and should advise businesses to seek appropriate professional advice where the model doesn't fit the operation.

Appropriate training and education is also essential including coverage of food safety hazards in an accessible way. People need to be **compelled** to do the right thing and to do it properly.

Retailers

As seen with the food service and catering example, retailers should also be able to adopt HACCP (and many do) to ensure that they sell safe food which the primary producers and processors have endeavored to ensure reaches them in good condition. Purchasing from reputable suppliers, correct temperature control, and prevention of cross-contamination will be essential control measures in both large and small premises. The HACCP application may be perceived as difficult for smaller vendors. In some countries, for example, both raw and cooked products have historically been sold by the same staff and from the same counter. However, in such examples changes to operating standards will almost certainly be required and these can be identified in a systematic way through use of the HACCP principles. Like the food service and catering operators, for some of the smaller and independent retailers, the application is likely to be less technical, given the lower level of technical expertise available. However, the HACCP principles, if truly understood and linked to good hygiene practices, should help to improve food safety control and hence significantly reduce risk. Effective training in both of these sectors is essential.

Consumers

This is a difficult area, as consumers do not necessarily have access to reliable sources of education and training in food safety. HACCP techniques can be applied very successfully in the home environment (Griffiths and Worsfold, 1994; Wallace et al., 2011), and to some extent there is much similarity between a domestic kitchen and that of the small caterer. It is important that consumers should take responsibility for storing, preparing, and cooking foods properly, rather than expecting all products to be completely free of microorganisms at the point of purchase. However, it is equally vital that they are provided with correct usage instructions that allow adequate cooking to be carried out. Reliable sources of consumer education may exist, but, other than the product labels themselves, the process of obtaining this information is ad hoc, and sometimes the consumer is subjected to conflicting messages. Television cookery programs are often very poor role models for good hygiene practice, and consumers are left to seek out literature from government bodies or retailers, if they want to know more (Mortimore, 1995).

Food hygiene education of the consumer is a vital element in prevention of foodborne illness. Education should include the principles of good consumer practices (GCPs), i.e., good hygiene practice in the home, how to prevent cross-contamination, the importance of temperature in controlling microbiological food safety and of reading labels. Some governments are starting to work with industry and trade organizations in acknowledgement that improved understanding and consumer ownership of preventative control measures will result in a decrease in the number of food poisoning outbreaks.

Additionally, the food industry is a major employer and the possibility of potential employees having a greater awareness of basic good hygiene practice is a real benefit.

Some schools have (re)introduced topics such as cookery, food technology, personal hygiene, and food safety into the curricula but it is often not mandatory and many children miss out. There are some freely available and excellent resource materials available to schools and the general public, such as those developed through the partnership for Food Safety Education (www.fightbac.org) in the USA. These include scripts for teachers and at time of writing the developers were working on “Apps” which would appeal to the younger generation. Targeting the schools education system seems to be a good strategy. Parents used to teach their children how to handle food but with less people cooking, this knowledge is being lost in the general population and is solely the province of the professional food safety scientist.

1.1.10 Why Should I Revisit My HACCP Program? I’ve Done This Already

At a simplistic level, the answer to this question is that you will need to routinely revisit your existing program because things change—new products, alternative raw materials, changes at the facility or in the process, and of course new information about hazards. But in addition to all that which will be discussed in detail in Chap. 7, consider whether you are **really using HACCP as a means of reducing food safety risk**. Be honest. There are some companies who have best practice programs—vibrant and fully integrated deep within the core of all that they do. Others have rather lack-luster documentation, a hazard analysis which is very general and lacking in any real detail, and they dutifully update the paperwork each year in time for customer or third-party audits, which may not challenge them in any depth.

These companies are also likely to have gaps in their PRPs, i.e., they have not utilized their HACCP skills to develop a risk-based program. HACCP needs to be a part of a wider food safety program. PRPs are essential, as is safe product design and a host of essential management support practices (Wallace et al., 2011). Above all, you need a culture of real commitment to food safety in order to get the best out of your program. Given the continued high numbers of foodborne illness, it seems that many companies are not yet using HACCP properly—be open to continually seeking out best practice to make an existing program even better.

In summary, HACCP is a well-known and widely used tool which when properly implemented can reduce likelihood of food safety failure. It is preventative in that the approach requires that food safety hazards are identified throughout the process thus avoiding the unreliable end-product testing method of assuring safe food.

1.2 External Position and Drivers for HACCP Use

Increasingly, as HACCP becomes a regulatory requirement around the world, this may be the main driver for its implementation along with customer pressure. However, the primary driving force should come from within the company and nothing should be more motivating than the genuine desire to reduce food safety risk and to improve consumer protection.

Panisello and Quantick (2001) report that HACCP needs to be built on four “Pillars,” i.e., management commitment, education and training, availability of resources, and external pressures, and that sustainable HACCP can only be built as a result of internal pressure and support (i.e., the decision to apply HACCP is internal to the company and its management), the alternative being an unsustainable model that is the result of external pressure (i.e., the company is pushed into HACCP application by others, e.g., customers or regulators) (Fig. 1.5).

Additionally, there is an increasing amount of global media interest in food safety issues primarily focusing on the food-processing industry and therefore brand protection and company reputation are major concerns. This makes the business case for food safety, i.e., maintaining consumers (and customers) trust. Years ago we were all concerned about newspapers and television channels, today we worry about the Internet—both through formal news media and the much less easy to manage, social media where stories spread very quickly.

We will go on to look at the main external driving forces for HACCP implementation.

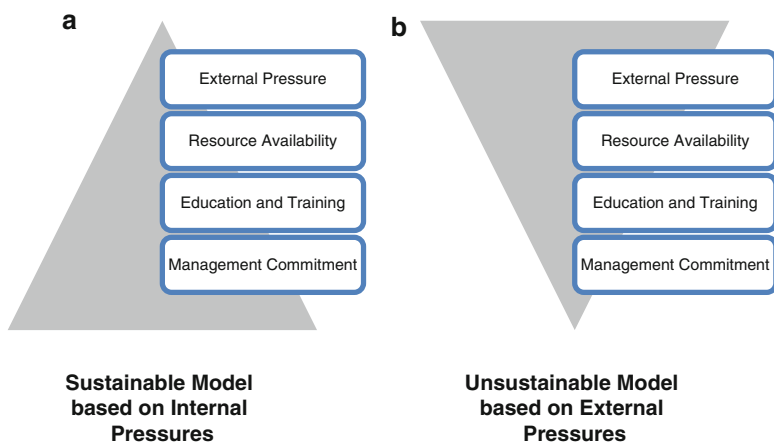


Fig. 1.5 HACCP success factors—prioritization of the four support “Pillars” (adapted from Panisello and Quantick, 2001)

1.2.1 *Customers and Consumers*

Consumers expect, and have a right to expect safe, wholesome food. We in the food industry have a responsibility to meet their expectations. The safety of our products must, without question, be considered our highest priority. That food is “safe” is often an unwritten requirement of many customer specifications. It goes without saying and, unlike many of the other attributes of the product (appearance, taste, cost), it is **not** negotiable.

While the end consumer may not know what HACCP means, those of you who are supplying private label products to retail and food service customers are most likely required to implement a HACCP system through the need for certification to one of the Global Food Safety Initiative (GFSI) benchmarked standards.¹ This tends to be carried out either as a part replacement or as an enhancement of the customer’s own inspection activities. There can be a benefit to the supplier being audited in that the certification bodies often have considerable experience within the industry sector and can provide a useful challenge to the HACCP system but the limitation needs to be understood. The audits are carried out over a typical 1–3-day period (depending on the size of the business), often using one auditor (there is still variable competency) and they are usually announced (the auditee can get ready for it).

For both the retailer and food service operator the customer is at the end of the supply chain, i.e., is also the consumer of the food. For the grower and food manufacturer, quite likely the customer is a food service operator, a retailer, or another industry manufacturer. Whatever the situation, customers have to be confident that the food being purchased is safe. They want to trust and have confidence in their supplier.

Long gone are the days when a customer inspection meant a walk around the factory to check hygiene and housekeeping, followed by a pleasant lunch, although as we will discuss later, audit time is still often insufficient to fully challenge the systems, understand the environmental control requirements, and assess food safety risk. Even with the emergence of GFSI, larger customers are still likely to issue their own “Codes of Practice” which almost certainly will include the requirement for a HACCP system to be in place. A crucial factor in any supplier inspection these days is an assessment of the competence of the management and overall culture of the organization. An **effective** HACCP system can go a long way in demonstrating to the customer that their supplier is managing the food safety hazards.

Whilst your customers are auditing you, you will be auditing your suppliers. No one wants to be buying-in a problem. If a food safety incident was attributed to your product, but was eventually traced to an ingredient, would it be you or your supplier who was held responsible? It may turn out to be the supplier’s fault, but what

¹ GFSI is the Global Food Safety Initiative. Formed by the Consumer Goods Forum in 2000, the initiative aimed to harmonize good safety standards and audit schemes by benchmarking against the GFSI reference.

damage will have been done to your business in the meantime if the media have taken an interest and your brand is involved? There are many examples where a single ingredient failure led to numerous product recalls and a high cost of failure to all involved. One of the most recent examples is that of the *Salmonella* contaminated peanut products in the USA in 2009. The manufacturing company supplied peanuts, peanut butter, peanut meal, and peanut paste to food processors to use in a wide range of products including cookies, ice cream, and snack items. These were sold to institutions such as hospitals, nursing homes, and schools as well as directly to consumers. This resulted in over 3,900 individual consumer product recalls from more than 350 companies, 9 people died and over 650 became ill as a result (Powell et al., 2010).

Where does the consumer feature with respect to food safety control? Sometimes not much at all as in the example shown above. The consumer has typically played the role of lobbyist in demanding assurance of safe food, and hence has been a driver for implementation of food safety management systems by the industry. However, consumer perception of risk severity does not necessarily always correlate with that of the food industry experts (Chap. 3). These perceptions are important for a number of reasons. Clearly, if consumers do not perceive themselves as being exposed to or the cause of a food safety risk, then they aren't going to adopt the necessary control measures.

1.2.2 International Government Regulation

Government recognition of HACCP as the most effective means of managing food safety continues to develop on a global basis. The difficulty in focusing on specific pieces of legislation in detail is that legislation is ever changing. HACCP is not governed by international legislation, but is being increasingly included in the food control legislation of many countries around the world. The development of food safety control systems has featured increasingly in the literature over the last 20 years and this is being reflected in food control legislation in a number of countries. Most countries adopt similar models for food control, based on international guidance.

In the USA, the HACCP techniques were used originally in the 1970s and 1980s to identify the controls specified in the Low Acid Canned Food Regulations. In 1998, the US Department of Agriculture (USDA) decreed that HACCP programs were required for all meat- and poultry-processing facilities. It was also required by law in the area of seafood inspection and processing (Federal Register, 1995, 1996) and for fruit juice in 1998.

In January 2011, Congress passed the Food Safety Modernization Act ("FSMA").

Food companies will generally be required to: (1) formally consider and identify all reasonably foreseeable food safety hazards; (2) develop written plans addressing

each of those hazards; and (3) closely follow those plans to reduce or eliminate such hazards to the greatest extent possible.

The Food Safety Modernization Act (FSMA) generally does not apply to the meat, poultry, or egg products regulated by the USDA but at the time of writing, it is reported that the Administration is reviewing some of the requirements.

FSMA is divided into four main areas:

- 1. Prevention of food safety hazards
- 2. Detection of and response to food safety problems
- 3. Improving the safety of imported foods
- 4. Various other miscellaneous provisions including new fees applying to food companies and importers (Table 1.2)

Table 1.2 Overview of the FSMA requirements (USA)

1. New preventative control responsibilities	<ul style="list-style-type: none">• Food Safety Plans<ul style="list-style-type: none">○ Companies are expected to conduct a hazard analysis of hazards reasonably likely to occur. This includes microbiological, chemical, and physical hazards and also the new category of exposure to radiation as a hazard.○ Controls designed to significantly reduce or prevent those hazards must be put in place.○ Implementation of the preventative controls includes monitoring, corrective actions, and verification activities. Verification activities may include environmental and finished product testing.○ Update of the program is required every 3 years.○ The food safety plan and all related records are available to FDA during inspection.• Supply Chain Management/Supplier QA<ul style="list-style-type: none">○ You need to know who your suppliers are (not just the distributors) at the production location level and have a plan for assuring adherence to their food safety requirements.○ The objective is to assure product that is not adulterated or misbranded (e.g., due to undeclared allergens).• Records Maintenance and Access<ul style="list-style-type: none">○ FDA will have legal access to see and copy records related to the food safety plan and related documents such as:<ul style="list-style-type: none">– Environmental and finished product testing– Corrective actions and related rationale– Supplier QA activities• Food Defense Plans<ul style="list-style-type: none">○ At time of writing the detailed expectations are still unknown but it is expected that food defense should be included in hazard analysis, including hazards that may be introduced by acts of terrorism.
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(continued)

Table 1.2 (continued)

2. New controls over imported food	<ul style="list-style-type: none"> • Each importer is required to perform risk-based supplier verification of compliance with the hazard analysis and prevention controls requirements. • Third-party certification can be used to assure that the food complies with US requirements. • There is a provision for a Voluntary Qualified Importer Program which will expedite movement of food through the import process.
3. Enhanced enforcement powers likely mean	<ul style="list-style-type: none"> • More frequent and risk-based FDA inspections. • Mandatory recall authority. • That the FDA can suspend a facility registration when it finds that foods present a reasonable probability of causing a serious adverse health consequence or death.
4. New fees on food companies and importers includes	<ul style="list-style-type: none"> • Reimbursement to FDA for re-inspections and recalls. • Provision for export certificates. • Imports voluntary program which will expedite imports.

FSMA refers to the development of a “Food Safety Plan” which companies with HACCP, PRPs, a Food Defense program, and a supportive culture will be able to demonstrate.

At the time of writing, regulatory frameworks under the FSMA are only now being developed but there are many other much needed areas (such as laboratory accreditation, traceability, whistle blower protection) that are mentioned in the FSMA. Whilst there is an exemption under FSMA for very small businesses (those who turn over <\$500,000 per annum) the FDA does have the ability to withdraw the exemption in the event of a major failure. It would be hoped that the industry implements the regulations as a level playing field recognizing that food safety hazards do not take account the size of the food business operation.

Historically, in Europe, one of the most powerful legal driving forces to entrench HACCP requirements in legislation was the European Community Directive 93/43 EC (1993) on the hygiene of foodstuffs. The Directive, while not using the precise wording of Codex Alimentarius or NACMCF, in Article 3 stated that “*food business operators shall identify any step in their activities critical to ensuring food safety and ensure that adequate safety procedures are identified, implemented, maintained, and reviewed.*” In essence the Directive listed the first six principles required to develop the system of HACCP and could be interpreted in virtually the same way as Codex/NACMCF, with the exception of any specific reference to record keeping. The Directive stated that competent authorities shall carry out official controls to ensure that this Directive was being complied with by food businesses; obviously evidence of compliance was required, i.e., records. Where failure to comply resulted in risks to the safety or wholesomeness of foodstuffs, appropriate measures should have been taken which extended to the withdrawal and/or destruction of the foodstuff or to the closure of the business for an appropriate period of time.

The adoption of the 1993 Directive meant that all food businesses throughout Europe were directed to use the HACCP approach in that it enabled them to meet the requirements of the legislation. In the European Union, the legislative position regarding HACCP changed on 1 January 2006 with the introduction of *Regulation (EC) No. 852/2004 on the Hygiene of Foodstuffs*. This EU legislation consolidated and replaced a number of previous pieces of national legislation, including the UK's 1995 *Food Safety (General Food Hygiene) Regulations*.

HACCP requirements of the Regulation 852/2004 are as follows:
Regulation (EC) No. 852/2004 on the Hygiene of Foodstuffs

Article 5

1. *"Food business operators shall put in place, implement, and maintain a permanent procedure or procedures based on the HACCP principles.*
2. *The HACCP principles referred to in paragraph 1 consist of the following:*
 - (a) *Identifying any hazards that must be prevented, eliminated, or reduced to acceptable levels.*
 - (b) *Identifying the CCPs at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels.*
 - (c) *Establishing critical limits at CCPs which separate acceptability from unacceptability for the prevention, elimination, or reduction of identified hazards.*
 - (d) *Establishing and implementing effective monitoring procedures at CCPs.*
 - (e) *Establishing corrective actions when monitoring indicates that a CCP is not under control.*
 - (f) *Establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively.*
 - (g) *Establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).*

When any modification is made in the product, process, or any step, food business operators shall review the procedure and make the necessary changes to it.

3. *Paragraph 1 shall apply only to food business operators carrying out any stage of production, processing, and distribution of food after primary production and those associated operations listed in Annex I.*
4. *Food business operators shall:*
 - (a) *Provide the competent authority with evidence of their compliance with paragraph 1 in the manner that the competent authority requires, taking account of the nature and size of the food business.*
 - (b) *Ensure that any documents describing the procedures developed in accordance with this Article are up-to-date at all times.*
 - (c) *Retain any other documents and records for an appropriate period."*

Annex 11 Chapter XII Training

“Food business operators are to ensure:

1. *That food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity.*
2. *That those responsible for the development and maintenance of the procedure referred to in Article 5(1) of this Regulation for the operation of relevant guides have received adequate training in the application of HACCP principles.*
3. *Compliance with any requirements of national law concerning training programs for persons working in certain food sectors.”*

Annex II also contains General Hygiene Requirements for all Food Business Operators—i.e., the PRP requirements.

Essentially, the legislation now requires that all food business operators apply HACCP principles to their operations and have appropriate training to do so. However, the flexibility allowed, especially for small businesses, means that a range of food safety management systems will be acceptable from the implementation of good hygiene practices for small low-risk businesses to the requirement for full Codex HACCP to be applied to large food manufacturing.

Although the Codex HACCP principles are not reproduced word for word, paragraph 2 (a–g) of article 5 has the same general meaning. Some commentators have noted that the legislation requires **identification** of hazards while Codex requires **analysis** of hazards. However, it could be argued that the only way to know which hazards **must** be prevented, eliminated, or reduced to acceptable levels is to analyze them.

It is important to remember that the caveats in respect of HACCP entrenched in Regulation (EC) No 852/2004 also have implications in respect of other interrelated legislation such as Regulation (EC) No 853/2004 which deals specifically with the approval of premises and laying down specific rules for foods of animal origin.

In the UK, the statutory defense of Due Diligence was contained within the Food Safety Act (1990) and despite recent amendments to the Act to take account of European Directives, legislation in the UK still retains this provision and requires that the business operator 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.”* A defendant using this defense in case of litigation would certainly have a stronger case if it could be proved that HACCP was in place.

Policies and standards, governing the safety and nutritional quality of all food sold in Canada are set by the Canadian Government’s Health Canada. These statutes and regulations are maintained by the Department of Justice. The Canadian Food Inspection Agency is responsible for administering and enforcing all Acts pertaining to food production.

The Food Safety Enhancement Program (FSEP) is the Canadian Food Inspection Agency’s (CFIA) approach to encourage and support the development, implementation, and maintenance of Hazard Analysis Critical Control Point (HACCP) systems in all federally registered establishments.

FSEP applies to the following groups: meat and poultry, dairy, processed fruit and vegetables, shell eggs, processed eggs, honey, maple, and hatcheries, and is voluntary in all other product sectors.

The CFIA verifies industry compliance with federal acts and regulations through activities that include the registration and inspection of abattoirs and food-processing plants and the testing of products. The CFIA encourages industry to adopt science-based risk management practices to minimize food safety risks. If a food safety emergency does occur, the CFIA, in partnership with Health Canada, provincial agencies and the food industry, operates an emergency response system.

Australia and New Zealand share food safety policy and regulation in many areas. In December 2003, when detailed research into the costs and benefits of HACCP-based food safety programs was completed, the Australia New Zealand Food Regulation Ministerial Council endorsed the *Policy Guidelines on Food Safety Management in Australia: Food Safety Programs* (Ministerial Policy Guidelines). The guidelines identified those food businesses that should be required to have a food safety management program based on the food safety risk they pose. As part of this process of policy development, the following four food industry sectors were identified as being high risk by the Regulators:

- Food service in which potentially hazardous food is served to vulnerable populations—hospitals, schools, nurseries care homes, etc.
- The harvesting, processing, and distribution of raw oysters and other bivalves.
- Catering operations serving food to the general public.
- The production of manufactured and fermented meat.

In determining policy in respect of which businesses should be required to have a HACCP-based food safety management system in place, a series of data was used to examine the costs to businesses of having a food safety management system and the benefit to consumers. Other systems which might have delivered a similar level of food safety were also reviewed as part of this process.

Irrespective of this particular piece of regulatory work aligning HACCP-based food safety management program requirements to risk, all food businesses in some States in Australia are still required to have in place a food safety management system based on HACCP with exceptions only noted for retail businesses selling low-risk pre-packaged food.

It is clear that international legislation continues to move towards making HACCP, or a HACCP approach, a mandatory requirement for the food industry. Key indicators include the legal requirement for use of HACCP in specific sectors of the food industry and the strong recommendation from many governments through directives and food safety reports and surveys.

1.2.3 Government Inspectors and Enforcers

The role of government inspectors is to ensure that legislation is being complied with correctly and to ensure that official controls are carried out in a risk-based,

competent, and consistent manner. In the UK this is the responsibility of the Local Authority Environmental Health Departments, but there are equivalent or similar bodies elsewhere, e.g., the Food Safety Inspectorate Service in the USDA and Health Canada.

The importance of enforcement officer competency in being able to evaluate the suitability and effectiveness of a food businesses HACCP system should never be underestimated and is entrenched in the overarching responsibility both central and local government has for the assurance of safe food. In several countries, enforcement officer HACCP audit competency is imbedded in the legislation associated with the administration of official controls itself, providing a legal framework for HACCP evaluation as part of food law enforcement practice. The way in which food law is enforced will inevitably have an impact on the way in which food businesses approach the legislative requirements for HACCP. Enforcement officers within the UK specifically are required to undertake HACCP training to a level commensurate with their inspection responsibilities and the guidance for this is laid down in The Food Law Code of Practice.

In nations where the implementation of food law enforcement is undertaken by numerous agencies and/or refracted by State and Federal Government infrastructure, the requirement to maintain consistency in enforcement practice becomes increasingly more challenging. Coupled with this are the difficulties inherent in the statutory obligations of many central and local government agencies to ensure that oversight of enforcement approaches and officer competency are independently maintained and reviewed. It is widely acknowledged that a failure by authorities to deliver risk-based, consistent, and competent enforcement to businesses of all sizes results in a fiscal detriment being sustained and the drive to ensure better regulation in the area of food safety in particular is being recognized as critical to economic stability and business growth the world over (Hampton, 2005; Macrory, 2006; Young, 2010).

1.2.4 International Standardization

Improvements in distribution technology have contributed to the increased globalization of food trade. The primary international reference standard for HACCP is published by Codex (2009b). The intent of the Codex Alimentarius Commission (CAC) is to facilitate international trade by providing a documented standard that is based on improved consumer protection and fair trade practices (Hathaway, 1995). The CAC is able to influence food regulation worldwide and utilizes the food safety best practice standards adopted by member governments in drawing up the Codex Alimentarius standards.

Since the early days in Pillsbury, HACCP principles have become accepted internationally, and the common understanding has been assisted by the publication of the seven HACCP principles within the CAC documents first published in 1993. From these documents, many manufacturing companies, food standards and

schemes, committees, consultancy groups and food research associations, large and small, have taken a lead. This has steered the way towards harmonization in HACCP worldwide and has been helpful with respect to international trade. As a result of the completion of the General Agreement on Tariffs and Trades (GATT) Uruguay Round and the establishment of the World Trade Organization (WTO) in January 1995, mutual agreement of the standards of each trading partner's country and/or the equivalence of food safety systems must occur before trade can proceed. Use of the Codex HACCP principles as the international standard means that the HACCP system implemented by one company is based on the same principles as those installed by its competitors, suppliers, and customers, wherever in the world they happen to be based. What remains then is the detailed interpretation of the principles which, to date, the CAC has not taken on as a role.

More recently, the International Organization for Standardization developed and published a certification standard for HACCP, ISO 22000 (2005). The standard is based on Codex (2009) and enables companies to have their systems certified to the standard by independent assessors. Probably the main difference between ISO 22000 and Codex is the inclusion of the management elements of the system. In summary it includes:

Food safety management system: requires the control of documents and records.

Management responsibility: requires evidence of management commitment, a Food safety policy, food safety management system planning, defined responsibility and authority (for food safety), an appointed food safety leader, established external and internal communication arrangements for food safety. Also includes Emergency preparedness and response (that the organization has established, implemented, and maintained procedures to manage food safety related events), and "Management review" ensuring that senior management use appropriate inputs (e.g., audits, verification activities, external events) to periodically review the food safety system with a view to continuous improvement.

Resource management: ensuring that suitable resources are provided for food safety—including trained and educated personnel, infrastructure, and operating environment.

Planning and realization of safe products—this includes PRPs, all the HACCP preliminary steps (see Chap. 6), the requirements of the (Codex, 2009) HACCP principles with the exception of validation and verification, and traceability.

Validation, verification, and improvement of the food safety management system—this is a set of requirements that we have covered in Chap. 7.

Because HACCP is a recognized, effective method, it will give you, your regulatory partners and your customers confidence in the safety of your operation and will indicate that you are a professional company that takes its responsibilities seriously.

1.2.5 Media Issues and Brand Protection

Most companies are aware of the power of the media but perhaps feel complacent when it comes to their own businesses, thinking “it will never happen to us,” “we are in control”, etc. Food safety scares have become big business; the media are always looking for a good story and consumers feel encouraged to go to the press, lured by the thought of cash rewards and a moment of fame.

Increasingly companies have to guard against stories being spread through social media such as Twitter™, Facebook™, and YouTube™ where it is hard to control any damage to the reputation. Some companies have been targeted by undercover journalists posing as workers in food plants. This has resulted in schemes such as “whistle blower” hotlines where workers and consumers can call anonymously to report any misdeeds that they have seen and are uncomfortable with. The details of several recent high profile events in a number of countries have emerged as a result of employees being willing to act as “whistle blowers,” including the peanut ingredients example described earlier.

Sometimes the issues may be very real, but not always. If a consumer goes to the press you will need to have evidence in order to dispute any claims made against you. This is particularly important if the consumer has falsified claims and the police are drawn into the case. Fully documented evidence, through HACCP records which have been efficiently maintained, is essential. Further product testing may also be needed, e.g., to establish whether a foreign object has entered a product before or after cooking.

Someone within the company who is trained in media handling plus an effective incident management system could be vital in ensuring that the company remains in business and the risk to the public is minimized in the event of an incident occurring.

1.3 Problems with Effective Implementation of HACCP: Why HACCP Fails

HACCP has been publically available as a technique for more than 40 years and was in use within Pillsbury and NASA for 10 years before that (Wallace et al., 2011). Given the number of foodborne illnesses that are still reported, is it not working as well as initially expected? The problem is not with HACCP but with how it has been misused and abused. If HACCP is not properly and fully applied, implemented, and maintained, then it will not result in an effective control system. This may be due to improperly trained or untrained personnel not understanding the principles correctly; it may be that the outcome of the HACCP study is not implemented within the workplace; or it may be that the implemented system fails through lack of maintenance, i.e., if a company implements a system and stops there, paying little or no heed to changes that occur in the operation, then new hazards may be missed. The effectiveness may also be lost if the company carries out the hazard analysis and then tries to make its findings fit with existing controls.

As we will discuss, HACCP is compatible with existing quality management systems but you must ensure that product safety is always given priority and that new HACCP-based recommendations are not ignored because they differ from existing programs. Problems may also arise if HACCP is carried out by only one person, rather than a multidisciplinary team with more comprehensive knowledge of what really happens in the plant. This is also true where it is done at the head office or external consultant level with little or no input from or connection to the processing facility.

Another reason for failure is because the hazard analysis process takes little account of the need for prerequisite hygiene and other support programs.

Let us consider some examples where food safety systems appear to have failed and some reasons for this.

1.3.1 Examples of Food Safety Incidents

When something goes wrong with a food product there may be localized or widespread illness and suffering, and alongside the effect on consumers, the cost to the company concerned can be huge. Even when no illness has been caused, the discovery of safety hazards in a product intended for consumption can lead to prosecution and damage the reputation of the company. Microbiological hazards generally have the potential to cause the greatest impact on consumer safety though more recently there have been a number of significant chemical hazard events—melamine in infant formula in China being just one example. However, frequent product withdrawals and prosecutions often result from failure to adequately declare allergens on packaging or foreign material being discovered in food. Table 1.3 compares a number of food safety incidents that have occurred world-wide. The true costs associated with such incidents are seldom documented, but where they have been established they can be shown to be substantial both to the industry and to society. For example, in the case of the *Salmonella* Napoli outbreak in chocolate, the quoted costs relate solely to the health care costs and do not include the costs associated with withdrawing 2.5 million chocolate bars from the market nor the cost in terms of reputation damage.

In the USA the latest estimates (CDC, 2011) are that one in six Americans are affected by foodborne illness each year. This is based on 48 million cases of illness, over 127,000 hospitalizations and over 3,000 deaths annually. The economic burden of this is in the \$billions. It is significant that the incidents listed in Table 1.3 involved both large and small companies and crossed international boundaries. Many of the companies involved received enormous publicity for the wrong reasons and not all are still in business. No company can afford to be a statistic in someone else's table. It is also noteworthy that many of the incidents included here enable other companies to learn from the failure, yet there are numerous examples of the same mistakes being made by other companies. This may be because the real findings from incident investigations are seldom published in the public domain.

Table 1.3 Examples of failure—past and present

Past incidents			More recent incidents			Discussion
When	Where	What	When	Where	What	
1982	UK/Italy	Salmonella Napoli (low numbers) in chocolate. Cross-contamination. 245 people ill. \$750,000 cost. (Shapton, 1989)	2006	UK	Salmonella Montevideo in chocolate. Cross-contamination through poor GMP (roof leaks). 60 people ill. \$40 Million (Hingley et al. 2009)	<p>These are both cases which involved post-process cross-contamination. There are a number of other cases of Salmonella in chocolate and often associated with poor environmental conditions. Kill step is at roasting of beans for Salmonella in cocoa and with no kill step during the chocolate process, the ingredients have to be sourced from reputable suppliers and GMPs in the plant need to be appropriate for high risk food products. Very low numbers are often found to be the cause of outbreaks associated with chocolate or other high fat products suggesting that the mere presence of the organism is a concern.</p> <p>Dried milk powders are often used as ingredients in products which receive no subsequent kill step so they are highly sensitive.</p>
1985	UK	Salmonella Ealing in infant's dried milk. Cross-contamination due to defective spray dryer. <i>S. ealing</i> isolated from	2009	USA	Potential Salmonella in dried milk powder for industrial sale. The company voluntarily recalled instant nonfat dried milk, whey	

		<p>scrapings taken from a silo into which waste powder and sweepings were stored. 76 people ill; 1 death. \$5Millions. (Shapton, 1989)</p>			<p>protein, fruit stabilizers, and gums (thickening agents) that it had manufactured over a 2-year period, because they might be contaminated with Salmonella. No illnesses reported. (Gieraltowski et al. 2012) Cost unknown but significant given the number of recalls.</p>	<p>Salmonella was isolated in a dairy shake product and then traced it back the plant. The regulatory inspection resulted in an expanded recall due to conditions observed.</p>
1998	UK	<p>Salmonella Enteritidis in shell eggs (Statement by Government Minister). Poor farm practices. 60 % reduction in egg sales. Cost > \$Millions. (North and Gorman, 1998)</p>	2010	USA	<p>Salmonella Enteritidis in shell eggs. Poor farm practices. 1,939 illnesses. Cost unknown. (CDC Web site)</p>	<p>This led to the development of Lionbrand eggs in the UK and vaccination of young birds. This was not done on a global basis through best practice producers did follow the approach.</p>
2007	USA	<p>Salmonella Tennessee in peanut butter. Route cause said to be due to cross-contamination. Congressional Research Service (2010)</p>	2009	USA	<p>Salmonella Typhimurium in peanut butter. Cross-contamination. Over 650 people ill; 9 deaths. Company bankrupt. 350 other companies impacted, cost to one major manufacturer was \$75 million. (Powell et al., 2010)</p>	<p>These two plants are situated just 80 miles from each other yet Peanut Corporation of America (PCA), the 2009 plant involved took no action based on earlier events.</p>

(continued)

Table 1.3 (continued)

Past incidents				More recent incidents			Discussion
When	Where	What		When	Where	What	
1989	UK	<i>Clostridium botulinum</i> toxin in hazelnut yogurt. Thermal process inadequate for reduced sugar recipe—27 people ill; 1 death. (Shapton, 1989)		2006	USA	<i>Clostridium botulinum</i> toxin in carrot juice. Inadequate pH control—design failure. 4 people ill. (Kaye, 2006)	Both of these cases illustrate the need for safe product design and design review systems.
1998	USA	Salmonella Agona in breakfast cereal. Environmental cross-contamination. 400 cases (ill). (Breuer, 1999)		2008		Salmonella Agona in breakfast cereal. Same plant as in 1998. Environmental cross-contamination. (Powell et al., 2011)	This was the same company and they had taken significant measures to prevent a reoccurrence. However, various operational events combined and a second event occurred but with no illnesses. The example is interesting however because it shows that more than 10 years ago, Salmonella shows up in dried foods as a hazard. Yet when standard developers defined a “high risk food” it was nearly always short shelf life and temperature controlled. This is very slowly changing but only as a result of numerous outbreaks in the low water activity shelf stable foods category.

1999–2000	France	Listeria in rillettes (a pate-like product) and pork tongue—two outbreaks (de Valk et al., 2001)	2008	Canada	<i>Listeria monocytogenes</i> in Maple Leaf Foods cooked, sliced delicatessen meats. Sanitary design failure on meat slicing equipment. (Powell et al., 2011)	Sanitary design was a root cause of the Canadian event. The company has since become a champion for food safety and freely shares its learnings.
2005	USA	July 1, 2005—Cold Stone Creamery together with the FDA notified the public that products containing “cake batter” ice cream sold at Cold Stone Creamery stores may be associated with outbreaks of Salmonella Typhimurium infection in four states. As a precautionary measure, Cold Stone Creamery was quick to respond and voluntarily removed all cake batter products from all of its stores throughout the country. Cake Batter’s possible contamination with this organism came to light after outbreaks of infection with this form of Salmonella were reported in Minnesota, Washington state, Oregon and Ohio. (FDA, 2005)	2009	USA	Nestlé, Cookie Dough U.S. Food and Drug Administration announced that it had found <i>E. coli</i> O157:H7 in a sample of pre-packaged Nestlé Toll House refrigerated cookie dough. Whilst the manufacturer undertook a recall, the warning was based on an epidemiological study conducted by the CDC and several state and local health departments. Subsequent tests determined the genetic fingerprint of the <i>E. coli</i> O157:H7 found in the FDA sample was different than <i>E. coli</i> O157:H7 linked to the outbreak strain in patients. Over 70 people from 30 plus states were infected with the outbreak strain. (FDA, 2009)	These are interesting as cookie dough and cake batter are not designed to be eaten raw but it is a known consumer behavior and therefore the HACCP study would need to account for that. An ingredient of cookie dough is flour—a minimally processed agricultural commodity. However this was never confirmed as root cause despite numerous tests.

(continued)

Table 1.3 (continued)

Past incidents			More recent incidents			Discussion
When	Where	What	When	Where	What	
1996/1997	UK	<i>E. coli</i> O157:H7 in cooked meat products from a small butchers shop in Scotland. Inadequate heat process and/or cross-contamination suspected. 20 deaths. (The Pennington Group, 1997)	2005	UK	157 people, primarily children became ill in an outbreak caused by <i>E. coli</i> O157:H7 in cooked meats. 31 people were hospitalized and 1 child died. The meats were supplied to schools by John Tudor. A packaging machine on the premises used for both raw and cooked meats was identified as the probably source of the contamination. In addition however the lack of a food safety culture was reported as significant. (Powell et al., 2011)	See Case studies in Appendix
2008	USA	Salmonella St. Paul in fresh jalapeno peppers. May have been cross-contamination on farm. 1,442 ill, 286 hospitalized, and 2 deaths.	2011	Germany	Sprouted seeds in Germany and other European countries contaminated with <i>E. coli</i> O104:H4. More than 4,000 illnesses and 40 deaths. (Giordano, 2011)	Many instances of contaminated ready to eat produce—too many to list here but clearly a problem that industry has to address. Cross-contamination on farm either through poor irrigation practices or from animals are common themes.

1993	Germany	Salmonella (90 serotypes isolated) in paprika powder mix used on potato chips. 1,000 cases of illness. Cost unknown. (Lehmacher et al., 1995)	2010	USA	Salmonella isolated in Crushed red pepper sold as an ingredient to the industry. No confirmed illnesses. Cost unknown but multiple recalls so likely significant. (Gieraltowski et al. 2012)	In the jalapeno peppers case the source was originally thought to be tomatoes. In the German case, there was also confusion during the initial investigation Blame veered from Spanish cucumbers back to German sprouts and eventually to Egyptian fenugreek seed. Investigators were criticized for their handling of the investigation which may have resulted in the case being more widespread than necessary.
2006	Worldwide	Sudan red in spices. Economic adulteration. No deaths but widespread recalls. \$100 millions. (Davies et al., 2006)	2008	China/ worldwide	Melamine contamination of dried milk. Estimated 54,000 sick children, 13,000 hospitalized, and 4 deaths. \$100 millions. (Congressional Research Service, 2008)	In the case of the paprika low numbers were involved. Economic adulteration has occurred since records began—in fact watered down beer in the UK resulted in some of the first food-related legislation. (Scarce and high price) High value items are most vulnerable. This can be built into your raw material risk assessment.

In looking at these examples and many others not listed here it is clear that cross-contamination or re-contamination following processing is a frequent cause of failure. We'll focus on this in Chap. 4 but the primary sources and vectors of contamination can be categorized as contaminated raw materials, airborne contamination, pests, food-processing environment (ILSI, 2005)—all managed by PRPs.

Currently there appears to be a move towards a more open sharing of information which will be helpful. This supports the fact that food safety should not be seen as a competitive advantage and it is in all our interests to do better.

1.3.2 Failure to Understand HACCP: Common Misconceptions

This section is adapted and abridged from Wallace et al. (2011) and Motarjemi and Käferstein (1999).

HACCP is a tool that was designed to help, not hinder, food safety management yet many years after it was developed many misconceptions remain. Here are a few of the most commonly heard:

“HACCP has been “done” already”

Mostly larger, more mature companies hold this view along with regulators who assume that the larger companies are in great shape. This is a BIG MISTAKE.

“Having a HACCP plan = HACCP”

The HACCP plan is just the document and that is all. Having a HACCP system is much more—it is about the way the company thinks and works 24/7 to analyze hazards and continually implement preventative controls. The document just captures those activities and thought processes.

“HACCP costs too much”

Try not having a system! Cost of failure is well documented as being significantly more than the investment in prevention. Putting in a food safety management system where there is no system actually saves money.

“HACCP is complicated and requires a huge amount of paperwork”

Usually this is because the system is unfocused. HACCP can help you to identify and document only what matters in terms of food safety.

“HACCP requires too many resources”

It requires the “right” resources. This is a concern of both large and small companies. It does take time during the startup and implementation phase but that reduces once up and running.

“HACCP by itself will control food safety”

Not at all. HACCP is at the center in the way that risk-based program requires hazard analysis and risk evaluation skills but many prerequisite and management support activities are needed—more than that—are essential as can be seen by the examples of failure (Table 1.3).

“HACCP is a one-time activity”

This fallacy is common in practice. Whilst HACCP training will explain that HACCP systems need to be updated, many plans are out of date because updating is seen as a once a year activity at best and is often done much less frequently.

“HACCP is not suitable for small companies”

Ask the consumer whether this should be true! Food must be safe whoever produces it and the HACCP mindset will add value to any food processor, large or small.

“Zero risk is possible”

If only that were true, life in the food industry would be so much easier. Zero risk is unattainable but that doesn't mean we shouldn't have that as the ultimate goal. HACCP and robust PRPs are the surest way of getting close.

“Farm to table HACCP is not possible”

There is some debate around this. Definitive control measures are not always possible either on the farm or at the consumer table. However, the process of undertaking a Hazard Analysis is very helpful and with scientific advances the control measures available will continue to develop.

“HACCP will slow down our product development process—we don't have time for that”

This is why it is important to build HACCP into the product development activities such that it isn't an “add on” activity once the product is presented in the final stages. Having to go back to the bench and start again at the request of the HACCP team will definitely add to the timeline.

1.4 Key Points Summary

- HACCP can be used by everyone and is an excellent tool for reducing food safety risk. Many companies have not taken full advantage of this.
- The HACCP process itself is fairly logical and it is the hazard analysis step that can be the most difficult to get right without the proper expertise, i.e., knowledge of hazards and control measures. Determining critical limits can also cause problems, but the application of HACCP techniques outlined within the remainder of this book can be interpreted for all sectors of the food industry.
- PRPs are **essential** alongside HACCP for prevention of cross-contamination from the environment or people. Just how essential needs to be determined through a hazard analysis and risk evaluation but typically, PRPs after any pathogen reduction step or in any high risk ready to consume product environment will be critical for food safety assurance.
- Food safety programs (HACCP and PRPs) require ongoing management commitment if they are to be sustainable and effective. This includes provision of resources and application of all the normal management practices that will provide an essential operating framework.
- There are many external pressures for using HACCP but none more important than the real desire to keep consumers safe. Regulatory requirements, media

interest, brand protection, and customer requirements are all external drivers for its use.

- There are many examples of failure to learn from—some where we could have prevented the events and some that pose more challenge, requiring research and collaboration.

Chapter 2

Preparation and Planning to Achieve Effective Food Safety Management

When the decision is taken to use HACCP within a company, there is often the inclination to charge ahead and start doing something without taking the time to consider the best approach for **your** company. It is important to have sufficient knowledge before getting started, i.e., to understand both the theory of HACCP and the practicalities of implementation. Therefore, if you are new to HACCP, you will want to read the remaining chapters of this book to gain an understanding of the entire process before planning your approach and preparing to get started. This chapter outlines the key stages in the HACCP process and considers both how to establish the current food safety status of the operation and plan the HACCP project.

The first thing you need to consider is where you are now and where you'd like to get to in terms of food safety management. In this chapter we will look at how to prepare and plan the application and implementation of the HACCP principles recognizing that for most companies this will be a revision or enhancement to an existing program. We'll include guidance on how to prepare, how to plan the project, how to evaluate and build effective support systems, and how to identify and train the people required in establishing and managing an effective system.

The way to implement the HACCP principles may at first seem obvious, particularly after an initial training course; but you should take time to consider the various alternatives in terms of the structure of the HACCP system and what your overall food safety program will look like. A degree of forethought at this stage will be beneficial later on, not least because it will give other people within the organization the chance to visualize what you are about to do and allow them to make relevant and valuable contributions to the program. This is more likely to result in the implementation of a successful system, which gains commitment for ongoing development and further improvement throughout the business.

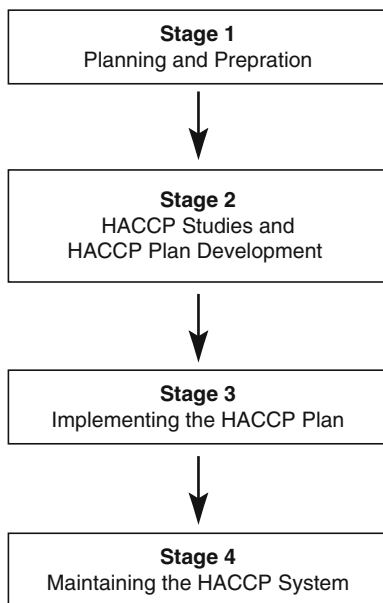


Fig. 2.1 The key stages of HACCP

2.1 The Key Stages of HACCP

Any company that is new to the HACCP techniques will go through four key stages to obtain an effective system (Fig. 2.1). This approach can also be used when updating the system.

In this chapter we will be discussing key stage one—Planning and Preparation (Fig. 2.2). This is where the foundations are laid and it is important to take time here to:

- Ensure that the appropriate people are identified and trained.
- Establish what support systems are already in place and what needs to be developed.
- Consider the most appropriate structure for **your** HACCP system.
- Plan the entire project, including a realistic timetable for development and implementation of the HACCP plan.

The first thing to do is to consider what you are trying to achieve. The path you take to a fully implemented HACCP system will then depend on where you are starting from and the maturity of your existing systems.

Another way to consider this is by way of Deming's Plan, Do, Check, Act (PDCA) cycle (Deming, 1993) where:

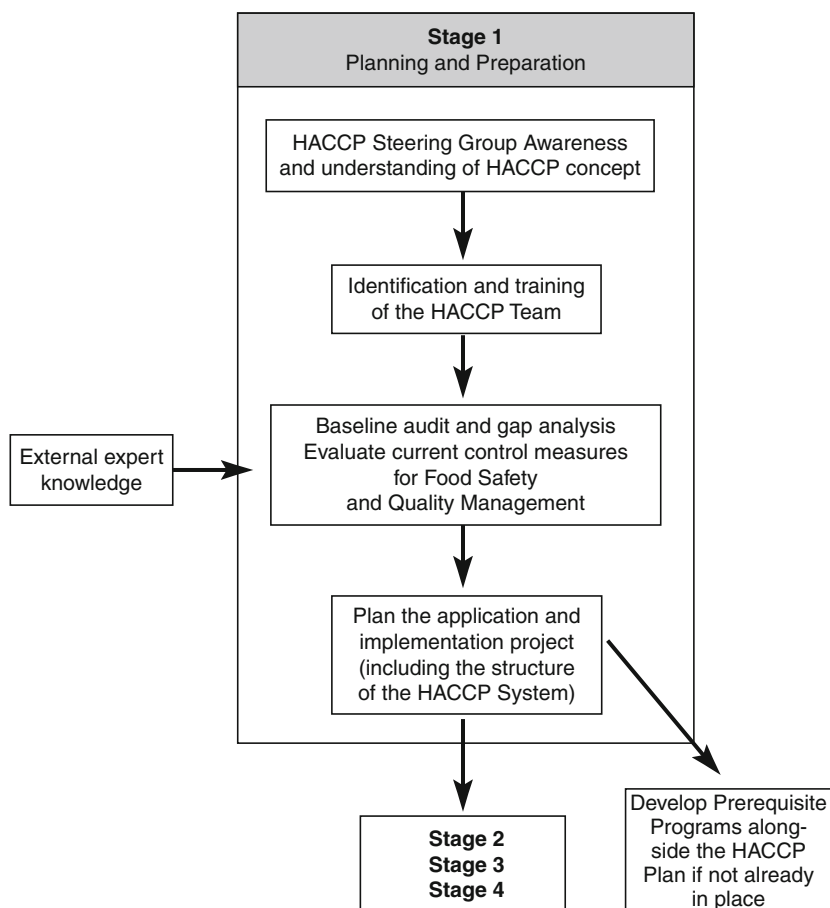


Fig. 2.2 HACCP Key stage one—planning and preparation

Key Stage 1 = The **Planning** stage (for HACCP and PRP requirements)

Key Stage 2 = The **Doing** Stage (both for HACCP program development and PRP upgrades)

Key Stage 3 = **Checking** that the HACCP plan is valid before implementation

Key Stage 4 = **Act** (24/7) to monitor and maintain the HACCP, PRP, and overall Food safety program

The PDCA cycle will be familiar if you have used the terminology already within your company. Choose a project framework that you are familiar and comfortable with using.

Although this chapter is focusing on the first key stage of planning and preparation (Fig. 2.2), for those who are learning the HACCP techniques it is easier to start with the HACCP theory and then go back and start planning the application of it. It is therefore recommended that those who are new to HACCP spend some time

reading the rest of the book before starting to plan their approach. However, it is also important to understand the resource implications of using HACCP so we will start by considering personnel involvement.

2.2 Preparing the Way: Personnel and Training

2.2.1 *Personnel Resources*

As we said at the start of this book, HACCP is a people-based system. As a tool, HACCP is used by people and if the people are not properly educated, experienced, and trained then the resulting HACCP system is likely to be ineffective and unsound. In this section we will discuss the people who need to be involved and assess their training requirements. Also we will help you to identify the right experts for your company.

(a) Senior management commitment

Early involvement of senior management is fundamental to the effective implementation of HACCP. Real commitment can only be achieved if there is complete understanding of what it takes to develop and maintain a food safety program and how HACCP fits into this. Senior managers do need a basic understanding of the most likely food safety hazards and ways to control them. This will include an understanding of what HACCP actually is, what benefits it can offer to the company, what is really involved, and what resources will be required. This understanding will be achieved not only by reading books such as this one (Chap. 1 contains much of the information they need) but also by attending a food safety and HACCP briefing and discussion session, as a senior management group. This may be undertaken by a reliable consultant if there is no one able to do it internally. Open discussion should be encouraged, with the end result that the decision to enhance the program is given full support by all members of the management team. This will be important in cascading commitment to everyone in the company.

Senior management from all disciplines must be encouraged to actively demonstrate their commitment and be unanimous in their support for the approach. It would be a pity if credibility was lost, for example, through the Sales Director continuing to make rash promises to the customer: “Yes, we can develop and produce this completely untried and untested high-risk product for you within 3 days, no problem,” or through the Engineering Manager purchasing equipment that may be unable to achieve the process criteria needed to make a safe product or be cleaned properly due to unsanitary design.

Identification of a HACCP or broader food safety steering group followed by in depth education and training will provide a valuable and visible support to the

implementation of HACCP. Functional Senior Managers plus the HACCP team leader are vital to form this group.

(b) The HACCP team

It is important that HACCP is not carried out by one person alone but is the result of a multidisciplinary team effort—the HACCP team. The second preparatory activity, therefore, is to identify and train the HACCP team. It is recommended that as a minimum the core HACCP team consists of experts (“expert” meaning having knowledge and experience) from the following areas:

1. **Quality Assurance/Technical**—providing expertise in microbiological, chemical, and physical hazards, an understanding of risk and hazard significance assessment, and knowledge of measures that can be taken to control the hazards.
2. **Operations or Production**—has responsibility for and has detailed knowledge of the day-to-day operational activities required in order to produce the product.
3. **Engineering**—able to provide a working knowledge of process equipment and environment with respect to hygienic design and process capability.
4. **Additional expertise**—may be provided both from within the company and from external consultancies. The following areas should be considered:
 - **Supplier Quality Assurance**—essential in providing details of supplier activities and in assessment of hazard and risk associated with raw materials. The person responsible for auditing and approving suppliers will have a broad knowledge of best practices gained through observing a wide range of manufacturing operations. They will also need to know how the raw materials are used in your company.
 - **Research and Development**—if the company is one where new products and process development is a continuous activity, then input from this area will be essential. Early involvement and sharing of information at the product/process concept stage could prove invaluable.
 - **Distribution/Logistics**—for expert knowledge of storage and handling throughout the distribution chain. This is particularly important if distribution conditions, e.g., strict temperature control, are essential to product safety or if bulk shipments are made.
 - **Procurement**—participation of purchasing personnel will mean that they are made fully aware of the risks associated with particular products or raw materials and can assist with communication of any proposed change in suppliers. They will also be a partner for communication of your specifications and expectations.
 - **Microbiologist**—if the company has its own microbiologists, then their expert knowledge is absolutely needed on the HACCP team. Many smaller companies do not have this option and, where microbiological hazards require consideration, they should identify a source of expert help from outside, i.e., a food research association, a university, a reputable consultancy, or analytical laboratory.

- Toxicologist—in all but the larger companies, this knowledge is likely to be located in a consulting analytical laboratory or university. A toxicologist may be needed particularly for knowledge of chemical hazards and methods for monitoring and control.
- Statistical process control (SPC)—there are many classes available which will be sufficient to give members of the HACCP team or their colleagues enough knowledge to carry out basic SPC studies on their process operations. This will be important in assessing whether a process is capable of consistently achieving the control parameters necessary to control safety. In some instances, however, it may be advisable to have an external expert join the HACCP team as a temporarily co-opted member. This would be useful when setting up sampling plans or for a more detailed assessment of process control data.
- HACCP experts—it may be appropriate initially to co-opt an external HACCP specialist onto the HACCP team. This may be useful in helping the company team to keep on the right track and become familiar with the HACCP approach. It could also be extremely important in helping the company to determine whether they have got the right expertise on the team and as an early assessment of whether the initial HACCP studies are correct. Ultimately, the right thing to do is to develop internal expertise but an independent review is often extremely helpful when upgrading the system. Those who have worked with it for a long time are often too close or too vested in it to see the opportunities for improvement.
- Other—facilitation skills are extremely useful and often can be found within Human Resource or training departments if available. Also, needed is a scribe or notetaker who can capture the discussions and prepare all the documents during and in between meetings.

If the company does not already use team working, it may be difficult initially for individuals to adjust to this approach. It should be emphasized that as a team effort the HACCP study will have input from a much greater diversity of knowledge, skills, and experience, far beyond that of any one individual. The team is made up of people with a real working knowledge of what happens in each area and therefore any processes that cross over departments can be tackled more accurately. You should also consider that HACCP studies may well result in recommendations for changes to processes and products and capital expenditure. These recommendations are far more likely to be accepted by senior management if they are supported by knowledgeable people across all disciplines within the company.

We have now considered the disciplines required within the team and, in summary, it should be emphasized that expert judgment is essential in assessment of hazards and risks. What else is important with respect to the type of people involved in the team? Personal attributes will include:

1. Being able to evaluate data in a logical manner using expertise within the team and perhaps using published data for comparison.
2. Being able to analyze problems effectively and solve them permanently, treating the root cause not the symptom of the problem.
3. Being creative by looking outside the team, the company, and the country for information and ideas.
4. Being able to get things done and make recommendations happen.
5. Communication skills. The HACCP team will need to be able to communicate effectively both internally within the team and externally, across all levels of the company.
6. Leadership abilities. Leadership skills of some degree will be useful in all members of the team. After all, they are leading the company in its HACCP approach to food safety management. It is recommended that one member of the team is appointed to HACCP team leader. This is often the QA Manager but consider carefully what the leadership of a team entails. Your Personnel or Human Resources department may be helpful in identifying suitable courses for development of these skills if they are not already sufficient.

The HACCP team leader will have a key role in the success of the HACCP system and he or she is likely to become the company HACCP expert and be regarded as such. In the leadership role the team leader will be responsible for ensuring that:

- The team members have sufficient breadth of knowledge and expertise.
- Their individual skills and attributes are taken into account.
- Individual training and development needs are recognized.
- The team and work tasks are organized adequately.
- Time is made available for reviewing progress on an ongoing basis.
- All skills, resources, knowledge, and information needed for the HACCP system are available either from within the company or through identifying useful external contacts.

The behavior within the team must be supportive, encouraging all members to participate. With all team members fully committed to producing and maintaining an effective HACCP system there should be no time for arguments or internal politics.

Within the HACCP team itself, consider the range of disciplines required. In smaller companies the same person may be responsible for both Quality Assurance (QA) and Operations. In terms of ideal team size, four to six people is a good range. This is small enough for communication not to be a problem but large enough to be able to designate specific tasks.

In large organizations there may be more than one HACCP team. It was stressed earlier that the members of the team must have a good working knowledge of what actually happens in practice. In large companies the “experts” and senior people in

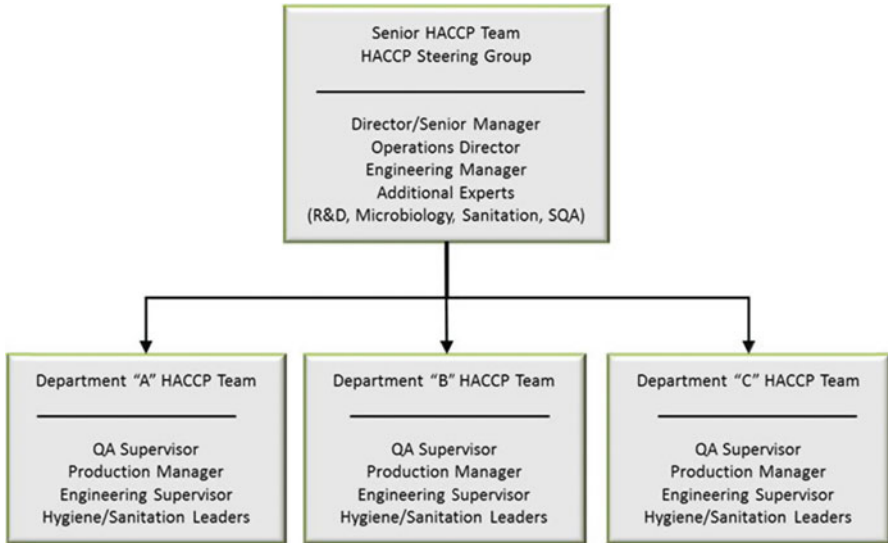


Fig. 2.3 Example of HACCP team structure in a large organization

the three main disciplines of QA, Production, and Engineering may not be close enough to the operation. It may then be more effective to have a series of smaller departmental teams, still made up of the three main disciplines but at a less senior level. The departmental teams then carry out the HACCP study for their own areas and, when satisfied with the resulting HACCP plan, pass it up to a more senior level HACCP team for approval. This ensures that the true working knowledge of activities is captured and subsequently reviewed by appropriate experts in each area. This approach is also common when HACCP is applied to the process in modular form (see Sect. 2.5.1). An example of this could be represented diagrammatically, as in Fig. 2.3.

(c) Additional personnel

In addition to the HACCP team(s) and senior management, personnel throughout the operation will need to be involved. This will include line supervisors, operators, incoming raw materials inspectors, cooks, and point of sale personnel. It is likely that these people will be involved later on, when HACCP moves into the implementation phase. It is important that they, too, are fully briefed on their role within the system, particularly if they are monitors of the controls critical to food safety.

The numbers of people needed in addition to the HACCP team will be dependent upon the type of operation and number of controls that need to be monitored. There should always be a sufficient number of people to ensure that the critical points are monitored effectively and that records are reviewed.

2.2.2 *What Are the Training Requirements?*

HACCP is only going to be effective as a means of managing food safety if the people responsible for it are competent. As a result, training and education becomes the single most important element in setting up a successful HACCP system. It not only provides the technical skills required in implementing HACCP, it also helps in changing attitudes of people where required. This cannot be stressed enough. Codex comments that the efficacy of any HACCP system relies on management and employees having appropriate HACCP knowledge and therefore, ongoing training is necessary for all levels of employees and managers and that this is an “essential element for the effective implementation of HACCP” (Codex, 2009b). ISO22000, *Food safety management systems—Requirements for any organization in the food chain*, states that the organization “shall identify the necessary competencies for personnel whose activities have an impact on food safety” (ISO 2005) and also requires that training be carried out to ensure that the competencies are met. Whilst this illustrates that training is clearly identified at the international level as being crucial to successful HACCP, there is no international standardization of HACCP training requirements. We believe that there is as much a need for international HACCP training standards as there is for international audit standards. Currently there is much variance in the levels and quality of training provided. A few countries, notably the UK, have oversight and core curricula for HACCP training, at least at some levels, but most countries do not.

In this section we will explore the training requirements for HACCP teams. In our experience, a number of key competencies are required of HACCP teams and a balance of these attributes throughout the team is necessary.

The training of these people is an investment and should be taken seriously. You should realize that the HACCP team members may need to be provided with many additional support skills in addition to the HACCP principle application knowledge such as project planning, SPC, audit skills, team working, communication, and influencing.

Table 2.1 outlines a HACCP training program which would usually be required for the various groups of people in the company. When choosing a course/class, it is vital to check that it covers all the required theoretical elements and includes practical, “hands-on” experience. If you have a strong internal training team, you may wish to use this book and other resources to develop your own training material, or use appropriate external HACCP courses or programs related to ISO 22000 (2005).

The HACCP team leader will need a more advanced level of HACCP knowledge to other personnel. This may be available through taught courses, but more likely it will be gained through an experiential approach, i.e., working with an experienced mentor on the application of the HACCP principles, perhaps within your own factory. More experience also comes through teaching the concept to others or being able to participate in the discussions and answering questions.

Table 2.1 Possible training subject matter and learning outcomes for HACCP by learner group (adapted from Wallace et al. (2011); after Mayes and Mortimore (2001))

Group	Learning outcome
Senior Management	<ol style="list-style-type: none"> 1. Understand the general principles of HACCP and how they relate to the food business. 2. Demonstrate an understanding of the training and knowledge requirements for Food Safety team members and the workforce as a whole. 3. Demonstrate an understanding of the links between HACCP and other quality management techniques and programs and how a combined product management system can be developed. 4. Understand the need to plan the HACCP system and develop a practical timetable for HACCP application in the whole operation.
HACCP/Food Safety Team Leaders	<p><i>HACCP system and its management</i></p> <ol style="list-style-type: none"> 1. Demonstrate an up-to-date general knowledge of HACCP. 2. Explain how a HACCP system supports national and international standards, trade, and legislative requirements. Describe the nature of prerequisite programs (PRPs) and their relationship with HACCP. 3. Demonstrate the ability to plan an effective HACCP system. 4. Demonstrate a knowledge of how to lead a Food Safety team. 5. Demonstrate an understanding of the practical application of HACCP principles. 6. Demonstrate the ability to design, implement, and manage appropriate programs for verification and maintenance of HACCP systems. 7. Explain the methods to be used for the effective implementation of HACCP. <p><i>Additional topics</i></p> <ol style="list-style-type: none"> 1. Demonstrate an understanding of the nature of hazards and how they are manifested in food products/operations and give relevant examples. 2. Demonstrate an understanding of the intrinsic factors governing the safety of product formulations and methods that can be used to assess safety of new products. 3. Carry out the steps to identify significant hazards relevant to the operation and determine effective control measures, i.e., assessment of risk (likelihood of occurrence and severity). 4. Demonstrate an understanding of the training and knowledge requirements for Food Safety team members and the workforce as a whole. 5. Develop appropriate training programs for CCP monitoring personnel. 6. Demonstrate an understanding of the links between HACCP and other quality management techniques and how a combined product management system can be developed.
HACCP/Food Safety team members	<p><i>HACCP system</i></p> <ol style="list-style-type: none"> 1. Justify the need for a HACCP system. 2. Show how the legal obligations on food business proprietors to analyze food hazards and identify critical steps in the business activities should be met in their appropriate industries. 3. List and explain the importance of the principles of HACCP. 4. Describe the method by which hazard analysis may be carried out and appropriate control measures ascertained to assess the practical problems.

(continued)

Table 2.1 (continued)

Group	Learning outcome
	<ol style="list-style-type: none"> 5. Identify critical control points including critical limits to ensure their control. 6. Develop suitable monitoring procedures for critical points and explain the importance of corrective action procedures. 7. Verify the HACCP system by the use of appropriate measures. 8. Carry out the steps to introduce and manage a fully operational HACCP system.
	<i>Additional topics</i>
	<ol style="list-style-type: none"> 1. Demonstrate an understanding of the nature of hazards and how they are manifested in food products/operations and give relevant examples. 2. Demonstrate an understanding of the intrinsic factors governing the safety of product formulations and methods that can be used to assess safety of new products. 3. Carry out the steps to identify significant hazards relevant to the operation and determine effective control measures, i.e., assessment of risk (likelihood of occurrence and severity). 4. Develop appropriate training programs for CCP monitoring personnel.
CCP monitors	<p>Understand the general principles of HACCP and how they relate to the food handler's role.</p> <p>Perform CCP monitoring tasks, record results, and initiate appropriate actions.</p>
Auditors of HACCP systems	<p><i>HACCP and regulatory Auditing</i></p> <ol style="list-style-type: none"> 1. Provide up-to-date general knowledge of HACCP and its relationship with national and international standards, trade requirements, and legislative requirements. 2. Examine the role of good hygiene practices as a foundation for HACCP-based food safety management systems. 3. Provide a comprehensive revision of the application of HACCP principles for the development of HACCP-based systems for food businesses. 4. Consider the design and management requirements associated with the application and implementation of HACCP-based food safety management systems in food businesses. 5. Enhance the skills required for the assessment of HACCP-based food safety management systems. 6. Consider the tools available to educate food business operators in the principles of HACCP and to provide advice and support during development and implementation of food safety management systems. <p><i>Additional topics</i></p> <ol style="list-style-type: none"> 1. Understand the need for audit preparation including the development of suitable checklists. 2. Perform HACCP audits using sampling, questioning, observation, and assessment skills. 3. Construct audit reports giving clear indication of findings and corrective action needed.
General workforce	<p>Understand the general principles of HACCP and how they relate to the food handler's role.</p>

Table 2.2 Suggested sources of additional HACCP team knowledge

Skill/knowledge	Means of providing it
1. Principles and techniques of HACCP	In addition to the training described in Table 2.1, reference books and scientific papers: Mortimore and Wallace (2001); Campden BRI (2009); Wallace et al. (2011)
2. Understanding of the types of hazards that could occur and methods of control. For example, in relation to foodborne pathogens this should include the frequency and extent of their occurrence in different foods; the severity and likelihood of transmitting foodborne pathogens and toxins through different foods; the means of and influence of contamination of all types and elimination or reduction by processing and procedures, i.e., the control measures	With a good mix of disciplines on the team this area should be covered, provided the team members, among them, have both academic backgrounds in microbiology or food science-related subjects and sufficient food industry experience. Useful courses in understanding hazards are provided by many training organizations if a refresher is needed. Use of hazard databases available through universities and NGO's organizations Use of the Internet Use of reference books: ICMSF (1980, 1986, 1996, 2002, 2010)
3. Detailed knowledge of good manufacturing practices	Essential food industry experience as above Reference books: IFST (2007), Shapton and Shapton (1991), ISO/TS 22002-1 2009, and PAS 222 (2011)
4. Team-working skills, including communication skills (especially important if this is a new way of working for most team members)	Personnel department may be able to assist with some in-house team-building training for the HACCP team External team-building courses are available, often lasting about 5 days Reference books: Lencioni (2002)
5. Project planning and management skills (the HACCP implementation project may have a separate Project Manager but, if the HACCP team itself is responsible, this skill will be invaluable)	External courses run by management consultancies or training organizations Use of an on-site consultant in the early stages Reference books: Bird (1992); Brown (1992); Oates (1993)
6. Auditor training—essential for the verification of the flow diagram and HACCP plan	A Quality Management Systems auditor course is recommended (internal auditors level is sufficient, which usually lasts 2 days). These can be run on your own site if numbers justify. Available from ISO 9000 assessment bodies, professional institutes, or training organizations Reference books: Chesworth (1997)
7. Statistic Process Control (a working knowledge in order to make valid process capability assessment and data handling)	External management consultancy groups who often provide training packages Reference books: Rowntree (1981); Price (1984)

(continued)

Table 2.2 (continued)

Skill/knowledge	Means of providing it
8. Problem-solving techniques—in order to tackle recurring problems in a structured way and ensure that permanent solutions are found. Can be very useful in learning how to draw process flow diagrams and in handling data	Training packages can be purchased from management and training consultancy groups Courses are also available through the above. Recommend an on-site session tailored to the need (HACCP) in order for it to be really understood and applied after the event
9. Change management—really important to be able to lead the transition. Here are a couple of books on change management and leadership that we've found to be very insightful	Reference books: Managing Transitions—Bridges and Bridges (2009) Superperformance—Guerra (2005) Strengthfinder—Rath (2007)
10. Trainer training skills—essential if HACCP training is to be carried out in-house	Food industry courses are now being run by many of the food training organizations. Management training consultancies may also be able to provide this type of training. Effective presentation courses may be a good foundation. Liaison with Personnel department recommended.
11. Documentation techniques for HACCP plans	Reference books: Jay (1993) Wick et al. (2006) HACCP Management Software (see listing in References, further reading, and resource material)
12. Understanding where others failed	Word-processing skills training Reference books: Mayes and Mortimore (2001); Wallace et al. (2011); Panisello and Quantick (2001)

Table 2.2 gives details of additional areas where training or knowledge may be required to support HACCP activities and provides suggestions on how these gaps may be filled. It may not be necessary for all HACCP team members to be trained in every area, but it will be helpful to have knowledge within the team.

Records should be kept of all training carried out along with a documented evaluation of its effectiveness. A written test is a measure of what people have learned in the classes but as important is verification of whether they can apply the theory in practice. For HACCP, this is an assessment of the resulting HACCP plan which can be undertaken by a reputable/competent third party—most often, as part of any HACCP audit. All of these activities will also be an assessment of the capabilities of the trainer and the suitability of the training program. As a reminder, it is essential to establish that HACCP trainers have the appropriate knowledge and experience of HACCP plus effective training skills and that the training program covers learning outcomes appropriate to the trainee group (Fig. 2.4).

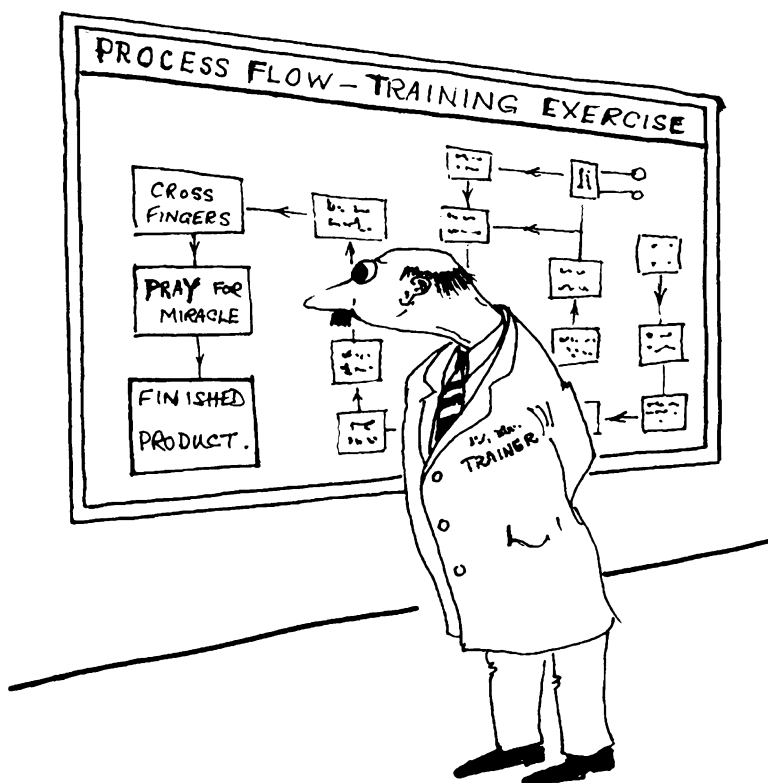


Fig. 2.4 Have you selected a good quality trainer?

2.3 What Is Our Current Status? Baseline Audit and Gap Analysis

It is important to evaluate the resources and systems in place and compare these against the requirements to manage HACCP effectively, before putting together a Project Plan for the HACCP initiative. This will include a review of your facility environment as well as an assessment of the current systems and personnel resources.

In order to plan the pathway to an effective HACCP system and food safety program, it is important to consider two basic questions:

1. What resources and systems (including PRPs) need to be in place for HACCP to work?
2. What resources and systems do I currently have?

The differences between 1 and 2 are the gaps that will need to be filled. A third question (How will I get there?) will be considered in Sect. 2.4. This sounds straight

forward but can be quite a lot of work if an in depth review hasn't taken place for some time.

The most effective way of identifying the gaps is to carry out a baseline audit of current control measures for food safety and quality management, using auditors with expert knowledge (ideally include a reputable independent expert who is external to the company or at least the facility) of the standards and systems required to support HACCP.

2.3.1 Performing the Gap Analysis: Questions to Consider for PRP Assessment

There are a number of questions to consider when assessing the effectiveness of existing systems. As a reference standard for gap analysis you could use, Codex (both the HACCP principles and PRP documents (Codex, 2009a, b)), ISO22000 (for the HACCP and management elements (ISO, 2005)), or one of the Global Food Safety Initiative (GFSI) benchmarked schemes which are HACCP based but are broader and also include the PRPs. Similarly you could use a PRP standard such as ISO/TS 22002-1:2009 *Prerequisite Programmes on Food Safety: Part 1 Manufacturing* (ISO, 2009a); formerly published as PAS 220 (BSI, 2008). Certification bodies for these schemes offer gap assessments but take care to choose a really experienced food safety auditor and acknowledge that a thorough review will likely take at least 3 days, possibly more, depending on the size of your operation. Some companies combine a GFSI gap assessment with an in depth pathogen control assessment and for this they use an experienced food microbiologist with proven field experience as well as food safety and HACCP systems audit skills.

An example of the types of questions that might be considered for the initial gap analysis assessment follows in Table 2.3 but this is very high level and in practice you'll need to expand out with particular focus on environmental and management controls.

If you already have a HACCP program and are planning to upgrade it, the checklist in Chap. 7 (HACCP audit) could also be used. As stated, these checklists are intended to serve as a starting point so you will likely want to add other assessment criteria before use.

Following the gap analysis, the Project Plan can be developed by using standard project planning techniques (Sect. 2.5). Most companies find that in carrying out a detailed gap assessment, improvements in the PRPs are needed. This should also be built into the project plan. As each gap is identified a risk evaluation should be done in order to aid with prioritization of corrective action. In some cases a short-term immediate action may be needed whilst the longer-term (capital) solution is being developed. This is where HACCP skills in terms of hazard analysis can be really helpful in managing food safety risk at a practical level.

Table 2.3 Prerequisite program and management status gap analysis checklist

Prerequisite program area	Questions	Status: in place (Yes/No)	Auditor notes
1. Environment			
(a) Facility design	Are your buildings, grounds, and equipment in good repair?		
	Is process flow logical?		
	Do you have a layout that enables the control of cross-contamination? Consider: <ul style="list-style-type: none"> • Traffic patterns—people, equipment • Air and drain flow • Personnel hygiene facilities • Captive uniforms and shoes • Hand washing stations • Rest room and cafeteria 		
	Do storage and distribution practices present a food safety risk?		
(b) Equipment	Is it of sanitary design? <ul style="list-style-type: none"> • Suitable for cleaning, maintenance, and preventative maintenance? 		
	Is it capable of control as specified in your program?		
	Is there a calibration program?		
(c) Utilities/services	Are utilities such as air, water, energy effectively controlled for food safety?		
	Lighting—is it adequate for inspection and observation of cleaning needs?		
2. Programs			
(a) Supplier quality assurance	<i>The basic question to be answered is whether you have confidence in the safety of all raw materials used:</i> Do you have an approved supplier list detailing the source (manufacturing location) of all raw materials?		
	Do you understand the safety criteria governing your raw materials?		
	Does the raw material need to be handled in a specific manner when it arrives at your location (for safety)?		
	Do suppliers provide analytical information and is it valid? <ul style="list-style-type: none"> • Are any tests carried out and is the lab certified/approved? 		

(continued)

Table 2.3 (continued)

Prerequisite program area	Questions	Status: in place (Yes/No)	Auditor notes
	Are approved specifications held for all raw materials? • Has the supplier signed their agreement to comply?		
	Are third-party audits carried out? • Who did them and to what standard?		
	Have all suppliers been audited? (and against which criteria?) • What training and calibration do your internal supplier approval auditors receive? • For the suppliers that were not audited, was a desktop review and approval undertaken?		
(b) Cleaning and disinfection (sanitation)	Are risk-based sanitation schedules in place?		
	Are cleaning procedures are complete including reference to the: • Equipment to be cleaned • Method of cleaning and materials used • Responsibilities for implementation • Validations and verification procedures		
	Are records complete and signed by responsible person?		
(c) Allergen control	Are allergens clearly identified in raw material specifications?		
	Are allergen production scheduling matrices up to date?		
	Have allergen cleans been validated?		
	Is the label verification program adequate?		
(d) Pest control	Is the building adequately proofed and protected against pest ingress or harborage?		
	Do you have a third-party contract with a licensed provider?		
	Is there someone on staff who has expertise and oversight of the program?		
	Are monitoring and corrective action procedures in place?		
	Has there been significant activity in recent or past history? • Was corrective and preventative action been taken in a timely manner?		

(continued)

Table 2.3 (continued)

Prerequisite program area	Questions	Status: in place (Yes/No)	Auditor notes
(e) Good laboratory practice	Does the laboratory (internal/external) operate to a good practice system?		
	Is the system independently accredited for the testing you need?		
	Are controls built into the sample testing procedures?		
	Is analyst performance monitored?		
	Are all laboratory staff routinely trained?		
	Is sampling carried out in a hygienic manner?		
(f) Preventative maintenance	Does a preventative maintenance schedule exist?		
	Does it cover all key equipment for food safety?		
(g) Food defense and bioterrorism	Is the plant secured against unauthorized access?		
	Is a food defense plan in place?		
	Has it been tested?		
(h) Trace, recall, and incident management	Would traceability systems ensure that all of the correct material could be identified and withdrawn/recalled in a timely manner?		
	Have lot traceability recall procedures been tested?		
	Is there a designated Incident Management team?		
	Are personnel trained in incident management and media handling?		
(i) Quality management systems	Is there a senior level supported Quality Policy?		
	Is there a Quality Management System in place?		
	Is it based on an accepted framework, e.g., ISO or a GFSI benchmarked scheme?		
	Is it externally and independently assessed?		
	Does it cover all parts of the operation?		
	Is there a well-established Corrective and Preventative Action (CAPA) program in place?		
(j) Other good practice program references	Should you be benchmarking against other externally recognized reference standards, e.g., for warehousing and distribution?		

(continued)

Table 2.3 (continued)

Prerequisite program area	Questions	Status: in place (Yes/No)	Auditor notes
3. People			
(a) Personal hygiene	Is there a program for restriction of jewelry, finger nail polish, hair, etc?		
	Is there a captive uniform and shoe program?		
	Is there an employee ill health monitoring and reporting program? Does it apply to visitors and contractors?		
	Have the programs been designed around product risk?		
(b) Personal behavior	Are rules in place?		
	Are they clearly communicated?		
(c) Training and education	Are employees trained commensurate with working activities?		
	Is training validated? • Are records in place to confirm this?		
	Is training verified? • Are records in place to confirm this?		
	How are training needs established?		
	Are job descriptions in place which include food safety roles and responsibilities?		
(d) Culture	Is there evidence of noncompliance with stated procedures?		
	Are employees engaged and knowledgeable about their food safety role?		
	Is action taken when irregularities/noncompliances are observed?		
	Does the environment appear to be well cared for?		
	Is there evidence that food safety is supported by functions other than quality?		
	Are adequate resources made available for food safety improvement?		

2.4 Use of the Hazard Analysis and Risk Evaluation Process as an Enabler to GMP Improvement

Sometimes it may feel like an impossible task even with full support and commitment from the senior management team. Don't worry, HACCP is the best place to begin and there is no right or wrong time to start using it. The normal use of HACCP is when PRPs are under control and it is fair to say that this view is widely accepted. A common misconception is that if you don't have any written specifications and procedures, and have very poor GMP and hygiene, then you are in no position to use HACCP. To the authors, it seems only common sense to say—use HACCP (or at least use the Hazard Analysis technique) to help you decide where to begin, i.e., in prioritizing against food safety risk and targeting resource.

So what happens when a plant has poor or limited PRPs? Can they not implement HACCP until everything is in place? Whilst it is most straightforward to work on the prerequisite foundations for HACCP first and then build the HACCP system, if a company has poor/no PRPs, as is often the case in developing markets, then it is important to prioritize the risks. We believe that a basic HACCP study, or at least the use of hazard analysis, can usefully be done as a means of ensuring that the likely hazards are under control. This can even be carried out as a desktop exercise. It will quickly identify which equipment is essential and help with prioritization, for example, in identifying a required metal detector or the need for rapid validation of a thermal process step. Working through the Codex list of hygienic requirements, i.e., the PRPs, can be quite daunting. It cannot all be done at once but, by truly understanding the HACCP concept and, in particular, hazard analysis and risk evaluation, focusing on the product itself, its intrinsic design factors that are making it safe, together with considerations of how to prevent product contamination (microbiological, chemical, and physical), rapid progress can be made in establishing foundational PRPs in a focused way—ensuring from the outset that food safety is not compromised. As an example, a foundational element of the PRP program is having a hygienic operating environment with appropriate hygienically designed equipment, building fabric, air, and traffic flow so as to prevent cross-contamination of the product. This is particularly important post-process and where the product may be vulnerable if contaminated, i.e., there is no further pathogen (or other hazards) control step.

You need to systematically walk the plant, ideally using a process flow diagram if you have one and identify gap areas for improvement together with establishing what the real hazard is that is associated with the gap. Once you have identified the hazard (remember to be as specific as possible) you can determine what the control measure should be, rather than simply recording what your process operation currently uses. Table 2.4 shows how this activity could be organized and used to help guide the organization in terms of short-term risk mitigation and longer-term capital spending. There is a column to indicate whether the control measure is currently present. There may be a long list of actions required so how should you prioritize and set the time scales? The cross functional team should carry out a risk

evaluation, i.e., what is the likelihood of the hazard being present (high, medium, low) and what would be the severity of that hazard if it was (high, medium, or low). The items with “high” or “medium” against them need the priority corrective actions, both now and longer term. For example, if the overall process environment is not as hygienic as you would like, you could build smaller more hygienic rooms within the plant around where the product is most vulnerable or depending on what the concern is, add line covers and catch trays under motors to protect the product. A longer-term solution might be different and require additional expenditure. This may perhaps seem obvious but it is particularly helpful where capital planning is involved.

Hazard analysis and risk evaluation of your processing operation will enable you to focus on high-priority areas for improvement and draw up a realistic action plan.

Another example is the immense challenge of setting up a prerequisite raw material control program (Supplier Quality Assurance) where use of a HACCP approach can again help to prioritize resources. Many companies purchase hundreds (often thousands) of raw materials (ingredients and packaging). Hazard Analysis can be used to identify which ingredients would have an impact on finished product safety if not effectively managed by suppliers. This enables the HACCP and SQA teams prioritize by risk, e.g., a microbiologically sensitive ingredient, such as chocolate or nuts, added to ice cream post-pasteurization. We will see later how some of the other HACCP tools and techniques, e.g., The raw material Decision Trees (Chap. 6), will be helpful in providing focus to SQA programs. This can be taking place at the same time as the HACCP team is drafting the Process Flow Diagrams and should involve those personnel responsible for purchasing. If you have no raw material specifications, use known data from reference books, a reputable hazard database, or bring in a HACCP expert to help you. A blank specification pro-forma can be sent to all suppliers for completion and cross checked against the external data but using the HACCP tools will help you to see where the priorities are in terms of your product safety, i.e., which suppliers should be audited first in order to assess their level of competence and where Certificates of Analysis are needed. It is important that this activity happens as quickly as possible because you might want to request that your suppliers of high-risk raw materials also upgrade their HACCP program. They can be working on their HACCP systems while you are working on yours.

With all of this information (PRP and management status gap analysis and the hazard analysis risk evaluation of the operating environment), you will have a lot of really focused and valuable information to help establish where you are in relation to the end goal. These activities can be done fairly easily in any size of business, whatever the level of maturity.

So, a number of parallel food safety improvement activities can be going on at the same time. Calibration of your key process equipment, for example, to control and monitor temperature process steps, can be done at an early stage, and this will likely have been identified during the baseline audit. Having HACCP knowledge to be able to prioritize through risk evaluation will be invaluable if not essential.

Table 2.4 Are all the required PRP controls in place? Case Study example from the Iced Delights (see Chap’s 4 and 6)

Process area/issue	Hazard associated with operating environment	Likelihood			Severity			Significance ranking	Control measure PRP/OPRP	Currently in place?			Immediate action	Is it effective? (Validation)	Longer-term action	Is it effective? (Validation)	Responsibility	Capital plan and timing
		H	M	L	H	M	L			Y	N	N						
Cracked floors in the filling room	Harborage area for microorganisms (Listeria) which could cross-contaminate product		M			H		M/H Likelihood of happening was deemed to be medium because the product is enclosed up until filling. However this is post-pasteurization so the team felt that it is a significant issue.	Keep floors as dry as possible.		N		Remove all high pressure hoses from the filling room Increase environmental monitoring	Yes	Repair floor	To be determined (tbd) once completed	Engineering and QA	Cost tbd. Timing within the next 6 months

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2.5 How Do We Get There? Project Planning

The next step is to evaluate all the data and formally plan the entire project. We will focus here on planning the structure of the HACCP system.

2.5.1 *What Structure Should the HACCP System Take?*

One of the key issues to decide early on is the structure of the HACCP system. This will depend on the complexity of the operation and types of processes being carried out, along with the status of Quality Management Systems and PRPs already in place. There are three basic approaches:

(a) 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. Depending on the type of operation, the HACCP plans may be extended to include distribution and customer/consumer issues.

Linear or individual product/process HACCP plans work best in simple operations, where there may be relatively few product types manufactured by a small number of processes. This approach is less likely to be helpful in larger, more complex operations. Here the application of HACCP principles to each product/process becomes repetitive and needlessly time-consuming and leads to a large number of similar HACCP plans, each with its own management requirements.

(b) Modular HACCP plans

If your products are manufactured using a number of basic process operations, it may be possible to use the modular approach when putting together a HACCP plan. This flexible approach allows the HACCP principles to be applied separately to each of the basic operations or modules. These HACCP plan modules are then added together to make up the complete HACCP system.

It is important to know where each module starts and ends so that no process step, and therefore no hazard, is missed when these are put together. Transfer steps from one module to the next can easily be missed and so should be clearly marked.

Since each module is specific to a part of the process and common to a number of products, the key issue is to ensure that the differences between products are picked up and all hazards addressed. Raw materials need to be assessed individually, considering their intrinsic hazards as they arrive and each use to which they will be put. Any special handling or processing measures used in a module for some products but not for others will also need to be considered.

An example, of how a facility may be broken down into process modules covering its basic process operations is shown below (Table 2.5). Throughout this book we are using a fictitious example of ice cream manufacture to illustrate the design and implementation of HACCP systems. This example assumes that the manufacturer is a medium-sized company producing a number of different varieties and operating to acceptable food industry standards. The products are packed in

Table 2.5 Process modules example—case study Iced Delights Ice Cream HACCP Modules (see Chap’s 5 and 6)

1. Ingredient receipt and storage modules	HM1 Bulk ingredient receipt and storage HM2 Non-bulk ingredients receipt and storage HM3 Packaging receipt and storage
2. Preparation modules	HM4 Pumping HM5 Dry powders preparation HM6 Frozen concentrates preparation HM7 Ambient liquids preparation HM8 Dry particulates preparation HM9 Frozen fruit/puree preparation HM10 Pots, film, lids, and spoons De-box/de-bag
3. Manufacturing and packing modules	HM11 Ice cream base manufacture HM12 Filling room HM 13 Low-care finishing and storage

family-sized and individual tubs for retail sale. Here, at the preparation and planning stage, we introduce the modules that the company has identified when designing its modular HACCP system. We will go on to consider the application of HACCP principles to these modules for development and implementation of modular HACCP plans in the remaining chapters.

The modular approach is a very effective way of structuring the HACCP system and is commonly used in complex manufacturing operations, and in catering operations which also split logically into a number of modular parts.

(c) Generic HACCP plans

Generic HACCP plans are based on a framework approach that is intended to fit similar operations where the same product is manufactured or handled. This approach has limitations because no two operations are exactly the same, and HACCP is designed to be applied to specific processes.

The danger with using purely generic HACCP plans is that the issues that are specific to an operation may be overlooked, and therefore hazards may be missed out. In theory, generic HACCP plans can be used as a helpful starting point, and an effective HACCP system can be built up around them, ensuring that plant-specific hazards are managed in addition to generic hazards. This can work well in practice but requires care in tailoring the generic plan to the operation.

This type of approach is most commonly used in process sectors involving relatively simple operations; for example, primary meat processing. Bearing in mind the limitations discussed above, a generic HACCP plan can be drawn up within a company for application to several sites, or generic plans published in the scientific literature can be adapted (The Seafood HACCP Alliance in the USA is a very good example of this approach <http://seafood.ucdavis.edu/haccpalliance.html>). There has also been a growth in the use of generic approaches for catering and foodservice, with examples such as Safer Food Better Business (FSA, 2006)

and Cooksafe (FSA, 2009). These are intended for businesses with limited technical resource on site, so are designed to be easy to understand. However, the ability to tailor adequately to individual operations may be lacking in the target businesses for these types of generic approaches, leaving questions about whether all relevant hazards will be controlled.

Of the three approaches described above, the modular approach is usually the most practical for most companies. The process can be broken down into logical sections and looked at in detail. If the process being studied is common for a number of products, then these will be included in the scope, but it is essential that no hazards arising from slight differences in product formulation are overlooked. This means that all raw materials must be subjected to hazard analysis and considered with the process flow diagram. Potential issues should also be highlighted in the individual Product Safety Assessment (Chap. 5).

Most likely you will chose to break down your process into modules. These need to be determined as part of the planning activity. Think about how the system will be maintained once implemented and design with that in mind. The project plan should include the progression of any necessary PRPs (support systems) which were identified as gaps during the baseline audit.

2.5.2 Using Project Planning Techniques

When we use the word “plan” in this section, we are referring to the development of a Project Plan and action timetable for the application and implementation of a HACCP Project, as opposed to the HACCP plan.

The application and implementation of HACCP and supporting systems can be best managed as a project. It will have a definite life cycle with a start date and a finish date, a defined scope, and budget. In a larger organization, the project may be managed by a temporary project team and the timetable and costs estimated at the start. This will involve the appointment of key people and the documentation of the actions and time scale required. The roles needed in managing a typical project are two key personnel plus a supporting team.

The Project Sponsor

As the champion of the project, the Project Sponsor is likely to be your company CEO (with strong support from Quality) and Operations Vice President or Operations Directors. Whoever takes on the role is likely to sit on the senior management team and have budgetary control. The main responsibilities are to:

- Provide funds
- Approve and drive the company HACCP or food safety policy
- Approve the business issues and ensure that the project continues to move forward and remains valid
- Appoint a Project Manager and Team
- Ensure that adequate resources are made available to the Project Team
- Establish a progress reporting procedure

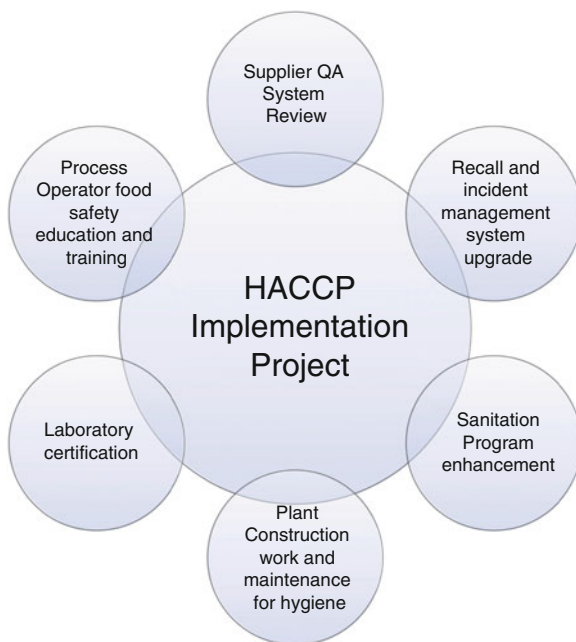


Fig. 2.5 HACCP interactions with business improvement projects

- Ensure that the Project Plan is realistic and achievable
- Approve any changes to the original project

The Project Manager

This role is likely to be taken by the Production or Quality Manager, who may also go on to become the HACCP Team Leader. The responsibility centers on ensuring that the Project Plan is drawn up and objectives achieved within the agreed time scale. This requires effective project management skills, specifically to:

- Lead and direct the Project Team
- Produce an achievable Project Plan
- Provide a regular progress report to the Project Sponsor
- Liaise with other Project Managers to ensure that areas of common interest are identified and resources are used effectively in these areas

As well as the HACCP Project itself, there may well be other business improvement projects going on within the business at the same time. These may include development of the systems required to fill the gaps in the HACCP Support Network, which we identified following the baseline audit (Sect. 2.3). It is useful to establish what these additional systems are early on, for example, as in Fig. 2.5.

Other projects may include the setting up or enhancement of a formal Supplier Quality Assurance program, facility environment upgrades, the introduction of SPC on certain lines, production rationalization, product development activities, cost of quality calculations, and so on.

As stated earlier, the project team will need a complete understanding of the starting point. This will be most simply achieved if all the project team members have already been involved in the baseline audit, including a review of documented procedures already in place, environmental issues, PRP status, resource availability, and current culture. In other words, the team will have an appreciation of the size of the task, the current capabilities, and the additional resource requirements.

2.5.3 *Drawing up the Project Plan*

Let's think about this in a little more detailed project terms as the discipline can be helpful.

What is a project?

- It has clear objectives based on need.
- It has a beginning and an end.
- It has defined goals and deliverables along its timeline.
- It requires resources in terms of time and money.
- It has a clearly defined scope.

In a food safety improvement project the scope is likely to include at least two, possibly three things:

- Product design review and improvement
- PRP review and improvement
- HACCP plan development

These are three separate projects or subsets of a larger Food Safety improvement project. Each element is highly related through the utilization of the Hazard Analysis process.

Each project element will have a defined lifecycle and can be simply described as having four main stages:

Initiating → Planning → Executing → Closing

In initiating the HACCP project you may choose to draw up a charter (Table 2.6) as a means of communicating the objectives to a wider audience. The key elements to include are **why** the project is being launched, and what **authority level** it is supported at. Ideally this will be a very senior member of the management team, i.e., someone other than the HACCP team leader. It can be a simple one page document and can be used as a reference point throughout.

For the HACCP component, once you have decided on the structure of the HACCP system and have an understanding of the additional tasks you will need to undertake, a detailed Project Plan can be drawn up. The complexity of this plan will relate to the amount of work to be done and it is important to ensure that sufficient time is allocated to develop an effective system.

The Project Plan may be divided into a series of main phases, with each phase further broken down into specific activities—a work breakdown structure, a schedule

Table 2.6 Example of a project charter—case study Iced Delights Ice Cream

Project charter: Iced Delights Ice Cream Manufacture	
Project Name: Project Eskimo: Food Safety system upgrade Key Assumptions: Food Safety is a foundation to the continued success of Ice Delights business. Building infrastructure, quality system, and cultural improvement are all needed.	Start date: Projected end date:
Scope: Ice Delights HACCP system and PRP upgrade	
Measure of success: – Third-party certification to a GFSI benchmarked standard – Compliance with all regulatory and customer expectations	
Project Team: HACCP Team Leader Human Resources manager Engineering Manager R & D Manager Sponsor: Manufacturing VP	Projected budget needs: – Capital improvements for PRP enhancements – Consultant – Training

of activities, and a communication plan. The start, finish, and activity time lines are determined, together with any dependencies (What needs to happen before this particular activity can take place?) and the resource allocated (Who will make it happen?). This can be plotted on paper to provide an implementation timetable or project schedule. A Gantt chart (a HACCP project example is given in Fig. 2.6) is an approach that many companies use for this purpose. In looking at the Gantt chart, it can be seen that whilst the duration of each task has been estimated, not all tasks can begin on Day 1. This is because some of them cannot start until another task has been completed.

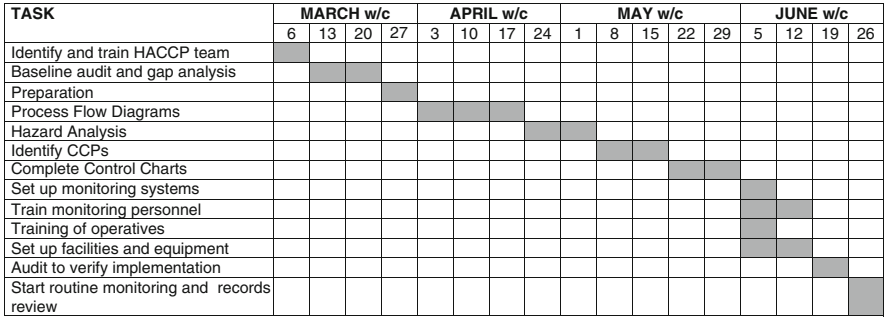


Fig. 2.6 Example of a Gantt chart—Generic HACCP Project Plan

The following are definitions of key terms introduced on the Gantt chart:

- **Critical:** This means that the task is critical in terms of timing. If these tasks do not run to time then the project completion date will be affected—there is no slack.
- **Non-critical:** This does not mean that the tasks are any less important than those referred to as Critical. It just means that there is some slack in the timing. If they don't finish at the precise date indicated, then depending on how long over they run, the end project completion date may not be affected.
- **Milestone:** This is usually an event or key decision date. It can be used as an indicator in terms of the project progress.

Gantt charts can be produced using computer software packages. They can also be drawn manually and kept fairly simple, e.g., this may be appropriate for a smaller business. The example shown here was developed using Microsoft Project™. The HACCP team and project leader (if different) are usually the people who draw up the plan.

The execution phase of the project is where the HACCP study is being carried out. It is important to communicate progress throughout.

Once complete, it is helpful to formally acknowledge that the implementation phase is complete, celebrate (!), and move straight away into a maintenance mode.

2.6 Continuous Improvement

Once the project is completed the team can start to focus on continuous improvement. This is a requirement of many formal food safety standards including ISO22000 (2005a). The model below (Fig. 2.7) shows how this is a cycle of activity from planning safe products (through design), conducting hazard analysis and developing the HACCP and PRP controls, validation that the controls are effective

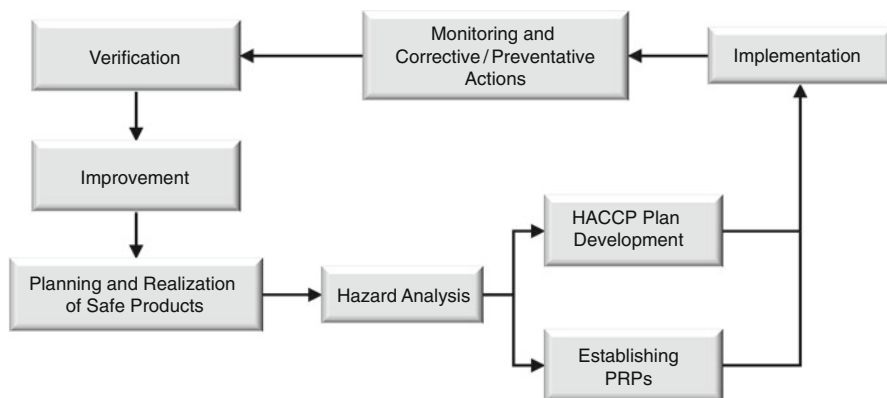


Fig. 2.7 Concept of HACCP continuous improvement

prior to implementation, monitoring, corrective and preventative actions, and verification lead to improvements where needed.

2.7 Key Point Summary

As we saw in Fig. 2.1, a successful HACCP system results from following four key stages. In this chapter we reviewed key stage one, Planning and Preparation (Fig. 2.2). To plan any system effectively, the scope of the entire project needs to be understood at the beginning.

The key things to remember are:

- Identify the key people involved and establish commitment
- Train and educate so the team understands the goal and has the skills needed to achieve it
- Undertake a gap assessment—from where you are now to desired future state
- Set priorities based on hazard analysis and risk evaluation
- Manage the implementation as a project in terms of discipline
- Reaffirm senior management commitment and alignment with regard to what needs to be done

Chapter 3

Hazards, Their Significance, and Control

This chapter is designed to give you a clearer understanding of different types of hazards and their significance in foods, along with the mechanisms that can be used for their control. This is not intended to be a complete source of information on all possible hazards; however, it will provide a valuable grounding to HACCP team members and can be used for familiarization/refamiliarization before a HACCP study or HACCP review. The information provided should not be used as a replacement for the correct blend of knowledge and experience within the HACCP team. Rather, it should be taken as suggestions for possible further investigation. There may be situations where HACCP team members do not have sufficient knowledge and experience to understand the implications of all the hazard information given here; in this case it will help to highlight areas where you may need to bring in specialist help to your HACCP team. However, it should also be noted that the sector of the food industry will also be important in identification and analysis of hazards, i.e., some hazards will be more relevant in some specific sectors but not in others.

3.1 Hazards and Their Significance

A hazard is any factor that may be present in the product, which can cause harm to the consumer either through injury or illness. Hazards may be biological, chemical, or physical and are the basis of every HACCP system.

HAZARD:

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

(Codex, 2009b)

Using the Codex (2009) terminology, physical agents are a common type of hazard to occur in foods in many sectors because of the possible presence of foreign material which may gain access to food products. However, the risk of consumer

injury is quite low for most types of foreign material, as few items are sharp or hard enough to cause physical damage, or are of dimensions that might cause choking. When present, physical hazards may affect only one or, at most, a few people so are less likely to cause a widespread food incident.

Chemical hazards are often looked on as the most important by the consumer but in reality they often pose a negligible health risk in terms of acute illness at levels likely to be found in food. There are some exceptions to this general rule, e.g., risks of allergens to sensitive consumers or risks due to high levels of chemical contaminants that should not be present, e.g., the problems seen with melamine contamination (Chap. 1). Small amounts of chemical hazards may contribute to chronic illness over time, e.g., certain mycotoxins are thought to play a potential role as carcinogens.

Biological hazards are generally seen to present the greatest and broadest danger to consumers. When a pathogenic microorganism grows in a food product, it can cause illness in many hundreds or thousands of consumers depending on the product and its distribution. Some of these illnesses can be very serious and may be fatal.

Statistics for foodborne illnesses are recorded routinely in many countries, although this is quite variable around the world. These data generally give a good indication of the levels of illness caused by enteric pathogens; however, it is difficult to trace these back to food products in many cases. Rocourt et al. (2003) report on estimates of cases of illness thought to be caused by transfer of pathogens from food, using the data from two previous studies. These estimates (Table 3.1) show that the percentage of cases transmitted by food varies greatly according to the specific pathogens involved.

This information indicates the major role played by foods in the transmission of enteric disease and underlines the need to control hazards during food production, handling, and storage at all stages in the food supply chain.

3.1.1 Hazards and the Consumer

Returning to the hazard definition, we can see that hazards always have the potential to cause harm to the consumer. Within human populations there will be groups of individuals who are more susceptible to illness. These include the elderly, the very young, and those with compromised immune systems. Whilst all food intended for consumption by any group should be safe, extra levels of control may be necessary for specific foods being produced for high risk groups.

Since HACCP was initially developed as a tool for human food safety then this has been its main focus in terms of the consumer. However, nowadays HACCP is also applied in the manufacture of animal feed, in which case different species of animals will be the consumer focus, according to the type of feed being produced. For animals that are kept as pets in the home, contaminated pet food could provide a source of cross-contamination to humans and human foodstuffs. All these issues need to be considered when performing hazard analysis (Chaps. 5 and 6).

Table 3.1 Percentages of foodborne transmission according to pathogens (*Source: Rocourt et al., 2003*)

		Percentage of foodborne transmission	
	Pathogens	USA ^a	England and Wales ^b
Bacteria	<i>Aeromonas</i>	ND ^c	0
	<i>Bacillus</i>	100 (<i>B. cereus</i>)	100 (<i>Bacillus</i> spp.)
	<i>Brucella</i>	50	ND
	<i>Campylobacter</i>	80	79.7
	<i>Cl. perfringens</i>	100	94.4
	VTEC O157 and non-O157	85	63
	Other <i>E. coli</i>	30–70 ^d	8.2
	<i>Listeria monocytogenes</i>	99	99
	<i>Salmonella non-typhoidal</i>	95	91.6
	<i>Salmonella</i> Typhi	80	80
	<i>Shigella</i> spp.	20	8.2
	<i>Staphylococcus aureus</i>	100	96
	<i>Vibrio cholera</i> toxigenic	90	90
	<i>Vibrio vulnificus</i>	50	ND
	<i>Yersinia enterocolitica</i>	90	90
Parasites	<i>Cryptosporidium parvum</i>	10	5.6
	<i>Cyclospora cayetenensis</i>	90	90
	<i>Giardia</i>	10 (<i>G. lamblia</i>)	10 (<i>G. duodenalis</i>)
	<i>Toxoplasma gondii</i>	50	ND
	<i>Trichinella spiralis</i>	100	ND
Viruses	Noroviruses	40	10.7
	Rotaviruses	1	2.5
	Astroviruses	1	10.7
	Hepatitis A virus	5	ND


^aMead et al. (1999)^bAdak et al. (2002)^cND = not determined^d70 for enterotoxigenic and 30 for other diarrheogenic

Consumer perception of food safety and hazards in food products has been studied from the perspective of trying to understand:

- Which food issues give consumers the highest level of concern
- Where consumers think the main problems are in the food chain
- Consumer knowledge about food safety and food handling requirements

Whilst this is an area that still requires further study, it is interesting to note the consumer perspective on food safety and food hazards. Some governments and some non-governmental organizations perform regular surveys of consumer attitudes to provide a barometer of current and emerging concerns. A good example of this is the UK Biannual Public Attitudes Tracker, a survey carried out on behalf of the Food Standards Agency. The latest figures for this (Table 3.2) show that true food safety hazards only emerge just before half way down the list of concerns (FSA, 2011).

Table 3.2 Food issues of total concern to consumers (adapted from FSA, 2011)

Rank order	Food issue	Percentage of respondents concerned about this issue
Highest	Food prices	61
	Amount of salt in food	50
	Food waste	44
	Amount of fat in food	44
	Amount of saturated fat in food	41
	Amount of sugar in food	41
	Animal welfare	40
	Food hygiene when eating out	37
	Food poisoning such as Salmonella and <i>E. coli</i>	30
	Use of additives	28
	Date labels	27
	Use of pesticides	26
	Foods aimed at children, including school meals	26
	Food miles	24
	GM foods	22
	Food hygiene at home	20
	Feed given to livestock	20
	Hormones/steroids/antibiotics in food	20
Lowest	BSE	18

This type of measurement (Table 3.2) is useful because it can detect changes in consumer perception over time but, of course, the data are only as helpful as the questions asked and so careful design of the survey instrument is paramount. From Table 3.2 it is interesting to note that only 20 % of people were concerned about food hygiene at home whereas 37 % were concerned about food hygiene when eating out. When comparing these figures with studies on consumer food hygiene practices (e.g., Redmond et al., 2004), it can be seen that the consumer perception of food hygiene at home is somewhat different from practice, i.e., actual practices show a higher cross-contamination risk. Nevertheless, these are the perceptions of consumers and it is important that food companies understand this type of information.

3.1.2 Assessing Hazard Significance

In order to assess which identified hazards must be controlled by the HACCP system, their significance needs to be evaluated at the hazard analysis stage (Chap. 6). This involves considering each potential hazard in turn and attempting to answer the questions:

- “Could this hazard reasonably be expected to occur in my raw materials, process, or product?”
- “If it did occur, would it cause harm to the consumer?”

This results in the identification of the “significant hazards,” i.e., those which must be controlled for the food product to be safe for consumption. Although the Codex HACCP Guidelines (2009) discuss the need to identify significant hazards, the term is not defined by Codex. However, a useful definition has been provided by ILSI-Europe:

Significant hazard: 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)

This identification of significant hazards through evaluation of likelihood and severity needs to be an educated judgment taken by appropriate, experienced personnel, and must be based on sound information which is up to date. This is an area that many companies find difficult—HACCP plans that are ineffective are often the result of an inadequate hazard analysis. If incorrect judgments are made at this stage, the resulting HACCP system will be unsound, and the company will be operating under a false sense of security. It is therefore essential to have the correct blend of expertise and information available, and inexperienced HACCP teams must recognize their limitations and supplement these with extra help where required. Further guidance on determining the significant hazards is provided in Chap. 6.

3.2 Understanding Control Measures for Practical Hazard Control

It is likely that you will have many controlling steps and factors in your processes and food handling procedures, some of which are controlling the hazards and others which are not directly associated with control of safety. These will probably be measures that are controlling the quality and legal attributes of your products. Within the HACCP system, the control measures are designed to exert control on the significant hazards and are defined as follows:

CONTROL MEASURES:

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

Codex (2009)

For any one hazard there may be a number of possible control measures. This will depend on the source or cause of the hazard or, for microbiological hazards, on the way the hazard is manifested. For example, *Listeria monocytogenes* may be a hazard in the raw materials for a cooked product. Here the hazard is **presence** of the organism and the control measure will be applied through the cooking step, at which the hazard might be **survival** of listeria. The same

microorganism may also be a **cross-contamination** hazard to the same product after cooking, where the control measure(s) will be associated with prevention of contamination through environmental management and good handling practices. If the product has become contaminated, even at very low levels that might not initially be dangerous, then there could be a hazard associated with **growth** of listeria over prolonged refrigerated storage. Similarly, the control measures for glass hazards in a raw material may be through effective supplier quality assurance (SQA), while the control for glass contamination during production will involve on-site glass management procedures, which will be part of the prerequisite programs (PRPs).

Food products will be safe only when all the relevant hazards are controlled. In order to achieve this, care must be taken in selection of appropriate control measures, both to operate at the CCPs within the HACCP plan (Chap. 6) and as part of the PRPs (Chap. 4). Examples of different types of hazards and possible control measures for their management are listed in the following sections. This information is provided as a guide for HACCP team members but is not intended to be an exhaustive list.

3.3 Biological Hazards

Most food-processing operations will be at risk from one or more biological hazards, either from the raw materials or during the process, and the design of the HACCP plan will need to accommodate and control the appropriate organisms. In theory, biological hazards can be either macrobiological or microbiological, however it is normally the microbiological hazards that are of concern for food safety.

This is because macrobiological issues, such as the presence of flies or insects, whilst unpleasant if found, rarely poses a risk to product safety in its true sense. There are a few exceptions to this, such as poisonous insects, but on the whole the appearance of macrobiological hazards causes revulsion rather than illness. However, they may still be an indirect risk by harboring pathogenic microorganisms and introducing these to the product. For example, an insect harboring *Salmonella* spp. could pose a major risk to the consumer if it gained access to a fresh, ready-to-eat product. However, the same insect gaining access to a canned product before retorting would not be a true food safety issue as it would be sterile in the finished product. Whilst they may not be true product safety issues, it is still very important to ensure that your products are free from such macrobiological hazards from the quality/consumer acceptance perspective; however, they are normally controlled by PRPs rather than HACCP plans. It is also usual practice to consider macrobiological issues as foreign material or physical contaminants, rather than biological hazards.

Returning to pathogenic or disease-causing microorganisms, these exert their effect either directly or indirectly on humans. Direct effects result from an infection or invasion of body tissues and are caused by the organism itself, e.g., bacteria,

viruses, and parasites/protozoa. Indirect effects are caused by the formation of toxins that are usually preformed in the food, e.g., by bacteria and molds. Interestingly, whilst bacteria and their toxins are normally considered under biological hazards, the presence of mycotoxins from mold growth is normally referred to as a chemical hazard issue. This may be because with molds it is the toxin left in the food commodity that may cause harm later on and most likely through chronic illness whilst with bacteria the shorter term multiplication of the organism and/or toxin produced during growth can cause acute illness.

Looking at the factors contributing to food poisoning outbreaks in England and Wales during 1992–2005 (Table 3.3; McLauchlin and Little, 2007), we can see that better knowledge of how to control the likely hazards may have prevented many of the examples given. These data underline the need to consider not only the hazard but also its likely causes or sources (the contributing factors) within food preparation processes. Only by understanding all these attributes can appropriate mechanisms for control be determined.

Table 3.3 Factors contributing to 1,262 outbreaks of microbiological food poisoning in England and Wales, 1992–2005 (adapted from McLauchlin and Little, 2007)

Pathogen/toxin	Contributing factor (i.e., processing or handling fault) recorded in outbreak ^a				
	Infected food handler	Inadequate heat treatment	Cross-contamination	Inappropriate storage	Other factors
<i>S. Enteritidis</i> PT4	71 (14)	217 (41)	191 (36)	163 (31)	48 (9)
<i>S. Enteritidis</i> non-PT4	24 (10)	87 (38)	97 (42)	64 (28)	50 (22)
<i>Cl. perfringens</i>	1 (<1)	81 (35)	14 (6)	100 (44)	18 (8)
Norovirus	48 (36)	10 (7)	18 (13)	6 (4)	23 (17)
<i>S. Typhimurium</i>	18 (15)	30 (25)	53 (44)	32 (26)	15 (12)
Other salmonellas	16 (15)	27 (32)	51 (51)	39 (38)	16 (16)
<i>Campylobacter</i>	1 (1)	21 (27)	37 (48)	9 (12)	10 (13)
Scrombrotoxin	0	0	5 (8)	30 (49)	11 (18)
<i>E. coli</i> O157 VTEC	3 (6)	11 (22)	23 (47)	4 (8)	8 (16)
Other and mixed etiology	11 (16)	10 (14)	15 (21)	34 (49)	9 (13)
Unknown	29 (12)	29 (12)	30 (12)	43 (17)	29 (12)

^aExpressed as number of outbreaks (%) where this factor was implicated. *Note:* In 30 % of outbreaks more than one factor was identified so rows may add up to >100 %

3.3.1 Biological Hazards and the Consumer

As we saw above in Sect. 3.1, it is necessary to think about hazards in terms of their likely adverse health effects on the consumer. Whilst the majority of food companies will be considering different groups of human consumers, depending on where your food business is located in the food chain, the consumer could be various animal species rather than humans.

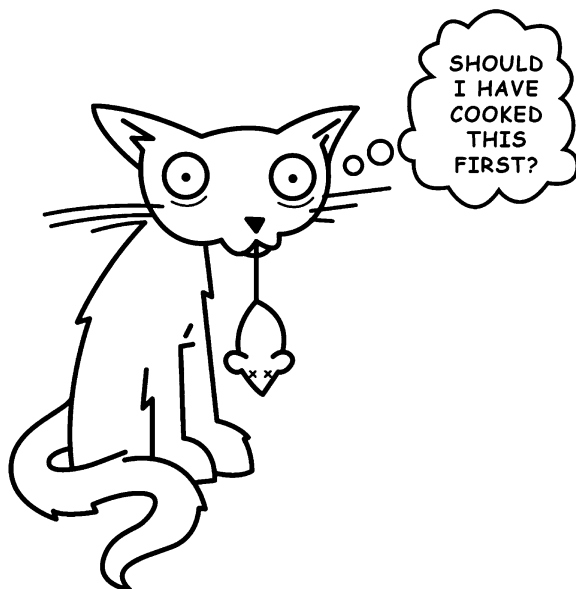


Fig. 3.1 The importance of consumer instructions for hazard control

Food pathogens are often agents of zoonotic disease, which means that they can affect both humans and at least one other animal species. However, biological hazards can affect individual animal species differently so it will be important for HACCP team members to have access to appropriate information on likely hazards in the relevant consumer group, such that appropriate control measures can be established. Control for biological hazards may be during the production process or with the consumer; in this latter case specific handling/cooking instructions will be needed (Fig. 3.1).

3.3.2 Major Pathogenic Bacteria of Relevance to Food

Bacteria are broadly divided into two types, depending on a simple color reaction produced by the Gram stain. Bacteria are therefore classified as either Gram-negative or Gram-positive. As a general rule, Gram-negative bacteria tend to exert their effects through invasion of the host (foodborne infection), whereas the effects of Gram-positive bacteria are usually mediated via preformed toxins (intoxication, formerly known as food poisoning). However there are exceptions to this rule and toxins are involved in infection by some Gram-negative bacteria whilst growth within the host can be involved in intoxication by some Gram-positive bacteria. Consequently it is important to have sufficient information and knowledge about microbiological food pathogens when evaluating their significance as hazards. This will involve not only knowledge of the microorganisms and the

illnesses that they may cause, but also an understanding of their growth and survival characteristics in food matrices such that the need for control can be evaluated.

The infections caused by Gram-negative bacteria generally have an onset period of at least 24 h, are long lasting, and debilitating. They are rarely fatal in healthy individuals but can cause death in the young, old, ill, or immunocompromised, e.g., *Salmonella* spp. illness caused by preformed toxins of Gram-positive bacteria have a rapid onset period of 1–6 h, are often short lived (lasting 24–48 h), and are not usually fatal, e.g., *Staphylococcus aureus*. This is an oversimplification and, as with most biological systems, there are always exceptions. For example, Gram-positive *Clostridium botulinum* produces a lethal toxin, *Listeria monocytogenes* causes abortions and meningitis, and the effects of some Gram-negative bacteria, e.g., *Escherichia coli* 0157:H7, are mediated via toxins. Accordingly, the reader is strongly advised to seek expert professional advice and the information in the following sections, as well as the pathogen profiles (Appendix B), is intended as a general guide only.

(a) Pathogenic Gram-negative bacteria

The Gram-negative pathogenic bacteria typically associated with foods include *Salmonella enterica*, *Escherichia coli* STEC, *Campylobacter jejuni*, *Vibrio parahaemolyticus*, *Vibrio vulnificus*, *Shigella* spp., *Yersinia enterocolitica*, and *Cronobacter sakazakii*. These organisms are usually present in the intestine and feces of man, animals, and birds. Consequently they can also be found in soil, water, raw agricultural products such as raw milk, raw meat, and raw shellfish. These bacteria are not particularly heat resistant and will generally cause problems as a result of improper processing, poor sanitation, inadequate personal hygiene, and the cross-contamination from raw materials to work surfaces, utensils, processing equipment/machinery, finished products, and packaging. Control is mediated by heat processing (e.g., pasteurization), segregation of raw and cooked foodstuffs, good hygienic working practices, and/or formulating and storing the product such that the pathogen is inactivated and/or prevented from growing (e.g., fermented raw sausage).

There are more than 2,500 serovars of *Salmonella enterica*, normally referred to by their serovar names (e.g., *Salmonella* Enteritidis, *Salmonella* Agona, etc.) and most of these are capable of causing foodborne illness in humans. Salmonellae grow in the intestines of all animals and are a common contaminant of raw meat, poultry, eggs, and dairy products. Capable of survival for long periods in frozen and dry conditions, salmonellae are “ubiquitous” in the natural environment. They can also be a persistent environmental contaminant in food plants.

A pandemic of *S. Enteritidis* phage type 4 related to shell eggs emerged in 1980. To some extent the pandemic was ameliorated by the widespread use of liquid pasteurized eggs instead of shell eggs in the manufacturing and food-service industries; however, the more recent use of vaccines for poultry flocks in some countries as well as improved on-farm hygiene practices has provided a very effective control mechanism. Further, more recent outbreaks of *S. Enteritidis*, e.g., in the USA in 2010, suggest the need for further use of these control measures. *Salmonella* Typhi, the cause of typhoid fever, is spread primarily by contaminated water, although food can be implicated where contaminated by irrigation water.

Most strains of *Escherichia coli*, a universal intestinal inhabitant, are harmless to their human and animal hosts. However, several strains are capable of causing foodborne infections. The most serious of these are the strains that can produce verotoxins, or shiga-like toxins, which cause bloody diarrhea, as exemplified by *E. coli* O157:H7. Such infections can proceed to hemolytic uremic syndrome and renal failure—*E. coli* O157:H7 is the most common cause of renal failure in children.

First detected in foods in 1982, *E. coli* O157:H7 was found to inhabit some dairy cattle, from which contaminated minced meat and raw milk were found to be responsible for illness outbreaks. Since 1982 the host range of this organism has expanded to other animals and outbreaks have involved a range of food products. Unlike most foodborne pathogens, *E. coli* O157:H7 is very acid-tolerant. It has been found to survive and cause illness in fermented sausages, mayonnaise, and unpasteurized fruit juices. Effective control of this organism depends principally on adequate cooking or pasteurization of foods. A serious outbreak of foodborne infection related to this organism occurred in Scotland in 1996, in which 20 elderly people died and 496 were infected in total (The Pennington Group, 1997). Since this date a number of further outbreaks have occurred, including additional fatalities (see also Chap. 1).

In 2011, a large **outbreak** of hemolytic-uremic syndrome caused by Shiga-toxin-producing ***Escherichia coli* O104:H4** occurred in Germany. This was associated with the consumption of sprouted seed products and, although the organism was not found in product, epidemiological investigations traced the outbreak back to one supplier of sprouted seeds (Bucholz et al., 2011). This was the first major outbreak caused by *E. coli* O104:H4 to be traced back to food and caused major difficulties in the European salad market while the cause was being sought.

Campylobacter jejuni is the most common cause of bacterial gastroenteritis in the UK. It is found principally in raw poultry and, unlike the other enteric pathogens, it does not grow well in foods as it requires exacting conditions for growth. The food itself is merely a vehicle (or vector) for infection, so segregation and inactivation via thermal processing are the most effective control measures. *Campylobacter* infection is also linked to Guillain–Barre syndrome, a debilitating condition of the peripheral nervous system that can result as a secondary illness following the primary infection.

Vibrio parahaemolyticus is more salt tolerant than the other Gram-negative pathogens and is found in marine environments and animals. This bacterium is typically associated with raw or under-processed seafood, and accounts for 50–70 % of food poisoning in Japan. *Vibrio vulnificus*, like the other species of vibrio, is associated with seafood and the marine environment. The organism is highly invasive and causes primary septicemia. Its virulence appears to be enhanced in individuals suffering from hepatitis or chronic cirrhosis, where it can be fatal. Other vibrio species can also cause gastroenteritis, for example, *V. cholerae*, which is associated with waterborne gastroenteritis.

Shigellosis can be caused by any one of four species; *Shigella dysenteriae*, *Shigella flexneri*, *Shigella boydii*, and *Shigella sonnei*. The illness, also known as bacillary dysentery, is primarily acquired by drinking water contaminated with human feces or by eating food washed with contaminated water. Most *Shigella*-

induced illness associated with food in the USA is caused by *Shigella flexneri* or *Shigella sonnei*. Transmitted by the fecal–oral route, the organism does not survive well in processed foods. It is a public health threat primarily when infected food handlers work in the food-service industry. *Shigella dysenteriae* has been involved in major outbreaks in developing countries.

Yersinia enterocolitica is a ubiquitous organism that has been associated with a wide variety of foodstuffs and, like *Listeria*, has the ability to grow at low temperatures. It can also produce an enterotoxin. The major sources of pathogenic types of *Yersinia* are raw pork, raw milk, and water. Outbreaks have been associated with these sources and from pasteurized milk. Thermal processing and the prevention of post-process cross-contamination are the principal methods of control.

Cronobacter sakazakii (formerly *Enterobacter sakazakii*) is an opportunistic pathogen that rarely causes illness and is widely distributed in food and environmental sources. Its significance relates to its ability to cause illness and death in rare cases with premature babies, usually linked to mishandling of rehydrated infant formula. Specific control measures are therefore developed by manufacturers of dried infant formula and education of parents and health care workers in the safe handling of the rehydrated formula before feeding is also important.

(b) Pathogenic Gram-positive bacteria

The Gram-positive pathogens are a diverse and unrelated group of organisms, including *Clostridium botulinum*, *Clostridium perfringens*, *Bacillus cereus*, *Staphylococcus aureus*, and *Listeria monocytogenes*.

Species of the genus *Clostridium* are anaerobic, i.e., they grow in the absence of oxygen and produce heat-resistant spores. They are generally widely distributed in nature and are usually found in soil, vegetation, fresh water and marine sediments, and animal faeces. Consequently, their elimination and control is achieved by processing with high temperatures (such as those involved in canning) and product formulation, e.g., adding acids (pickling) or reducing the available water (preserving with sugar or salt).

Clostridium botulinum is an obligate anaerobe, which means that it cannot grow at all in the presence of oxygen. It is important because it produces a lethal neurotoxin that paralyses the respiratory muscles. Historically, botulism has been associated with under-processed canned foods, particularly home-canned foods. In recent years, cases of botulism have been caused by a wider range of foods, including improperly handled baked potatoes, garlic-in-oil preparations, and home-fermented meat products.

Strains of *Cl. botulinum* are broken down into groups on the basis of the toxin type that they produce. There are two sets of strains that must be considered by the HACCP team. The first of these (usually in toxin groups A, B, or F) produce heat-resistant spores and are highly proteolytic, thereby producing obvious signs of putrefaction when growing in a food. This proteolytic set does not grow below 10 °C. It is found in intestinal tracts and soil; therefore, it is a common contaminant of vegetables.

The second set (usually in toxin groups B, E, F, or G) produces weakly heat-resistant spores and is non-proteolytic, usually producing no signs of spoilage when

growing in food. These strains are psychrotrophic, capable of growth at 3.3 °C. They are commonly found in aquatic environments; the usual foodborne sources are fish and other seafood.

Botulism typically occurs when an individual consumes preformed toxin in a food. The botulinal toxins are heat-labile and can be inactivated by cooking. In rare cases botulinal spores from food or soil can be ingested and grow in the intestine if the usual microflora is not in place. Infant botulism occurs in this manner. It has sometimes been associated with the use of honey in infant foods; however, it is now thought to be mainly due to infants picking up environmental contamination, e.g., from dust or dirt.

In comparison to *Cl. botulinum*, the mode of action of *Cl. perfringens* is quite different. Food poisoning due to this organism is usually associated with insufficient cooling of cooked foods or improper holding temperatures particularly in catering operations. It can grow rapidly at temperatures as high as 50 °C. The organism grows to large numbers in the food and produces its toxin during spore formation in the intestine after consumption. The toxin causes diarrhea and nausea but is not normally fatal. The controls required are effective thermal processing, effective hot holding or rapid chilling, segregation of raw and cooked materials, chilled storage of cooked meat before consumption, and adequate reheating and hot storage before consumption.

In contrast to the clostridia, species of the genus *Bacillus* are normally aerobic spore forming, i.e., they need oxygen to grow. *Bacillus cereus* also produces two types of toxins: a very fast-acting emetic toxin which causes vomiting, and a diarrheal toxin. The former is very heat stable and will survive cooking; the latter is easily inactivated by cooking. The organism is commonly found in soil, vegetation, and raw milk. Food poisoning is frequently associated with cooked rice and other starchy products, where the spores have not been inactivated by the initial heat process and have subsequently been allowed to germinate and grow due to inadequate handling and poor temperature control.

Unlike the other Gram-positive pathogenic bacteria, the sources of *Staphylococcus aureus* are frequently human in origin, i.e., from the skin, nose, throat, cuts, and sores. Consequently it is easily transmitted to any foods by handling and poor hygienic practices. If the bacterium is allowed to grow in foods, it will produce a toxin that is stable to further heat processing and therefore cannot be made safe again.

Staphylococcus aureus does not form heat-resistant spores and is more versatile than other pathogens because it is able to tolerate a greater range of growth conditions. For example, it is capable of growth at water activity values as low as 0.86; however, it will not normally produce toxin below 0.92. Accordingly, strict personal hygiene is of paramount importance for the control of this organism, as well as thermal processing and segregation.

The importance of *Listeria monocytogenes* as an agent of foodborne disease was only fully recognized in the latter half of the twentieth century. This organism is important because it has a high mortality rate in immunocompromised individuals. The fetus, for example, is particularly susceptible; spontaneous abortion is a frequent

complication of listeriosis in pregnant women. *Listeria monocytogenes* is widely distributed in the soil, vegetation, and animal feces. It is, therefore, a common contaminant of raw foods. It is psychrotrophic, able to grow at 1 °C, and proliferates in cool, moist processing environments. Production controls are necessary to avoid environmental contamination of cooked foods during handling and packing.

The expanding array of psychrotrophic foodborne pathogens, *L. monocytogenes*, *Y. enterocolitica*, and non-proteolytic *Cl. botulinum* has drawn a great deal of attention to the safety of perishable refrigerated foods. It is highly recommended that such foods be restricted to a short shelf-life unless food safety barriers in addition to refrigeration are incorporated into the food.

3.3.3 Viruses

Viral gastroenteritis greatly exceeds the incidence of foodborne bacterial gastroenteritis. There are several types of viruses but the greatest number of outbreaks are due to hepatitis A and small round structured viruses (SRSV) such as Norovirus (formerly known as the Norwalk virus). Shellfish (particularly molluscan shellfish) are a common food source contaminated with viruses because they concentrate the virus from contaminated water during the filter-feeding process. Despite this, much less is known about the incidence of viruses in food than about bacteria and fungi. This is because viruses are obligate parasites; they do not grow on culture media or in foods (food is a vector only). In addition they are very small and therefore very difficult to detect. However they tend to be readily inactivated by heat.

Viruses are present in man, animals, feces, polluted waters, and shellfish. They are transmitted from animals to people and from person to person. Hence high standards of personal hygiene are essential. Viruses can sometimes be transmitted by foods contaminated by infected food handlers, and they have been associated with a wide range of foods, including processed food such as pastry dough as well as the more commonly contaminated items such as produce and seafood.

3.3.4 Parasites and Protozoa

The larvae of parasites such as pathogenic flatworms, tapeworms, and flukes may infect man via the consumption of the flesh of infected pork, beef, fish, and wild game. Examples include *Taenia saginata* (beef tapeworm), *Trichinella spiralis* (nematode in pork), and *Clonorchis sinensis* (trematode or fluke from Asian fish). Prevention of parasite infestation is achieved by good animal husbandry and veterinary inspection, along with heating, freezing, drying, and/or salting, the most effective methods being heating (>76 °C) and freezing (−18 °C).

Protozoa such as *Toxoplasma gondii*, *Giardia intestinalis*, *Cyclospora cayetanensis*, and *Cryptosporidium parvum* produce encysted larvae which subsequently infect man

on ingestion. Infected meat and raw milk serve as the sources for *Toxoplasma*, whereas raw milk and contaminated drinking water are the sources of *Giardia*, *Cyclospora*, and *Cryptosporidium*. Human infection can also be contracted by direct contact with infected pets and animals. Protozoa can cling to the intestine and form oocysts which pass out through the feces. These oocysts are resistant to chemical disinfection, but can be inactivated by heating, freezing, and drying.

While most causes of protozoan parasites are waterborne infections, contaminated foods are a possible vector. A large outbreak of *Cyclospora* was traced to fresh raspberries which had been sprayed with a pesticide mixture that had been prepared with contaminated water (Herwaldt and Ackers, 1997).

3.3.5 Prions

Prions are transmissible agents, which are characterized as misshapen normal cellular proteins that cause disease by initiating abnormal folding of normal cellular prion proteins in the brain. This in turn causes destruction of brain cells leading to the formation of microscopic holes or plaques in the brain tissue, giving the brain a spongy appearance. Diseases caused by prions are known as Transmissible Spongiform Encephalopathies (TSEs) and this group includes a range of human and animal variants.

The most famous TSE from the point of view of the global food supply chain is Bovine Spongiform Encephalopathy (BSE) which was first detected in cattle in the UK in the 1980s. This new disease had originated from contaminated meat and bone meal fed to cattle that contained prions from the sheep disease, Scrapie, which had been known for many years but previously thought incapable of crossing the barrier between species. Contaminated meat products from infected cattle entered the food chain and led to a further new human disease, variant Creutzfeld-Jacob Disease (vCJD¹), i.e., the disease had jumped the species barrier again. Whilst stringent controls on the beef supply chain were able to bring the diseases back under control, around 200,000 cattle contracted BSE and, to date, approximately 200 humans have died from vCJD.

3.3.6 Emerging Pathogens

The term “emerging pathogens” is used to describe those organisms that have not historically been recognized as agents of human disease. The term can also be used to describe previously recognized pathogens that have begun to cause disease in a

¹ vCJD was a completely new disease and is unrelated to the original Creutzfeld-Jacob Disease, which is believed to occur sporadically worldwide, caused by the spontaneous transformation of normal prion proteins into abnormal prions. Other traditional human TSEs include Kuru, a disease found mainly in Papua New Guinea and associated with cannibalism.

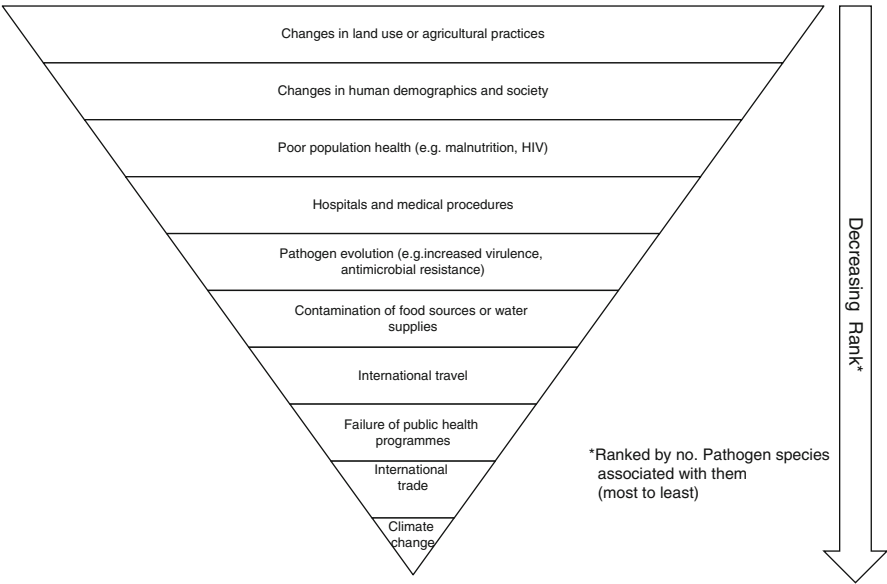


Fig. 3.2 Emerging pathogens—main categories of drivers associated with emergence and re-emergence (adapted from Woolhouse and Gowtage-Sequeria, 2005)

novel food. It has long been known that human pathogens can emerge from animal pathogens, i.e., they are zoonoses, however there are a number of factors believed to be drivers of pathogen emergence and re-emergence (Fig. 3.2).

A recent study of human pathogens (Woolhouse and Gowtage-Sequeria, 2005) produced a count of 1,407 human pathogen species, of which 177 (13 %) were described as emerging or re-emerging (Table 3.4). Whilst only some of these will be associated with food, the sheer numbers of emerging pathogens demonstrate that there is no place for complacency in the protection of public health.

In the past 25 years several prominent food pathogens have “emerged” as serious threats to human health. These include *L. monocytogenes*, *E. coli* O157:H7, *E. coli* O104:H4, Cronobacter, and the prions causing BSE and vCJD. This is an important lesson for food safety professionals who should expect the continued emergence of

Table 3.4 Numbers of emerging and re-emerging human pathogens (Woolhouse and Gowtage-Sequeria, 2005)

Pathogen group	Known pathogens	Emerging pathogens
Bacteria	538	54
Fungi	317	22
Viruses and prions	208	77
Helminths	287	10
Protozoa	57	14
Total	1,407	177

new foodborne microbial pathogens in the future. Continued diligence on the part of microbiologists, epidemiologists, and HACCP teams will be necessary to quickly identify and control new pathogens as they emerge and this illustrates the essential requirement to keep knowledge and systems up to date.

3.3.7 Animal Pathogens of Relevance to the Global Food Supply Chain

Many of the pathogens mentioned above affect both humans and animals, i.e., they are zoonoses. Within the global food supply chain we need to consider animal pathogens both from the point of making food animals ill and unsuitable for human food, and for the possibility of introducing pathogens of concern to humans into the food supply. To control these issues we need to understand good farming practices and animal husbandry techniques but also, crucially, to ensure that food being manufactured for animals, i.e., animal feed, is also safe for consumption by the target animals.

This is a specialist area of the food supply chain and producers both of animal feed and food animals need to ensure that they have sufficient expertise and information to identify and control all relevant hazards. Several guidance documents have been produced by national and international bodies to help outline the issues and standards required. These include the FAO/WHO reports, *Food Safety and Quality as affected by animal feedstuff* (FAO, 2000), *Animal Feed impact on Food Safety* (FAO/WHO, 2007), and the *Guide to Good Farming Practices for Animal Production Food Safety* (FAO/WHO, 2010). In addition, the US FDA is active in providing guidance for the sector via its “Center for Veterinary Medicine,” at the time of writing, the FDA is working on draft guidance for industry—*Ensuring Safety of Animal Feed Maintained and Fed On-Farm*—which is expected to be published in 2012. These guidelines should provide useful information for identification and control of hazards in the animal feed and animal production links of the global food supply chain.

3.4 Control of Biological Hazards

This section provides an introduction to the types of control measures available for biological hazards. Often several different controls will be in place at the same time, for example, intrinsic factors within the product formulation and heat processing or chilling.

3.4.1 Intrinsic Factors

Intrinsic factors are the compositional elements of a food product and these can often have a controlling effect on the growth of microorganisms. The major

intrinsic factors found in foodstuffs and considered here are pH and acidity, organic acids, preservatives, water activity, and the ingredients themselves. For control of microbiological hazards, the use of more than one intrinsic factor within the product formulation is known as the hurdle effect (Fig. 3.3), since each additional factor makes it more difficult for the organism to grow. The information given here is an introduction only and, where necessary, HACCP teams should refer to specific and more detailed reference books.

(a) pH and acidity

Acidity is often one of the principal preserving factors in food products, preventing the growth of many food poisoning or food-spoilage organisms at certain levels. In fact, fermenting and acidifying foodstuffs are food preservation techniques that have been used for thousands of years. Examples of foods that can be preserved safely by pH and acidity are yogurt, which is fermented to low pH by the action of starter cultures, and pickled vegetables, which are acidified with acetic acid (vinegar) and normally also pasteurized to prevent spoilage.

Although measurement of acidity is still often used in manufacturing for flavor control, the more useful parameter of measurement from the food safety viewpoint is that of pH. This is because published information on the growth and survival characteristics of microorganisms at different levels of acidity is normally based around the pH scale.

There is a characteristic pH range across which microorganisms can grow and the limiting pH for growth varies widely between different species. Most microorganisms grow best at around neutral pH 7, but may also grow at values ranging from pH 4 to pH 8. A small number of bacteria can grow at $\text{pH} < 4$ or $\text{pH} > 8$ but those able to grow at $\text{pH} < 4$ are not normally associated with food poisoning. However, the growth of these acid-tolerant organisms could have food

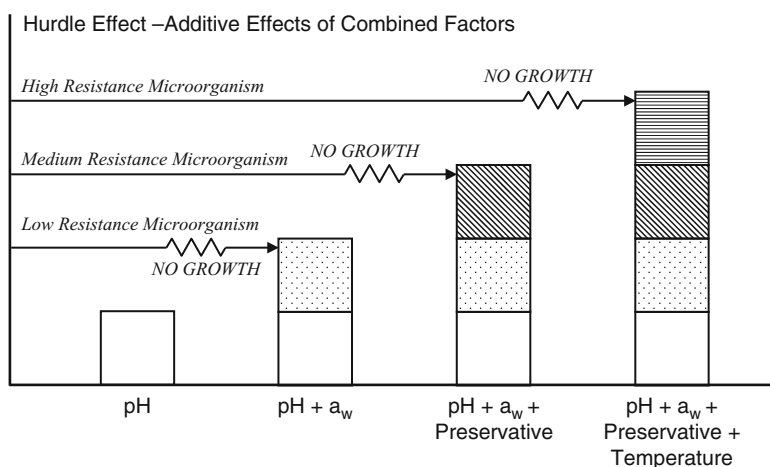


Fig. 3.3 The Hurdle effect (adapted from Wallace et al., 2011)

safety implications if their growth in the foodstuff is involved in raising the pH to a level where other microorganisms, including pathogens, can grow. This is also true for yeasts and molds which can grow at pH values considerably lower than pH 4.

It should also be remembered that microorganisms may survive at pH values outside their range for growth. This has significance for food safety when other factors cause the pH to change. For example, spores of *Bacillus cereus* might be present in a low-pH raw material where they are unable to grow. If this is then mixed with other raw materials to make a higher-pH product, the spores may be able to germinate and grow to dangerous levels.

The pH limits for growth of a number of potential food pathogens can be found in Appendix B. The data shown in the Appendix are absolute limits for growth, many of which have been established in pure culture experimental studies. In real food situations the organisms may not be able to grow to these extremes for a number of reasons. These include water activity, oxygen concentration, heat or cold damage, and competing microflora. The effect of pH on growth is particularly affected by temperature and an organism that can grow at pH 4.5 at 30 °C may not be able to do so at 5 °C, and vice versa. The tolerance of microorganisms to pH can also be greatly affected by the type of acid used.

(b) Organic acids

Certain organic acids are widely used as preservative factors in food manufacture, although some of these are only permitted to be used in defined concentrations. The antimicrobial activity of organic acids is due to the undissociated molecules, although the exact mechanism of their action is unknown. The effectiveness of these acids is related to the pH of the sample, as the dissociation of the molecules is pH dependent. For example, the level of sorbic acid (usually added to a product as potassium sorbate) which will be effective in a product which has a pH 7 will be only 0.48 % compared with 97.4 % in a product which has a pH 3. Tables 3.5 and 3.6 (adapted from ICMSF, 1980) illustrate the antimicrobial activity of organic acids and pH dependence.

Organic acids are most effective against microorganisms in combination with other preserving factors, although there are several drawbacks to their use:

1. Resistance of individual strains of microorganisms to organic acids varies considerably
2. Organic acids are less effective if high levels of microorganisms are present initially
3. Microorganisms may become resistant to their use
4. They can be utilized as carbon sources by many microorganisms

Organic acids commonly used as preserving factors in foods include acetic, citric, lactic, benzoic, sorbic, and propionic acids. Acetic, citric, and lactic acids are often added as part of the formulation from the flavor point of view, while benzoic, sorbic, and propionic tend to be used only for their preservative action. The specific organic acid chosen depends on the target microflora for inhibition, along with the formulation and other intrinsic factors present in the foodstuff.

Table 3.5 Percentage of organic acid undissociated at various pH values

Acid	pH value				
	3	4	5	6	7
Acetic	98.5	84.5	34.9	5.1	0.54
Citric	53.0	18.9	0.41	0.006	<0.001
Lactic	86.6	39.2	6.05	0.64	0.064
Benzoic	93.5	59.3	12.8	1.44	0.144
Sorbic	97.4	82.0	30.0	4.1	0.48
Propionic	98.5	87.6	41.7	6.67	0.71

Table 3.6 Percentage of undissociated acid that inhibits growth of most strains

Acid	Enterobacteriaceae	Bacillaceae	Micrococcaceae	Yeasts	Molds
Acetic	0.05	0.1	0.05	0.5	0.1
Citric	>0.005 ^a	>0.005	0.001 ^b	>0.005	>0.005
Lactic	>0.01	>0.03	>0.01	>0.01	>0.02
Benzoic	0.01	0.02	0.01	0.05	0.1
Sorbic	0.01	0.02 ^c	0.02	0.02	0.04
Propionic	0.05	0.1	0.1	0.2	0.05

^aActual inhibitory concentrations likely to be far in excess of these values

^bThis value is for *Staphylococcus aureus*; micrococci are more resistant

^cClostridia are more resistant

(c) Preservatives

Chemical preservatives can be added to certain foodstuffs to inhibit the growth of food poisoning and spoilage organisms. There are usually carefully controlled legal limits for addition, and different preservatives are effective against different groups of microorganisms. Examples of preservatives commonly used in foods are sodium nitrite, which is often used in cured meat products, and potassium sorbate, which is used in many areas, including bread, cake, and jam manufacture. Other food preservatives include nisin, sodium nitrate, sulfur dioxide, sodium benzoate, sodium and calcium propionate, and sodium metabisulfite. Some of the commonly used chemical preservatives are the soluble salts of the previously mentioned organic acids.

Sodium nitrate and nitrite have long been used in meat curing to reduce spoilage and stabilize color. Their safety effect is to prevent the germination of spores, thus controlling pathogens such as *Clostridium botulinum*. Their effectiveness depends on a number of factors, including the types and numbers of microorganisms present, the curing temperature, and the meat pH.

As we saw in the previous section, potassium sorbate or sorbic acid is effective in acid foods, particularly against yeasts and molds. It will also limit the growth of micrococci, enterobacteriaceae, and bacilli, although not clostridia. Similarly, sodium benzoate or benzoic acid is also effective, mainly in high-acid foods. It

will inhibit the growth of yeasts and molds and is commonly used in pickles, salad dressings, and fruit juices.

Nisin is an antibiotic which prevents the growth of many bacteria, and which has been used in cheese manufacture and canned foods. This preservative tends to be relatively expensive and this has limited its application. Sulfur dioxide is an antioxidant which inhibits the growth of bacteria and molds, and which can be used in gaseous or liquid form. It is commonly added to beers and wines and to comminuted meat products. The propionates, sodium and calcium, are used to control molds in low-acid foodstuffs such as cakes and bread.

The smoking of food also has a preservative effect due to chemical compounds present in the smoke. Although the exact mechanism of preservative action is poorly understood, smoking is a traditional method of food preservation which has remained popular, e.g., for smoked salmon. In recent years it has become fairly common to add smoke flavor to food rather than using the smoking technique. This has little or no preservative effect.

(d) Water activity

Water activity (a_w) is a measure of the availability of water in a sample. As microorganisms can only grow in the presence of an available form of water, they can be controlled by controlling the a_w . The a_w is the ratio of the water vapor pressure of the sample to that of pure water at the same temperature:

$$a_w = \frac{\text{water vapour pressure of sample}}{\text{pure water vapour pressure}}$$

Pure water has an a_w of 1.0, and as solutes are added making a more concentrated solution, the vapor pressure decreases and along with it the a_w . The a_w is directly related to the equilibrium relative humidity ($a_w = \text{ERH}/100$), as well as to the boiling point, freezing point, and osmotic pressure of the sample.

Traditionally, a_w has been used as a preservative factor against microorganisms in foods through the addition of salt and/or sugar and the reduction of moisture content through drying. Sugar has traditionally been added to fruit products, such as jams and soft drinks, while salt has wide application in products such as pickled, salted fish and dry cured meats. The minimum a_w values permitting growth for a number of food pathogens is given in Appendix B.

(e) Ingredients

The individual ingredients and their interactions with each other should also be considered as intrinsic factors within a product formulation. Particular attention needs to be paid to hazards entering the product in this way. This will often be addressed during hazard analysis of the raw materials, when questions such as “do the ingredients contain hazards?” and “are any ingredients allergenic?” will be asked. Consideration of the ingredients in terms of how they affect the product formulation is also necessary, e.g.:

- Would the wrong quantity of an ingredient be hazardous? For example, too much or too little of a preservative or acid added, or too much of a specific nutrient in animal feed for a particular species.
- Could ingredient interactions cause a hazard? For example, by neutralizing the preserving acid.

Consider whether an incorrect formulation could cause a hazard to occur. Recent trends have been to design products which have fewer inherent preservation factors. This might be for public health reasons associated with chronic disease, e.g., reduction in sugar, salt, and fat, or for consumer acceptability reasons, e.g., fewer/no preservatives. As this affects the stability and safety of the product, the HACCP team should be aware that the significance of safe raw materials and control during processing, in addition to the intrinsic formulations controls, may have changed and need to be strengthened.

3.4.2 Process Technologies

There is a wide variety of different process technologies available and it is necessary that the type of process being used is fully understood.

It is essential that any planned **thermal processes**, in terms of heating, cooling, and holding temperatures and times, are known, along with their effect on potential hazards. Where the consumer is expected to cook or heat a product, the exact instructions to achieve the desired heat process should be determined. Often product development is carried out on samples manufactured in a laboratory or pilot kitchen. Where this is true, the process requirements to achieve the correct heat profile when scaled up to the manufacturing environment must be understood. This will vary depending on the type of heat processor chosen, e.g., band oven, plate heat exchanger, rack oven, bulk vessel, microwave, etc.

Where a product is being made by **fermentation**, it is important to understand the chosen culture system and how it is controlled. Would you know if the fermentation failed, and would this allow microbiological hazards to grow?

In the production of a **dried product**, how is the final moisture controlled? The potential for the presence of microbiological hazards that have survived through the process or have entered through contamination must be established, as these could cause a problem when the product is reconstituted. This is particularly important for products that are reconstituted without further heating, e.g., infant formula, dessert mixes.

In a **freezing process**, the length of time to freeze and any holding stages before freezing could be significant. The potential cross-contamination risk is also important here, particularly for foods to be consumed immediately after defrosting. If you are using frozen ingredients in a product you will need to consider whether or

not these need to be defrosted before addition. Adding frozen ingredients may help with temperature control, but they may change the product's intrinsic factors as they defrost, e.g., diluting the dressing of a low-pH salad and raising the pH.

Irradiation may be used to improve the microbiological quality of certain foodstuffs. However, if the product has been mishandled before the irradiation process, it is possible that microbial toxins could be present which would not be affected by the process and which could pose a risk in the final product.

Consider also whether it will be a **continuous process** or whether there will be a number of holding or delay stages. The maximum holding time or delay at all stages should be understood, along with the associated temperature at this stage. This information will need to be assessed during the hazard analysis to establish the potential for growth of microbiological hazards.

The chosen **packaging system** may have an impact on product safety, so the influence that packaging has on the growth of microorganisms during the product shelf-life should be established. The use of controlled and modified atmosphere packaging systems has increased in recent years, along with that of vacuum packaging. The absence of oxygen means that only anaerobic or facultative organisms can grow, and so these systems have been promoted for the extension of product shelf-life by reducing/preventing the growth of the normal microflora. However, they allow the growth of a different microflora which could include food pathogens. It is vital that these organisms cannot grow to hazardous levels during the proposed shelf-life.

If any **new technologies** or less well-established processing options are employed, then the hazards associated with these must be determined for full consideration during the hazard analysis. An example here is ohmic heating, which allows the sterilization of liquid-based foods without overcooking the liquid phase. Here a voltage is applied between electrodes inserted in a tube through which a continuous stream of food passes. The food is sterilized by the heat generated in it due to its electrical resistance. Initial considerations of this technique suggested that toxicological hazards might be formed by metal ions from the electrodes leaching into the food or by the formation of free radicals in the food through the heating process. Detailed examination of the technique by expert toxicologists found that free radicals were not likely to be formed and that any traces of metal in the food from the electrodes would not represent a hazard to health. The technique was therefore cleared for these hazards. Where new technologies are used as replacements to well-established processes such as traditional methods of heat processing, it is important that they are validated as achieving the same degree of lethality across all products. Examples include UV treatment of water and the use of microwave cooking rather than traditional methods.

3.4.3 Summary of Control Options for Biological Hazards
(Table 3.7)

Table 3.7 Examples of practical hazard control options^a—biological hazards

Hazard	Control measures
All types of biological hazards	<ul style="list-style-type: none">• Prerequisite programs/support systems, e.g., SQA, cleaning• Effective trace and recall procedures
Bacteria	
(a) Heat-stable preformed toxins, e.g., <i>Staphylococcus aureus</i> , <i>Bacillus cereus</i> emetic toxin	<p>Raw materials</p> <ul style="list-style-type: none">• Specification for organism and/or toxin• Evidence of control during supplier process• Testing (positive release with statistically valid sampling)• Certificate of analysis (checked for compliance with specification) <p>People</p> <ul style="list-style-type: none">• Hand wash procedures• Covering cuts/wounds, etc.• Occupational health procedures• Management control of food handlers <p>Build-up during process</p> <ul style="list-style-type: none">• Control of time that ingredients, intermediate, and finished products are held within the organism’s growth temperature range• Design of process equipment to minimize dead spaces• “Clean as you go” procedures• Control of rework loops
(b) Vegetative pathogens, e.g., <i>Salmonella</i> spp., <i>L. monocytogenes</i> , <i>V. parahaemolyticus</i> , <i>Y. enterocolitica</i> , <i>E. coli</i> STEC, etc.	<p>Raw materials</p> <ul style="list-style-type: none">• Lethal heat treatment during process• Specification for organism^b• Evidence of control during supplier process^b• Testing (as previous)^b• Certificate of analysis (as previous)^b• Temperature control to prevent growth to hazardous levels^c• Intrinsic factors^c such as pH and acidity; a_w—salt, sugar, drying; organic acids; chemical preservatives <p>Processes/during processing</p> <ul style="list-style-type: none">• Processes^c such as irradiation, electrostatic field sterilization <p>Cross-contamination at the facility (from the environment and raw materials)</p> <ul style="list-style-type: none">• Intact packaging• Pest control• Secure building (roof leaks, ground water, etc.)• Logical process flow, including where necessary:<ol style="list-style-type: none">1. Segregation of people, clothing, equipment, air, process areas2. Directions of drains and waste disposal

(continued)

Table 3.7 (continued)

Hazard	Control measures
(c) Spore formers, e.g., <i>Cl. botulinum</i> , <i>Cl. perfringens</i> , <i>B. cereus</i>	<p>Raw materials</p> <ul style="list-style-type: none"> • Specification • Evidence of control during supplier process • Certificate of analysis (as previous) <p>Processing/during process</p> <ul style="list-style-type: none"> • Lethal heat treating during process <ol style="list-style-type: none"> 1. For example, for <i>Cl. botulinum</i> F03 process required for low-acid products for ambient storage 2. Lethal combination of heat treatment and acidity or sugar level for high-acid/sugar products for ambient storage 3. For products to be stored at chilled conditions (<5 °C) a sublethal heat treatment may be used but this must be accompanied by intrinsic factors which will prevent the growth of psychrotrophic organisms (e.g., <i>Cl. botulinum</i>) during the product shelf-life 4. For all the above processes, pack integrity, cooling water chlorination, and handling practices for cooling container are essential • Temperature control to prevent growth to hazardous levels • Intrinsic factors such as pH and acidity; a_w—salt, sugar, drying; organic acids; chemical preservatives • Other processes lethal to the organism of concern, e.g., irradiation, etc.^d <p>Cross-contamination at the facility (from the environment and raw materials)</p> <ul style="list-style-type: none"> • Intact packaging • Pest control • Secure building (roof leaks, ground water, etc.) • Logical process flow, including where necessary: <ol style="list-style-type: none"> 1. Segregation of people, clothing, equipment, air, process areas 2. Direction of drains and waste disposal <p>Foodborne viruses, e.g., Norovirus, hepatitis A</p> <ul style="list-style-type: none"> • Strict Supplier control concerning irrigation and wash water of salads and vegetables, and sourcing of filter-feeding shellfish—avoidance of shellfish likely to be grown in sewage-contaminated waters • Consideration given to proven lethal treatments such as irradiation or heat treatment • Stringent personal hygiene procedures among food handlers

(continued)

Table 3.7 (continued)

Hazard	Control measures
Parasites	<ul style="list-style-type: none">• SQA procedures to include farm animal husbandry and veterinary inspection for control of parasites such as <i>Toxoplasma gondii</i>, <i>Taenia</i> in beef and pork, and <i>Trichinella</i> in pork• Freezing (–18 °C), heating (>76 °C), drying, and salting
Protozoa, e.g., <i>Cryptosporidium</i> , <i>Giardia</i> , <i>Cyclospora</i>	<ul style="list-style-type: none">• Use of filtered water• Pasteurization of raw milk• Heat treatment of water and raw milk used as ingredients

^a*Note:* These control options are not necessarily effective on their own and will often be used in combination to control specific hazards. Some of the suggestion options will be more appropriate to prerequisite programs than to inclusion in the HACCP plan

^bEssential when your process has no lethal heat treatment

^cNB *Salmonella* spp. may cause infection at low numbers in your product. Therefore absolute confidence in your raw materials as supplied is necessary if there is no lethal process step. Remember also that heat-labile toxins will not necessarily be destroyed by other processes/controls such as irradiation or acidity

^bRemember that heat-labile toxins will not necessarily be destroyed by other processes/controls such as irradiation or acidity

3.5 Chemical Hazards

Chemical hazards have perhaps been the least well understood category of hazards within food companies. Whilst many food companies employ or have access to microbiologists and will generally have in-house expertise on physical contaminants, there is still a lack of toxicological expertise within industry, making chemical hazards one of the most difficult areas for the HACCP team to understand and manage. For many food companies, the majority of chemical hazard issues will be most applicable to their ingredient supply chain and so strong supplier controls will be necessary to assure safety of ingredients.

This lack of expertise in chemical hazards is exacerbated by the “chasing zero debate,” i.e., where test methods improve and are able to detect smaller and smaller amounts of chemical contaminants, does this mean that the levels allowed in food should decrease? The answer to this question from a food safety viewpoint is that levels should decrease where there is a known toxicological risk to health; however, the change in relative levels of risk may be miniscule such that the real risk to public health is not well understood.

Since the previous edition of this book we have seen several high profile chemical contamination issues, including accidental and deliberate contamination of foods. Deliberate contamination is perhaps best exemplified by the industrial melamine contamination of a range of products in China, the melamine being added as a cheap protein replacer. In human food (infant formula) this was economic

adulteration at its worst since the toxic effects of melamine and its derivatives were known and resulted in harm to a large number of consumers. However in the pet food case (which occurred **prior** to the infant formula event), the situation was slightly more complex and perhaps highlights some cultural differences that also come in to play. Use of melamine in animal food was a common practice in China—indeed it was openly advertised as an ingredient for this purpose. The subsequent event concerning infant formula was very different. Animals had already died as a result of the consumption and this was well publicized, i.e., the hazardous nature of the practice was well known and the necessary food withdrawals and recalls affected a huge section of the global food supply chain. These issues would most likely not have been considered by HACCP teams in food companies previously and demonstrate the need to keep up to date with information on chemical hazards from a variety of sources.

Similar to microbiological hazards, the level of risk associated with chemical hazards will also depend on the consumer of the final product, so there may be different concerns for human food and for feed intended for different species of animals. Animals are usually dependent on the one single source of food and so it has to be safe. In animal feed the wrong nutrient or wrong amount of nutrient can be hazardous, and even fatal, for a particular species and so the evaluation of chemical hazards is likely to focus more strongly in this area.

Levels of salt and fat in human food (both of which are known to contribute to a range of chronic health conditions, e.g., coronary heart disease) are not currently considered as hazards in a HACCP study on human food. This is mainly because the variety in the human diet mean that salt and fat levels in individual products do not give major cause for concern unless products are consumed in excess. Government initiatives to reduce these nutrients across a wide range of manufactured human food products, such as in the UK, mean the need for careful reformulation, although salt and fat are still not thought of as chemical hazards. The danger here is that reduction, particularly of salt, can mean that pathogenic microorganisms are more likely to grow so it is important to consider the whole picture. For animal feed the situation with ingredient/nutrient control is very different since food companies are managing the safety of the feed provided and animals may only eat one or limited varieties of feed—if you only eat one product, it must be safe.

From the consumer perspective, it has long been accepted that there are concerns about the use of “additives” in foods (see Table 3.2); however, these fears have largely been fuelled by publicity around the presence of chemicals in foods that are not “natural” ingredients rather than true toxicological risks. In fact, the majority of chemicals used as food additives have been through stringent testing and risk assessment and are allowed at specific levels in foods. Where additives have been found to have potential risks to health, e.g., some historically used food colors, these are normally swiftly banned from use through legislation. However, the differences between legislative standards around the world make this more difficult to understand, particularly when substances are banned in one country or region but not in others.

Other substances that may be initially thought of as chemical hazards are chemicals that cause off-flavors or taints and so make food products unacceptable

to the consumer. A good example here is the group of chemicals known as chlorophenols and chloroanisoles—these produce powerful off-flavors but do not actually make the product unsafe for consumption. The key here, as for microbiological and chemical hazards, is to assess the significance of each item to consumer health, through the consideration of likelihood of occurrence and severity of outcome. Again, HACCP teams must recognize their limitations in knowledge and experience in this area and seek appropriate advice from experts in the field.

In summary, chemical contamination of foodstuffs can happen at any stage of their production, from growing of the raw materials through to consumption of the finished product. The effect of chemical contamination on the consumer can be long term (chronic), such as for carcinogenic or accumulative chemicals (e.g., mercury) which can build up in the body for many years, or it can be short term (acute), such as the effect of allergenic foods. The current main chemical hazard issues in food products are described below. The following notes provide an introduction to some of the common chemical hazard types. It is not intended to be an exhaustive list, nor will it provide a detailed database of considerations on these issues; however, it should give some good background to the issues of major concern to food producers.

3.5.1 *Mycotoxins*

Mycotoxins are produced as secondary metabolites of certain fungi and can cause long-term carcinogenic effects at ongoing low levels or short-term acute toxic effects at high levels of exposure in food. Acute effects are rarely seen in the developed world but may be seen in less developed countries where resources are limited. Mycotoxins are normally considered under the category, chemical hazards, although they have sometimes previously been regarded as biological hazards because they are products of microbial growth and, in fact, were listed in this way in the previous edition of this book.

According to the “European Mycotoxins Awareness Network,” any crop that is stored for more than a few days is a target for mold growth and, therefore, mycotoxin formation, and this can occur both in tropical areas and in temperate regions of the world, depending on the species of fungi. Major food commodities affected are cereals, nuts, dried fruit, coffee, cocoa, spices, oil seeds, dried peas, and beans and fruit, particularly apples. Mycotoxins also enter the human food chain via meat or other animal products such as eggs, milk, and cheese as the result of livestock eating contaminated feed. They may also be found in beer and wine resulting from the use of contaminated barley, other cereals and grapes in their production (<http://www.mycotoxins.org/>).

Most mycotoxins are very stable once formed and will survive further processing, including high heat processes. For these reasons prevention of entry into the food chain is key to protecting public health and most food industry controls will be around prevention of mold growth during cultivation and storage of crops, and rejection of mold contaminated materials at early stages in the food

chain. However, poor storage at any stage in the food chain could allow mold growth and mycotoxin formation so it is important that susceptible commodities are handled correctly.

Mycotoxins are the subject of ongoing study and risk assessment at national and international levels and legislation on allowable levels in food commodities is seen in many countries. However, like other chemical hazards, the legislative values vary among countries. This might be due to differences in national diets but these differences mean that food companies exporting and importing susceptible commodities need to take particular care with mycotoxin prevention and control. Because of the potential severity of chronic exposure to mycotoxins, it is generally accepted that amounts in food should be reduced to the lowest levels that are technologically possible (www.mycotoxins.org).

The following notes provide some general information on some of the key mycotoxins of concern to the food industry. Further, more detailed information can be found in a range of sources, such as the publications of the European Mycotoxins Awareness Network (EMAN), which offers a range of factsheets on different mycotoxins plus useful publications on application of HACCP to mycotoxin control (see “*Expert Factsheets: HACCP—Prevention/Control*” on the EMAN Web site at www.mycotoxins.org). In addition, the FAO/IAEA *Manual on the application of the HACCP system in Mycotoxin prevention and control* (FAO, 2001) offers useful examples of HACCP application plus further background information on mycotoxins.

(a) Aflatoxins

Most countries have established regulatory limits on the presence of aflatoxin. These mycotoxins are produced by *Aspergillus flavus* and a few other molds growing on foodstuffs. There are six aflatoxins of concern, four of which (B1, B2, G1, and G2) occur in various foods, and two of which (M1 and M2) are metabolites found in the milk of lactating animals that have eaten aflatoxin-contaminated feed. Aflatoxin B1 is found most commonly and occurs in groundnuts and in grain crops, particularly maize.

Aflatoxins normally contaminate crops during the growing or storage periods. During the growth period, the aflatoxin contamination risk is increased by those environmental conditions which stress the plants and allow contamination with the mold, for example insect damage or drought conditions. Poor storage conditions, such as dampness and humidity, will increase the chance of unacceptable contamination. In order to control aflatoxins in your products you must understand the risks associated with each raw material source and with storage at your facility.

(b) Patulin

This is a mycotoxin associated with fruit and fruit-juice products. Produced by several *Penicillium* spp., it is considered to be a carcinogen, and high concentrations may cause acute effects such as hemorrhages and edema. The presence of patulin in food products is normally associated with the use of moldy raw materials, and this can be prevented by building effective control measures into your HACCP system.

(c) Deoxynivalenol (DON)

This is a member of the tricothecenes group, which is of particular importance because it has been found in grain crops worldwide. Tricothecenes are produced by a range of different fungi but particularly by species of *Fusarium*. Vomitoxin is known to cause toxic effects in animals and human illness has also been reported. It is controlled through legislation in some countries where there have been particular problems and, alongside other tricothecenes, is the subject of further study at international levels regarding toxicity and safe levels in foods.

(d) Fumonisin

Produced by several species of *Fusarium*, fumonisins have been linked epidemiologically to esophageal cancer in humans and have serious toxic effects in some animals, particularly horses. It is most commonly associated with maize, although it has been found at lower levels in other crops, such as sorghum and rice, and must be controlled at the commodity level.

3.5.2 Marine Toxins (Fish and Shellfish Poisoning)

Marine toxins enter the food chain through the contamination of shellfish and fish by toxic dinoflagellates and diatoms and through the growth of certain strains of bacteria in fish products. Key problems are seen with filter-feeding shellfish such as mussels, oysters, and clams, which concentrate levels of dinoflagellates in their tissues whilst filtering seawater for food, however the consumption of dinoflagellates/diatoms of concern by fish species can also result in disease. The main types of marine toxins are listed in Table 3.8.

From Table 3.8, it can be seen that the majority of issues involving marine toxins are associated with raw material supplies, as the toxins may be present in fish/shellfish from contaminated waters (e.g., during red tides). However formation of the toxins related to bacterial growth, particularly in Scombroid poisoning, can be prevented through adequate chilled storage of fish following harvest. Fugu poisoning can only be prevented through correct removal of the organs concerned so this will remain a high risk food.

3.5.3 Cleaning Chemicals

Cleaning chemicals are perhaps the most common potential chemical contaminants used at the facility level in any food preparation or production operation. Cleaning residues may remain on utensils or within pipework and equipment and be transferred directly onto foods, or they may be splashed onto food during the cleaning of adjacent items.

Table 3.8 Marine toxins

Type of "Poisoning"	Cause	Effect
Paralytic shellfish poisoning	Caused by several genera of dinoflagellates, some forming heat resistant and lethal toxins (e.g., saxitoxin from <i>Saxidomus</i>).	Depending on the type of dinoflagellate and toxins involved, illness may include tingling sensation, nausea and respiratory paralysis, and may be fatal.
Diarrhetic shellfish poisoning	Caused by dinoflagellates.	Mild gastroenteritis.
Neurotoxic shellfish poisoning	Caused by consumption of brevetoxin, produced by the dinoflagellate <i>Gymnodinium breve</i> .	Gastrointestinal illness with low fatality rate.
Amnesic shellfish poisoning	Caused by domoic acid, which is produced by the diatom, <i>Pseudonitzschia</i> .	Gastroenteritis, which can proceed to neurological symptoms, coma, and death.
Ciguatera poisoning	Caused by the dinoflagellate <i>Gambier discus toxicus</i> , which produces a ciguatoxin. Associated with approximately 400 species of tropical fish.	Gastroenteritis, which can proceed to neurological symptoms, coma and death.
Scombroid poisoning	Associated with fish with high histidine levels, such as tuna and mackerel. Scombroid poisoning occurs when <i>Proteus</i> spp. grow on the fish and decarboxylate histidine to histamine. Normally associated with poor temperature control.	Can produce symptoms similar to an allergic response.
Fugu (Puffer Fish) poisoning	Tetrodotoxin, a neuroparalytic toxin, is produced in the liver and internal organs of the fish by several genera of Gram-negative bacteria.	Potentially lethal where internal organs have not been adequately removed during food preparation.

It is therefore vitally important that HACCP team members consider the implications of the cleaning procedures in their operation. Problems can be prevented by the use of nontoxic "food grade" cleaning chemicals and through the design and management of appropriate cleaning procedures. This will include adequate training of staff and may involve post-cleaning equipment inspections and audits of chemicals in use on site. This issue is most commonly addressed as part of the PRPs.

3.5.4 Pesticides

Pesticides are any chemicals that are applied to control or kill pests and include the following:

- Insecticides
- Herbicides
- Fungicides
- Wood preservatives
- Masonry biocides
- Bird and animal repellents
- Food storage protectors
- Rodenticides
- Marine anti-fouling paints
- Industrial/domestic hygiene products

Pesticides are used in a wide range of applications all over the world—in agriculture, industry, shipping, and the home. The use most relevant to food safety is in agriculture but contamination from other sources must also be considered.

In agriculture pesticides are used during production to protect crops and improve yields, and after harvest they are again used to protect the crops in storage. However, not all pesticides are safe for use in food production (for example, some of those used for the treatment of timber) and even those that are safe for food use may leave residues that could be harmful in high concentrations. To overcome these problems most countries have very strict control of the pesticides that can be used and on the residue limits that are acceptable. These are set through expert toxicological studies and are normally laid down in legislation.

From the food safety point of view you need to understand any pesticide risks from your raw materials at any stage in their preparation. You also need to know which pesticides are permitted for use and what the maximum safe residue limits are in each case. Control can be built into your HACCP system to ensure that the safe levels are never exceeded in your products.

In addition to raw materials that have direct pesticide contact, you must also consider the possibility of cross-contamination with pesticides at any stage in food production. This could be cross-contamination of your raw materials or it could happen on your site, e.g., from rodenticides. These issues should again be considered as part of your PRPs.

3.5.5 Allergens and Food Intolerances

Some food components can cause adverse responses in sensitive individuals and these are commonly described as allergies or food intolerances. These reactions can range from mild to extremely serious, depending on the dose and the consumer's

sensitivity to the specific component. Extreme anaphylactic responses are seen in individuals with severe allergies.

There are many mechanisms causing adverse reactions to foodstuffs. These include:

- Immune mediated
 - IgE immediate reactions (true allergy)
 - Cell-mediated reactions (gastrointestinal tract mucosal damage)
 - Unknown and poorly characterized
- Nonimmune mediated
 - Enzymatic abnormalities
 - “Pharmacological-host interaction” effects
- Behavioral/psychological effects

An important point here is that most adverse reactions to foods (also known as food hypersensitivities) are not caused by reactions involving the immune system, thus they are not true Food Allergies; however, the terms food allergy and allergens are widely used in the food industry and allergens will therefore be used here to describe materials capable of causing an adverse response.

Allergens are normally considered under the heading of chemical hazards since it is a chemical, usually protein, component of the food product that causes the response in susceptible individuals. This is clearly an issue for concern with respect to protecting the health of a specific sector of the population. In fact the population levels affected are considered to be approximately 2 % of adults and 7 % of children; however up to 20–30 % of adults believe that they are affected by some sort of allergy or adverse reaction to food.

Common allergens of concern include:

- Peanuts (groundnuts)
- Tree nuts
- Eggs
- Milk products
- Shellfish
- Fish
- Soy/soya
- Wheat

The above list is often described as the “big 8” allergens due to commonality of occurrence. However, allergens of concern vary across the world depending on the susceptibility of populations to different materials. A good example of this is lactose intolerance, which is linked to an enzymatic abnormality. However in this case the abnormal situation is to be lactose intolerant since it is normal for mammals (including most humans) to lose the intestinal lining enzyme lactase after early childhood, once the young have stopped suckling. In fact approximately 70 % of adult population worldwide are lactase deficient but most people of northern

European origin have a (dominant) genetic variation that allows lactase to persist into adulthood. Thus they can drink milk. However, after intestinal disease, lactase deficiency with lactose intolerance can develop either transiently or permanently.

Differences in population susceptibility to allergens around the world have resulted in differences in the legislation on allergen labeling across national boundaries. For example, in the EU it is a requirement to label not only the “big 8” but also a range of additional allergens such as celery, lupin, mollusc, mustard, cereals containing gluten (wheat, oats, barley, rye), sulphites, and sesame whilst in Australia honey and royal jelly are included in labeling legislation.

The control options open to the food processor manufacturing products with allergenic components are raw material control, effective pack labeling, control of rework, and effective cleaning of equipment. The label must describe the product contents accurately, highlighting any potentially allergenic components. A manufacturer or caterer who produces several different products must also consider the chance of cross-contamination of allergenic components into the wrong product where they will not be labeled. This is particularly important in the case of recycling loops and rework of product, and these issues should be considered as part of the HACCP Study. The possibility of mislabeling through using misprinted or incorrect packaging, e.g., packing a ready meal product into the wrong sleeve, should also be evaluated. The general control of allergens at each facility to minimize the risk of cross-contamination is usually managed as part of PRPs.

Recent trends and guidelines mean that some food companies use “catch all” warnings on product packaging, for example, “Warning : this product may contain traces of peanut” or “this product is made in a facility that handles nuts.” This is normally done where a number of products containing nuts are manufactured on the same line or in the same facility as non-nut containing products, e.g., in breakfast cereal manufacturing, or where rework is involved which may have been in contact with nuts, e.g., in the confectionery industry where enrobing chocolate is reclaimed. Such labeling is only felt to be helpful by anaphylaxis sufferers when no other control options are possible as it is otherwise seen as a limitation of their diet. In the USA, the FDA policy is that precautionary labeling cannot be used in lieu of efforts to minimize allergen contamination in facilities. Manufacturers continue to be challenged to find better ways of preventing cross-contamination with allergens.

3.5.6 Toxic Metals (*also known as heavy metals*)

Metals can enter food from a number of sources and can be of concern at high levels. The most significant sources of toxic metals to the food chain are:

- Environmental pollution
- The soil in which food stuffs are grown
- Equipment, utensils, and containers for cooking, processing, and storage
- Food-processing water
- Chemicals applied to agricultural land

Particular metals of concern are tin (from tin containers), mercury in fish, cadmium and lead, both from environmental pollution. Also significant are arsenic, aluminum, copper, zinc, antimony, and bismuth, and these have been the subject of research studies.

Just as for any other chemical hazard, you need to understand the particular risk of toxic metals to your products, and this is likely to be associated with the raw materials, metal equipment, and finished-product packaging. Control can be built in as part of your HACCP system, product and process design, and prerequisite programs.

3.5.7 Nitrites, Nitrates, and N-nitroso Compounds

Nitrogen occurs naturally in the environment and is present in plant foodstuffs. It is also a constituent of many fertilizers, which has increased its presence in soil and water.

Historically, nitrites and nitrates have been added to a number of food products as constituents of their preservation systems. This deliberate addition of nitrite and nitrate to food is closely governed by legislation as high levels of nitrites, nitrates, and *N*-nitroso compounds in food can produce a variety of toxic effects. Specific examples include infantile methemoglobinemia and carcinogenic effects.

N-nitroso compounds can be formed in foods from reactions between nitrites or nitrates and other compounds. They can also be formed in vivo under certain conditions when large amounts of nitrites or nitrates are present in the diet. In common with a number of other chemicals, nitrate can cause additional problems in canned products, where it can cause lacquer breakdown, allowing tin to leach into the product.

The HACCP team must ensure that nitrite and nitrate being added to products do not exceed the legal, safe levels and must give appropriate consideration to the risk of contamination from other sources and other ingredients, giving an increased overall level.

3.5.8 Polychlorinated Biphenyls

Polychlorinated biphenyls (PCBs) are members of a group of organic compounds that have been used in a number of industrial applications. Because these compounds are toxic and environmentally stable, their use has been limited to closed systems and their production has been banned in a number of countries. The most significant source of PCBs in foodstuffs is through absorption from the environment by fish. PCBs then accumulate through the food chain and can be found in high levels in tissues with high lipid content. This issue should be considered by HACCP teams dealing with raw materials of marine origin.

3.5.9 Dioxins and Furans

Neither of these two groups are manufactured directly but they are created as by-products in the processes used to manufacture pesticides, preservatives and disinfectants, and in paper processing. They can also be formed when materials such as plastic, paper, and wood are burned at low temperatures. There are several hundred dioxins and furans, some of which are nontoxic, some only slightly toxic and a small number are amongst the most toxic substances known. Dioxins are ubiquitous environmental contaminants and are generally present in very low concentrations in all foods.

Since the publication of the previous edition of this book, there have been several high profile contamination incidents involving dioxins. These include Belgian animal feed in 1999 resulting in contaminated meat, poultry, and dairy products; Irish pork products in 2008 and German eggs in 2010/2011, both of which were also associated with contaminated animal feed.

3.5.10 Polycyclic Aromatic Hydrocarbons

Polycyclic aromatic hydrocarbons (PAHs) are composed of benzene rings linked together and are the largest class of known environmental carcinogens. They are found in water, air, soil, and food. They originate from coal-derived products, charcoal broiling, engine exhausts, petroleum distillates, smoke curing, and tobacco smoke.

3.5.11 Plasticizers and Packaging Migration

Certain plasticizers and other plastics additives are toxic and are of concern if they are able to migrate into food. Migration depends on the constituents present and also on the type of food, for example, fatty foods promote migration more than some other foodstuffs.

The constituents of food-contact plastics and packaging are normally strictly governed by legislation, along with the maximum permitted migration limits in a number of food models. The HACCP team should be aware of current issues for both food packaging and plastic utensils and should build control into the HACCP and product design systems. This might mean the requirement for checks on migration at the packaging concept stage.

3.5.12 *Veterinary Residues*

Hormones, growth regulators, and antibiotics used in animal treatment can pass into food. Hormones and growth regulators have been banned from food production in many countries, and the use of antibiotics and other medicines are normally tightly controlled. Carry-over of antibiotics can cause major problems due to the potential for serious allergic responses in susceptible individuals. Similarly, hormones and growth regulators can potentially cause health issues when consumed by humans, and it has also been suggested that over use of antibiotics in agriculture can make antibiotics less effective in human disease. The HACCP team should consider the risks of contamination in their raw materials and product so that appropriate control and monitoring can be instigated. This will include control at the primary producer and may also involve monitoring at the incoming raw material stage.

3.5.13 *Melamine and Cyanuric Acid*

Melamine is used in the production of melamine resins, typically by reaction with formaldehyde. It has many industrial uses, including in the production of laminates, glues, adhesives, molding compounds, coatings, and flame retardants (WHO, 2008). Melamine alone is considered to be of low toxicity; however, the melamine analogue, cyanuric acid, has been shown to lead to renal tissue damage, possibly due to crystal formation in the kidneys and subsequent kidney toxicity. Cyanuric acid is found as an impurity in melamine and is also used as an industrial chemical in its own right.

As previously mentioned (Sect. 3.5), melamine and cyanuric acid have been involved in several major food contamination incidents, including contaminated pet food in the USA in 2007, which was caused by use of adulterated wheat flour from China, and contaminated infant formula in China in 2008, which included milk adulterated with melamine and caused the deaths of several infants. In both these incidents the melamine and cyanuric acid were deliberate adulterants as part of food fraud. This underlines the need to understand potential chemical contamination issues and to keep fully up to date with industry news on food/ingredient contamination at all times.

3.5.14 *Chemical Additives*

Additives are used not only to make products safe and hygienic but also to assist processing and to enhance or beautify what would otherwise be bland but nutritious products. They may also be directly beneficial to human health, as in the case of vitamins.

The use of chemical additives is governed by regulation in almost all countries in the world. In Europe, legislation classifies additives according to their purpose (such as preservative, acidulant, or emulsifier) and lays down guidelines and

limitations for their use across various categories of foodstuffs. This, in effect, provides a positive listing of permitted additives. Therefore, if an additive appears in this or other countries' positive legislation, it may be assumed to have undergone appropriate toxicological testing and be deemed, by advisory committees of experts, to be safe. This testing procedure led to the European "E" number system of classification for approved and tested materials and also to the RDA (Recommended Daily Allowance) levels which are set for such materials.

Nevertheless, it is still possible to imagine situations where careless or unnecessary use of additives poses a potential hazard in a foodstuff. Over the last 30 years there have been trends towards more "natural" food products with less additives, often due to consumer pressure. Whilst this can have positive outcomes, it is important to ensure that preservative systems for food safety are still effective after any reformulation and it is also wise to remember that "natural" does not always mean "safer." Many natural plant extracts, for instance, are acutely toxic. Generally, materials can be used only if they are derived from normally consumed foodstuffs. Care must also be taken so that the "natural additive" is not offered in amounts greatly in excess of those encountered in the native foodstuff. Additives may be beneficial, benign, or, if misused, harmful. Great care and understanding must be exercised in their selection and use.

3.6 Control of Chemical Hazards

The majority of the chemical hazards listed above are issues associated with potential contamination in the early stages of the global food supply chain (growing/harvesting) and will, therefore, be raw material hazard issues for many food businesses. This means that control has to be applied further up the supply chain to ensure that materials entering food-processing facilities will be safe. This will normally be controlled through use of SQA procedures, which may be operating within the PRP. There are some exceptions to this rule and any chemicals being used at processing sites, e.g., cleaning chemicals, must be effectively controlled to prevent product contamination. Similarly, storage and handling procedures need to be designed to prevent conditions where further chemical hazards could arise, e.g., effective storage of materials susceptible to mold growth and mycotoxin formation.

At the initial stages of the food supply chain, e.g., growing and harvesting, controls need to be in place to prevent contamination. These will include management procedures for chemicals used routinely in food production, e.g., pesticides/antibiotics, awareness of potential environmental threats and management of crops/animal herds accordingly, good agricultural practices (GAP) during growing, harvesting and storage, and awareness of potential adulteration threats through unscrupulous suppliers. Overall it is important to be aware of potential chemical hazards and to remain vigilant for conditions that may result in hazard presence. Much of this will require confidence in suppliers and a detailed understanding of the complexity of the supply chain.

3.6.1 Summary of Control Options for Chemical Hazards (Table 3.9)

Table 3.9 Examples of practical hazard control options^a—chemical hazards

Hazard	Control measures
All types of chemical hazards	<ul style="list-style-type: none"> • Prerequisite programs/support systems, e.g., SQA,^b GMP/GAP, cleaning, handling, and storage systems • Effective trace and recall procedures
Mycotoxins	<ul style="list-style-type: none"> • SQA control of harvesting and storage to prevent mold growth and mycotoxin formation in cereals, groundnuts, dried fruit • Heat treatment during process to destroy mold and prevent growth in product • Controlled dry storage • Intrinsic factors to reduce a_w to <0.7
Marine toxins	<ul style="list-style-type: none"> • SQA control of harvesting and storage to prevent the presence of dinoflagellate/diatom toxins and to prevent the growth of bacteria resulting in histamine formation.
Cleaning chemicals	<ul style="list-style-type: none"> • Use of nontoxic, food-compatible cleaning compounds • Safe operating practices and written cleaning instructions • Separate storage for cleaning reagents • Covered designated labeled containers for all chemicals
Pesticides, veterinary residues, and plasticizers in packaging	<ul style="list-style-type: none"> • Specification to include suppliers compliance with maximum legal usage levels • Verification of supplier records • Annual surveillance program of selected raw materials
Toxic metals/PCBs/dioxins and furans/PAHs	<ul style="list-style-type: none"> • Specifications and surveillance where appropriate
Nitrates, nitrites, and nitrosamines and other chemical additives	<p>As contaminants:</p> <ul style="list-style-type: none"> • Specifications and surveillance where appropriate <p>As additives:</p> <ul style="list-style-type: none"> • Safe operating practices and written additive instructions • Special storage in covered, designated labeled containers • Validation of levels through usage rates, sampling, and testing
Allergens/food intolerance	<ul style="list-style-type: none"> • Awareness of the potential allergenic properties of certain ingredients. Special consideration given to adequate labeling, production scheduling and cleaning, segregation or cross-contamination controls, rinse water testing, dedicated equipment, and to the control of rework

^aNote: These control options are not necessarily effective on their own and will often be used in combination to control specific hazards. Some of the suggestion options will be more appropriate to prerequisite programs than to inclusion in the HACCP plan

^bNB Supplier Quality Assurance (SQA) procedures should include maximum acceptable levels in specifications. Sampling and visual inspection will supplement control measure

3.7 Physical Hazards

Physical hazards, like biological and chemical hazards, can enter a food product at any stage in its production. There is a huge variety of physical items that can enter food as foreign material, some of which may also be described as microbiological, but only a few of these are hazards to food safety. Here we must ask ourselves very carefully whether or not any potential foreign material items are likely to cause a health risk to the consumer. Only if they are should they be considered in the main HACCP Study (Chap. 6). As part of the wider food safety management system, your terms of reference will include all potential foreign material, whether they are true food safety hazards or not. Whilst it is clearly not good business to have product contaminated with any foreign material, it should be noted that you could be prosecuted in some countries (e.g., the UK) for its presence in a product, regardless of whether or not it is a true safety hazard, but simply because the product is not of the true nature and substance demanded by the consumer. For these reasons, foreign material control will be a major area of focus for prerequisite programs.

It is important to remember that any foreign material item could be a safety hazard if it has the potential to make the consumer choke. This is particularly important in foods that may be consumed by small children, where even pieces of paper sacks or boxes could pose a safety risk. As with microbiological hazards, it should also be noted that any foreign material item could transport microbiological hazards into the product, and this is particularly significant if they gain access after all processing steps that would control these hazards.

Foreign material items are food safety hazards if they fall into one or more of the following categories:

- Items that are sharp and could cause injury
- Items that are hard and could cause dental damage
- Items capable of blocking the airways and causing choking

The main physical food safety hazards are as follows.

3.7.1 *Glass*

Glass fragments can cause cuts to the customer's mouth and could have very serious consequences if swallowed. Smooth pieces of glass, e.g., watch glasses, could also cause injury by choking or could be broken into sharp pieces when the consumer bites into the product.

Glass may be present in the raw materials, e.g., as foreign material from the growing site, or may be the raw material container. Containers made from glass should be avoided wherever possible and should be kept out of the processing area. In addition, personnel should be prevented from bringing any glass items into

production and sight glasses or glass gauges on equipment should be avoided. Glass light fittings should always be sheathed with plastic to prevent product contamination if the light shatters. Most of these issues will be managed under prerequisite programs for the general reduction of broken glass risks throughout the production facility.

It may be that your finished product is filled into glass containers. In this case it is obviously not possible to keep glass out of the production area, but it must be properly managed and you should always have stringent breakage control procedures in place.

Another control mechanism for glass in food products is the use of X-ray detection devices, although these are currently not widely used due to expense and problems in application.

3.7.2 *Metal*

Like glass, metal can enter the product from the raw materials or during production and can cause injury, either due to the shape and nature (sharp pieces), or by causing choking. It is particularly important with this hazard issue that you ensure that your equipment is properly maintained so that parts do not drop into the product and that any likely metal to metal contact is known. All engineering work must be properly managed and parts, e.g., nuts and bolts, must not be left lying around. Where raw materials are delivered in metal containers, these should be opened carefully to minimize swarf contamination. This should be done outside the main production area if possible.

All products should be metal detected and/or passed over a magnet at least once, and this should be at, or as close to, the end of production and filling as possible. Ideally there will be several devices in the product stream to act as a diagnostic in the case of failure, i.e., if metal is detected at the end of the line, knowledge of where it might have entered the process will be invaluable during the investigation.

Where the finished product is held in metal containers, these should be adequately managed and product metal detection should take place immediately before product filling and closure. Metal detectors and magnets should be carefully chosen and calibrated to pick up the smallest pieces of each potential metal type. They are however only detection devices and cannot be expected to remove all potential metal.

3.7.3 *Stones*

Stones are most likely to originate in raw materials of plant origin, where they may be present within the plant, e.g., between leaves, or be picked up during harvesting.

They can cause the consumer dental damage or choking, and sharp stones may cause similar problems to broken glass and metal.

Stones can most easily be prevented by careful choice of raw material supply and can be removed through the use of sieving/filtration, flotation tanks, and centrifugal separators.

3.7.4 Wood

Sharp splinters of wood could be a hazard to the consumer, causing, for example, cuts to the mouth and throat. Pieces of wood could also get stuck in the consumer's throat and cause choking.

Wood can enter the production area and the product in a number of ways. It may be present in raw materials, e.g., in plant material brought in from the fields, or it may be part of the raw material packaging. Wooden crates and pallets should be avoided where possible and must not be allowed into production areas. Where wooden packaging or pallets have to be used, these must be carefully managed and must not be allowed access to production areas where product is exposed.

Ideally all such wood should be contained in separate raw material handling and outer packaging areas and personnel must be prevented from bringing any wooden items into production areas. This should be part of every company's prerequisite programs and should be included in induction training for all staff.

Some products actually contain wood as one of their raw materials. These include ice cream stick bars and traditional fish products such as herring rollmops. Obviously, here it is not possible to keep wood out of the production area, but it should be obtained from an approved source and handled in a controlled manner to prevent any splintering.

If you are operating from an old manufacturing site, it is possible that there is some wood built in to the processing area environment. Here you need to assess the risk of splinters breaking off into the product, but from a general hygiene point of view you should put together a plan for its removal and replacement. The HACCP techniques can be used to help prioritize the essential areas for improvement.

3.7.5 Plastic

Plastic is often used to replace other physical hazards, such as glass and wood, although it should be noted that hard plastic shards, e.g., from broken equipment guards, can also be hazardous. Soft plastic is also used as packaging or for protective clothing such as aprons and gloves. While more shatterproof than

glass, you should implement similar breakage control procedures for hard, brittle plastic as for glass. For soft plastic, handling procedures and staff awareness are important, and soft plastic used during processing is often brightly colored (usually blue) to assist with its identification.

3.7.6 *Pests*

We have already considered pests as causes of biological hazards through the introduction of pathogenic microorganisms into foods. Pests may also be thought of as physical hazards as their presence in foodstuffs may cause injury or choking. Most important here are large insects and parts of rodents or birds. An effective pest control program must be in place to control these hazards on all food production, storage, or preparation premises.

3.7.7 *Intrinsic Material*

Bones in meat/fish products, nut shells, and extraneous vegetable matter would fall into this category. Control options include the use of X-ray detectors. However, this type of equipment can be costly and some industries therefore use careful sorting and inspection to minimize risk.

3.8 Control of Physical Hazards

Many of the physical hazard issues described above can be controlled effectively as part of PRPs at the facility. If you already have these procedures in place properly, then the HACCP study will be able to concentrate on the critical product contamination areas. In some cases, having identified potential hazards, you may be able to “design them out,” for example, by changes to the building or equipment. Care should be taken here, however, to ensure that the hazards are fully controlled by any design changes before they are dropped from consideration in the hazard analysis and of course that the effectiveness of the prerequisite systems is fully verified (see Chap. 4).

3.8.1 Summary of Control Options for Physical Hazards (Table 3.10)

Table 3.10 Examples of practical hazard control options^a—physical hazards

Hazard	Control measures
All types of physical hazards (including intrinsic to the product, i.e., fruit stalks, stones, nut shells)	<ul style="list-style-type: none"> • Prerequisite programs/support systems, e.g., Supplier QA, cleaning • Effective trace and recall procedures • Detection systems, e.g., vision sorters, X-ray
Specific extrinsic physical cross-contaminants, e.g.,	
Glass	<ul style="list-style-type: none"> • Elimination of all glass except lighting which must be covered—light breakage procedure • Glass-packed products—glass breakage procedures, inversion/washing/blowing of glass packaging before use
Wood	<ul style="list-style-type: none"> • Exclusion of all wooden materials such as pallets, brushes, pencils, tools from exposed product areas • Segregation of all packaging materials
Metal	<ul style="list-style-type: none"> • Equipment design—preventative maintenance • Avoidance of all loose metal items—jewelry, drawing pins, nuts and bolts, small tools • Metal detection—sensitivity appropriate for the product, calibrated (3-monthly) and checked (hourly), ferrous, nonferrous, and stainless; fail-safe divert systems; locked reject cages; traceability
Plastic	<ul style="list-style-type: none"> • Avoidance of all loose plastic items—pen tops, buttons on overalls, jewelry • Breakage procedures in place where hard brittle plastic is used
Pests	<ul style="list-style-type: none"> • Pest control program: <ol style="list-style-type: none"> (i) Prevention, e.g., facility design, avoidance of harborage areas, waste management, ultrasonic repellents (ii) Screening/prooing, e.g., strip curtains, drain covers, mesh on windows, air curtains, netting (iii) Extermination, e.g., electric fly killers, poisoning, bait boxes, traps, perimeter spraying, fogging
Building fabric	<ul style="list-style-type: none"> • Design and maintenance

^aNote: These control options are not necessarily effective on their own and will often be used in combination to control specific hazards. Some of the suggestion options will be more appropriate to prerequisite programs than to inclusion in the HACCP plan

3.9 Radiological Hazards

This is specifically included within the FSMA in the USA where it is required that radiological hazards be considered during hazard analysis alongside the more usual biological, chemical, and physical hazard categories. You should assess your raw materials in terms of whether any are been sourced from regions where an environmental radiological event recently occurred. Search literature and involve your suppliers for assurance of safe levels as a control measure.

3.10 Conclusions

Food safety hazards are a diverse and widespread group of factors which may cause food to be unsafe for consumption. Where relevant to a food process, products, ingredients, or food facilities, significant food safety hazards must be controlled by effectively designed and adequate control measures that are fully implemented in practice. This may be through CCPs within the HACCP plan or prerequisite programs applied at various stages of the food supply chain.

Appropriate knowledge, experience, and awareness needs to be maintained within food companies; within HACCP teams, product development teams, and SQA personnel. It is unlikely that any one person will have sufficient knowledge of all likely hazard types in a given food operation so effective hazard identification, analysis, and control relies on a team effort and may require bringing in specialist expertise where relevant. All businesses need to remain vigilant and to employ methods of information update and horizon scanning to ensure that new or unanticipated threats can be dealt with swiftly.

3.11 Key Points Summary

- Hazards are biological, chemical, or physical agents in food or conditions of food, with the potential to cause an adverse health effect.
- Significant hazards are those 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). These are identified by considering likelihood of occurrence and severity of outcome should the hazard be present in food.
- It is important to understand the source or cause of the hazard in the ingredients, the process, or the facility in order to determine appropriate control measures. The same hazard arising in different places might need different control measures.
- A range of control measure options are available for biological, chemical, and physical hazards. These should be chosen according to their proven

effectiveness and, in some cases, several control measures may be needed to give security of control systems.

- Where HACCP teams do not have expertise of a particular group of hazards that may be important to the facility and its products, appropriate expertise should be sought so that decisions are based on adequate knowledge and expert, risk-based judgment.

Chapter 4

Prerequisites for Food Safety: PRPs and Operational PRPs

This is not a book that claims to describe the detail of prerequisite programs (PRPs) but we do need to look at the essential role of PRPs in the context of supporting HACCP for effective food safety management. It is important to understand that hazard analysis must consider **how** hazards are managed (by CCPs or PRPs) and that there is a need to understand both the product **and** the production environment in order to do this.

PRPs are just as important as HACCP when it comes to assurance of safe food. A simple way to think about the relationship is that HACCP focuses on raw materials, the product, and the manufacturing process, whilst PRPs tend to focus on the hygienic operating environment and QA support programs (Fig. 4.1) managed by people who are knowledgeable and exhibit a supportive attitude towards food safety. The term prerequisite programs (PRPs) is used to describe the foundational elements for food safety. Whilst the term is relatively new compared to HACCP, the understanding that a hygienic operating environment is needed for food safety has been in place for many years. The thinking that continues to evolve is how essential PRPs are in **preventing** food safety issues, for example, in managing post-process contamination after a pathogen reduction step. In this chapter we will explore contemporary thinking on PRPs along with a discussion of the current status and use of Operational PRPs.

4.1 Definitions and Standards

Thanks to Codex (2009b), there is a global HACCP standard, universally accepted definitions, and broad understanding of what the seven principles require. Whilst there is still much room to improve in terms of implementation, we do see consistency of HACCP principle application, e.g., in having a process flow diagram and a HACCP plan, in monitoring, and record keeping. It is the quality, particularly in the technical content and the level of documentation, that still varies considerably. There are a number of possible reasons for this; key factors being confusion

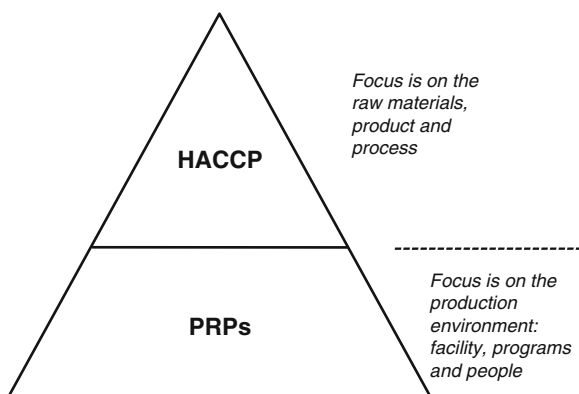


Fig. 4.1 The relationship between HACCP and PRPs (Warren 2012)

regarding PRPs and the relationship with HACCP, and regulatory HACCP where agencies dictate how HACCP systems must be written.

4.1.1 Definitions

Unlike other aspects of food safety where one or two definitions may be in place, a number of definitions have been proposed for PRPs. The Canadian Food Inspection Agency (CFIA, 1998) suggests

“universal steps or procedures that control the operational conditions within a food establishment allowing for environmental conditions that are favorable for the production of safe food.”

The US National Advisory Committee on Microbiological Criteria for Foods (NACMCF, 1997) defines PRPs as

“procedures including good manufacturing practices that address operational conditions providing the foundation for the HACCP system.”

The World Health Organization (WHO, 1998) has also published a definition for PRPs:

“Practices and conditions needed prior to and during the implementation of HACCP and which are essential for food safety.”

WHO mentions that these are described in Codex Alimentarius Commission’s General Principles of Food Hygiene and other Codes of Practice.

Many practitioners consider that the Codex International Code of Practice General Principles of Food Hygiene (2009a) is the reference standard for PRPs. In fact, the guidelines for the application of HACCP systems (Codex, 2009b) state that *“Prior to the application of HACCP to any sector of the food chain, that sector should be operating according to these general principles along with appropriate*



Fig. 4.2 The HACCP support network

Codex Codes of Practice and appropriate food safety legislation.” In other words, these are seen as pre-requirements or prerequisites to HACCP.

When thinking about the foundation of HACCP, traditionally we have tended to think of the good manufacturing practices (GMPs) that need to be in place in any food company in order to ensure wholesome food. This is not a new concept, it has been well understood by responsible food manufacturers for many years and has required the formalization of PRPs as the foundation for HACCP, thus ensuring that HACCP is focused on the real CCPs that are essential for the control of significant hazards.

In the second edition of this book we described PRPs as the “HACCP Support Network” and identified a number of programs for important HACCP support (Fig. 4.2).

Most of the systems in the HACCP Support Network are considered PRP elements, as they are all required to some extent for HACCP to function effectively as a part of an overall food safety program. In a manufacturing operation, it is unlikely that a HACCP system could be implemented effectively in the absence of these other management systems. In a very small business, e.g., takeaway sandwich bar, these additional systems would probably be fewer and might include Good Hygiene Practice and use of reputable suppliers. The name *prerequisite* applies

because these systems are normally in place *before* the HACCP plan is developed. Since the previous edition was published these support systems have become more formally identified as PRPs and their essential role in food safety control has become better understood.

4.1.2 Standards and Guidelines

In listing typical expectations we will start with the requirements¹ found in the Codex general principles of Food Hygiene (2009a) which is the principle reference document.

We will consider some of the detailed requirements later but in summary the (Codex, 2009a) guidelines cover the following (Table 4.1).

Table 4.1 Summary of codex prerequisite program guidelines (Codex, 2009a)

Codex Heading	PRP Topics	Elements to be considered are:-
Primary production	<i>Environmental hygiene</i>	• Requires that any potential food safety contaminants that could arise from the environment are managed.
	<i>Hygienic production of food sources</i>	• Includes prevention of cross-contamination from soil, air, water, pesticides, veterinary drugs, etc. also protection from fecal and other contamination.
	<i>Handling, storage, and transport (includes temperature and damage control)</i>	• Anything needed to protect the foodstuffs from contamination or deterioration.
	<i>Cleaning, maintenance, and personnel hygiene</i>	• Refers to the need to have, at primary production, procedures and controls in order to maintain these elements.
Food processing establishment: design and facilities	<i>Location</i>	• The need to assess the likely contamination from, for example, industrial pollution, pest infestation, flooding and waste removal.
	<i>Premises and rooms</i>	• Design and layout to avoid cross-contamination.

(continued)

¹The Codex document can be downloaded free of charge from the Internet to see the full requirements (www.fao.org).

Table 4.1 (continued)

Codex Heading	PRP Topics	Elements to be considered are:-
	<i>Equipment</i>	<ul style="list-style-type: none"> • Sanitary design of the internal structures and fittings, e.g., use of impervious materials, smooth cleanable surfaces, and floors that allow adequate drainage. • Overhead fittings that are cleanable and minimize build-up of dirt and condensation. • It shall be adequately maintained • It shall be of sanitary design, i.e., cleanable and easily inspected. • Food control and monitoring equipment should be capable and fit for the purpose. • Waste and control of chemicals—clearly identified and controlled to prevent cross-contamination.
	<i>Facilities</i>	<ul style="list-style-type: none"> • Water supply shall be potable at point of use. • Drainage and waste disposal shall be considered. • Cleaning shall be effective to avoid cross-contamination. • Temperature control of storage facilities or production environment as needed. • Air quality and ventilation—to minimize airborne contaminants and humidity. • Lighting—to be able to see properly for hygiene and designed to avoid physical cross-contamination. • Storage—to avoid pest access, cleanable, separated from non-food items such as cleaning chemicals and lubricants.
Control of Operation The rationale in Codex (2009a) for this is to “reduce the risk of unsafe food by taking preventative measures to assure the safety and suitability of food at an appropriate stage in the operation by controlling food hazards.”	<i>Control of food hazards</i> <i>Key aspects of hygiene control systems</i>	<ul style="list-style-type: none"> • Here Codex references use of HACCP by the food business operator including the need to ensure that there is a system for change control. • Time and temperature control (one of the most common causes of foodborne illness and food spoilage).

(continued)

Table 4.1 (continued)

Codex Heading	PRP Topics	Elements to be considered are:-
		<p>Requirements need to take account of the nature of the food product, how it is packed, the shelf life, and consumer usage.</p> <ul style="list-style-type: none"> • Temperature recording devices need to be accurate. • Specific process steps (especially microbiological kill or control steps), e.g., chilling, drying, and heat treating. • Microbiological and other specifications which are based on sound scientific principles. • Avoidance of microbiological physical and chemical cross-contamination. This is not specifically mentioned by Codex but this would naturally include avoidance of allergen cross-contamination as unwanted chemicals.
	<i>Incoming material requirements</i>	<ul style="list-style-type: none"> • Control of ingredients through supplier control and incoming inspection. • Packaging (to protect the product and for proper labeling).
	<i>Packaging</i>	<ul style="list-style-type: none"> • Ensuring that the design will provide the necessary protection during distribution and through shelf life.
	<i>Water</i>	<ul style="list-style-type: none"> • Use potable water unless there are no risks associated with not doing so.
	<i>Management and supervision</i>	<ul style="list-style-type: none"> • Includes a note that managers and supervisors should have sufficient knowledge of food hygiene principles and practices to be able to judge potential risks, etc.
	<i>Documentation and records</i>	<ul style="list-style-type: none"> • As necessary and as appropriate.
	<i>Recall procedures</i>	<ul style="list-style-type: none"> • In case everything goes wrong!
Establishment: Maintenance and Sanitation	<i>Maintenance and cleaning</i>	<ul style="list-style-type: none"> • Having procedures and methods. • Includes the cleaning of the cleaning equipment and drains.

(continued)

Table 4.1 (continued)

Codex Heading	PRP Topics	Elements to be considered are:-
Establishment: Personal Hygiene	<i>Cleaning programs</i>	<ul style="list-style-type: none"> • Methods and frequency. • Validation and verification of effectiveness of systems.
	<i>Pest control systems</i>	<ul style="list-style-type: none"> • Prevention through access control, avoidance of harborage, and infestation though having a clean environment (with no available food sources). • Monitoring, detection, and eradication systems.
	<i>Waste management</i>	<ul style="list-style-type: none"> • Safe removal and storage. • Avoidance of cross-contamination or harborage of pests.
	<i>Monitoring effectiveness</i>	<ul style="list-style-type: none"> • Verification on a periodic basis to ensure that the programs are working. • Use of audit, inspection, and tools such as environmental (microbiological) monitoring.
	<i>Health status (of employees)</i>	<ul style="list-style-type: none"> • This is important to understand whether individuals might be carriers of disease that can be transmitted through food.
	<i>Illness and injuries</i>	<ul style="list-style-type: none"> • Reporting of infectious diseases. • Exclusion from food handling duties.
	<i>Personal cleanliness</i>	<ul style="list-style-type: none"> • Including hand washing, appropriately controlled protective clothing, and footwear.
	<i>Personal behavior</i>	<ul style="list-style-type: none"> • Spitting, coughing, or sneezing over food is considered inappropriate behavior. • Personal effects such as jewelry, cell phones, etc. should be prohibited in food handling areas.
	<i>Visitors</i>	<ul style="list-style-type: none"> • Should be adequately supervised and required to follow the same standards as employees.
Transportation	<i>General</i>	<ul style="list-style-type: none"> • Protection against sources of contamination and damage. • Control of the environment, e.g., temperature.

(continued)

Table 4.1 (continued)

Codex Heading	<i>PRP Topics</i>	<i>Elements to be considered are:-</i>
Product Information and Consumer Awareness	<i>Requirements</i>	<ul style="list-style-type: none"> • Design of containers and conveyances such that food safety is protected.
	<i>Use and maintenance</i>	<ul style="list-style-type: none"> • Includes cleaning and disinfection between loads. • Dedicated for food use where appropriate. • Use of temperature control devices.
	<i>Lot identification</i>	<ul style="list-style-type: none"> • To enable efficient and effective product recall. • For stock rotation purposes.
	<i>Product information and labeling</i>	<ul style="list-style-type: none"> • For allergens, preparation, or cooking instructions and storage requirements. • Straightforward language to ensure that the next person in the food chain (e.g., the consumer) understands.
	<i>Consumer education</i>	<ul style="list-style-type: none"> • Must be able to understand, for example, about the importance of avoiding cross-contamination and the importance of time/temperature control in controlling foodborne illness
Training	<i>Awareness and responsibilities</i>	<ul style="list-style-type: none"> • All personnel should be aware of their role in protecting food from contamination and deterioration.
	<i>Training programs</i>	<ul style="list-style-type: none"> • The level of training should take account of the risk profile of the food, i.e., how critical is hygienic behavior.
	<i>Instruction and supervision</i>	<ul style="list-style-type: none"> • A reminder that managers and supervisors need a greater level of knowledge. Also that training should be assessed for effectiveness.
	<i>Refresher training</i>	<ul style="list-style-type: none"> • Don't train just once!

Based on the Codex listing (Table 4.1) it might be easy to think that PRPs are straightforward to standardize and, given that they are best practice requirements, easy to write down and follow. However, standards of implementation and what appear to be acceptable PRP practices for food manufacturers varies enormously around the world.

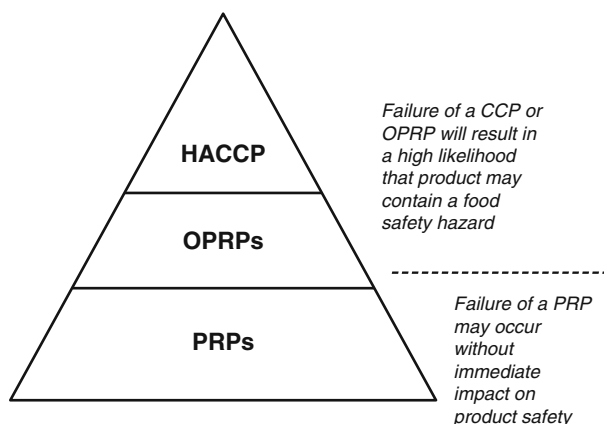


Fig. 4.3 The relationship between HACCP, OPRPs, and PRPs (Warren 2012)

As the Global Food Safety Initiative (GFSI) continues to be used this variability in standards of application may decrease and the exciting point about this is that best practices will, hopefully, be built into the global standards, thus raising the operating standards everywhere.

Before leaving definitions and standards it is important to mention a further definition in the PRP area. More recently, the term Operational PRP (OPRP) has been introduced within ISO22000; 2005 (ISO, 2005) but is not part of Codex HACCP (Codex, 2009b). The OPRP definition is actually similar to the WHO definition for PRPs.

“Operational PRP: a PRP defined 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 or in the processing environment” (ISO, 2005)

The difference between this and the WHO definition is the reference to control of food safety **hazards** which is more specific. We will discuss this in more detail in Chap. 6 but the approach is quite helpful in that it requires the team to call out those PRP activities that are essential for food safety (Fig. 4.3). Whilst all food operations need to be hygienic the programs that are determined to be OPRPs will be identified through the hazard analysis process and will be specific to the product being produced. What this means is that the OPRPs are working alongside CCPs to assist in the management of the significant hazards. Used in this way, OPRPs become a formal part of the overall HACCP and food safety management program and need to be managed in a similar manner to CCPs. There is considerable discussion and debate about whether OPRPs are helpful or whether they cause confusion. It is still early days, but some companies find the higher level of control associated with OPRPs to be useful in communicating hazard management requirements to employees. It is for you to decide whether this is a helpful approach in your organization and whether to adopt the use or not.

4.2 Environment, Programs, and People

We said earlier that this was not a book that would describe PRPs in detail. Having summarized the Codex general hygiene principles in the previous section, let's next look at how these might be organized on a practical basis in your facility and consider their role as preventive control measures.

It is unlikely that any two companies would have identical PRPs, but this isn't rocket science and, in general, PRPs will be very similar in their requirements though often arranged to suit the particular company or plant specific needs.

4.2.1 *Environmental Focus: Design for Good Hygiene*

As companies focus on their prerequisite **programs**, the design aspect of preventive controls can sometimes be overlooked in favor of time spent on programs and procedures, and yet it is a key issue for assurance of product safety, i.e., in preventing the risk of cross-contamination from occurring during the process from the internal factory environment and activities.

Cross-contamination can arise from a wide range of sources and the inherent risks in a particular processing area must be understood. Most of these issues are managed through adherence to good hygiene practices (GHP) or often just referred to as good manufacturing practices (GMPs). Some of the main sources of potential cross-contamination are as follows:

(a) Facility Design

The facility layout should be considered carefully. It must minimize the risk of product cross-contamination as this is often a root cause of failure. The layout should include adequate segregation of raw materials and finished products. Depending on the type of product, full segregation between raw and ready to eat product may be required, and in most facilities the outer packaging activities, both for raw materials and finished products, will need to be kept separate from the main processing area. If you do not have the standards you require already in place, then a facility upgrade and/or segregation will need to be timetabled into your Project Plan for HACCP development and implementation (see Chap. 2).

Availability of the required services and facilities for manufacture of the product should also be considered. This will include the availability of potable water and adequate cleaning facilities for plant, equipment, and environment.

The number of holding stages within processes and processing areas should also be considered as it is important that there is both adequate space for holding the required amount of work in-progress product at each stage without causing a cross-contamination risk and that the appropriate temperature control is available.

The patterns of movement of staff and equipment should also be evaluated by the team, including the provision of adequate hygiene facilities, such as changing rest rooms and hand-wash stations, along with cafeteria and recreational facilities.

Many companies divide their facility into GMP areas or zones. GMP Area 1 being the area where “high risk” ready to eat product is exposed (with no further kill step), i.e., the highest level of hygiene control, and GMP Area 4 being the lowest product risk area, usually warehousing and loading bays.

Environmental management is essential for microbiological food safety in instances where cross-contamination of the product (typically at the post-process ready to consume stage) is a concern. The HACCP team really needs to understand this as they work through Principle 1 of the HACCP study. To more clearly understand the likely vectors of cross-contamination, many companies map out their plant (the pest control companies often provide a one page schematic which can be a good template if you don’t have one). The plant can be divided up into the various risk areas and could be color coded for visual communication. The team can then discuss movement of raw materials, equipment, people, and utilities through the plant. A simple example of this approach is provided (Fig. 4.4). The map is divided up to clearly indicate the various areas of the plant and the level of hygiene control needed. A very good reference document has been prepared for Salmonella Control in Low-Moisture Foods (GMA, 2009) and can be downloaded free of charge from the Grocery Manufacturers of America Web site (www.gmaonline.org). Also see the ILSI Europe publication on *Persistence and Survival of Pathogens in Dry Foods and Dry Food Processing Environments* (ILSI Europe, 2011).

Food handlers and other personnel with access to the high control food process area could cross-contaminate the product with microbiological, chemical, or physical hazards if control measures are not in place. Typically this will include restricted entry, positive pressure filtered air, dedicated uniforms, and shoes that are captive to the high control area, maintenance and cleaning tools that are dedicated and captive, and procedures to ensure that anything (ingredients, packaging) entering the area is clean and sanitary. Transition between areas is important but especially in going in and out of the high control (Area 1) area. Hygiene junctures which incorporate a bench barrier for foot traffic control can be effective if properly designed. GMA (2009) recommends that hand-wash stations in dry process facilities be located on the non-critical side of the bench barrier hygiene juncture and that two sets of open shelves are provided for clean captive and “dirty” general plant shoes. Many European models show the hand-wash facilities to be on the clean side of the bench barrier (Fig. 4.5). For a wet process operation this is probably best practice but for a dry process, keeping water out is essential as a preventative control for microbiological hazard proliferation.

The process layout and traffic patterns should be considered in order to minimize the likelihood of cross-contamination, and appropriate training programs and clear signage will need to be in place. Microorganisms will move around a facility but they need vectors to transport them (Chap. 3 and 6). These can be carried through the air via dust, aerosols, and water/waste, or on contact surfaces—feet, hands, clothing, tools, and equipment. As a HACCP team, it is important to spend time in the process environment observing what goes on and thinking about sources and vectors of contamination.

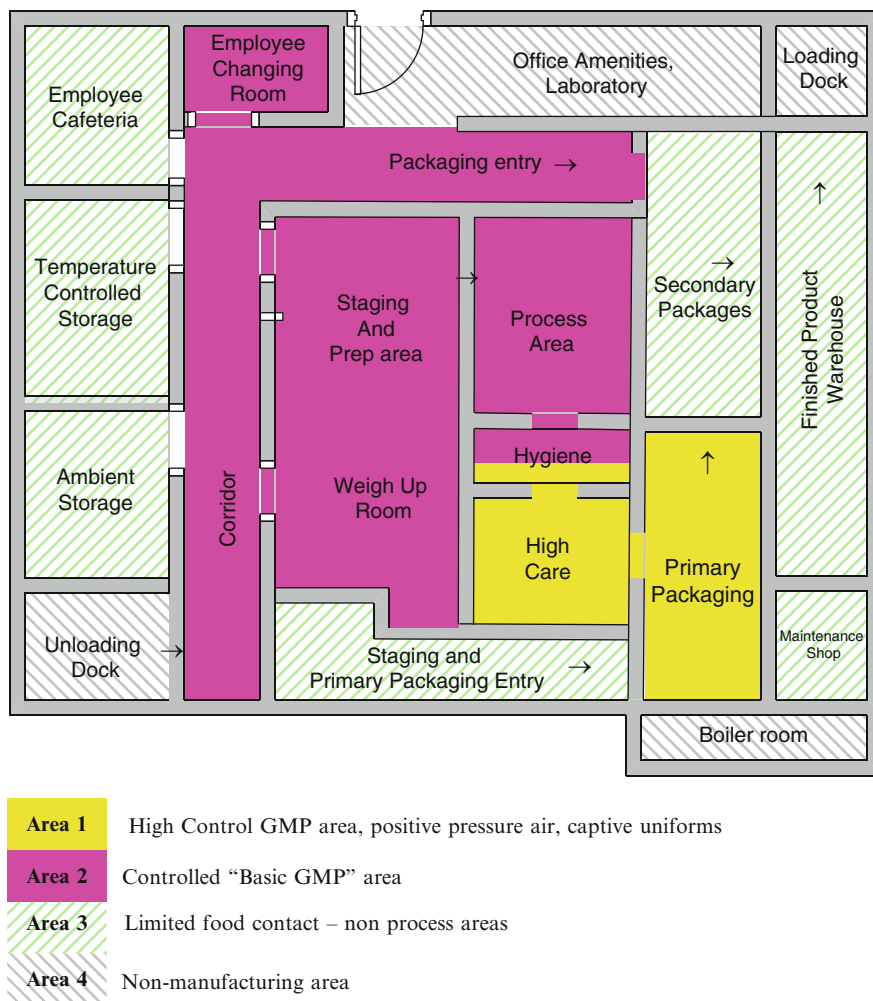


Fig. 4.4 Plant “GMP” area map: simplified example. The *arrows* indicate the direction of flow where doors are not shown on the diagrams

In terms of personnel hygiene, you will need to look at the types of protective clothing required, along with frequency of changing and laundering procedures. Here, consider whether uniforms receive a heat kill step, how cross-contamination is managed at the laundry and in transportation back to the plant. In conducting an evaluation of the effectiveness of your current control measures, you will have to consider the design of employee locker rooms and changing facilities, hygiene amenities and hand-wash stations as part of the building layout, and double check whether you have made sufficient provision. Movement between areas, particularly as you move from area 4 to 3 to 2 and then 1 will require increasingly stringent

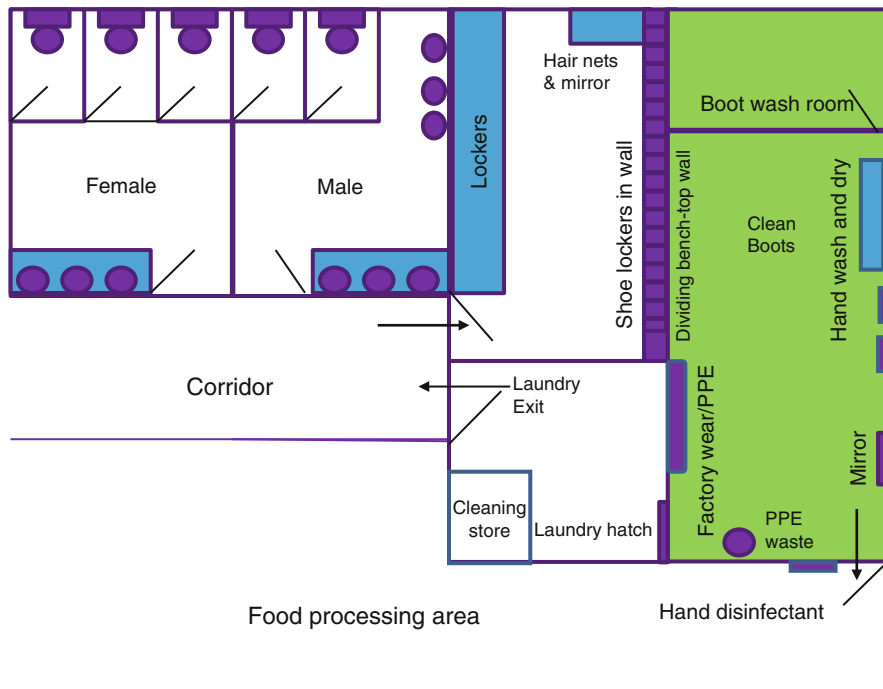


Fig. 4.5 Example hygiene juncture for entry/exit of high control zones (adapted from Holah, Campden BRI)

control. For high food safety risk (typically ready to eat) products, area 1 will require maximum hygiene control.

The fabric of the building itself could be a source of contamination and pose a safety risk to the product, through harborage of pests and other contamination or through physical contamination due to poor design and maintenance. Surfaces should be non-porous and easy to keep clean, with all cracks filled and sealed. Overhead services should be kept to a minimum and ventilation designed to minimize condensation. Windows, doors, and other openings should be screened. All buildings should be well maintained to prevent ingress of water from outside and physical hazards falling into the product. Drains should be designed and serviced so that the flow is always away from production areas, with no likelihood of back flow or seepage and they should be trapped and covered.

Essentially, PRPs need to be such that they **prevent** the product being contaminated from the environment, particularly with regard to microbiological contamination. Kornacki (2009) suggests factors to consider which may be helpful:

- How close might any microbial sources in the form of growth niches or harborage points be to the product stream?
- How many niches or harborage points might there be in the plant?

- How do the niche and harborage areas get cleaned and how large a microbial population might there be? Here you need to think about what microorganisms need to grow—time, temperature, food source, and moisture.
- How much do the niches and harborage points get disrupted during the normal process. Here you need to think about use of compressed air or water for cleaning which could be vectors for the disturbed microorganisms.

You must also have knowledge of the area surrounding the plant. The external area should be maintained in good order, vegetation kept short or not permitted, and you should ensure good drainage on hard paved areas to avoid standing water. There should also be knowledge of neighboring properties and activities, e.g., farms where the wind may blow unwanted microorganisms on dust particles toward your plant.

(b) Equipment

A basic principle of hygienically designed equipment means that:

- Surfaces should be smooth, accessible, and self-draining if wet cleaned.
- Made of materials compatible with what it's going to be in contact with—both the product and the cleaning chemicals.
- Easy to access for cleaning, inspection, and maintenance.
- Fit for purpose, i.e., being used for what it was designed to do. In reality many companies adapt existing equipment to run a new product or process and incur additional food safety risks as a result.

If equipment has any dead-end areas, is difficult to clean or is poorly cleaned, microbiological build-up could contaminate the product or allergen cross over could be a concern. Chemical contamination could arise through lubricants or cleaning residues remaining on the equipment food-contact surfaces. Parts of the equipment could break off and gain entry to the product as physical hazards. Remember also to ensure that you are able to clean around and under equipment. If it is too close to the floor to be able to clean and inspect then the equipment should be sealed around the base.

You will also need to consider what the equipment is made of. For example, is it stainless steel or is it mild steel which may corrode leaving a surface prone to providing a microbiological growth niche which may lead to cross-contamination? Is it painted and could your product be at risk from paint flakes? Does it have any wooden parts, bristle attachments or another difficult component that cannot be effectively cleaned?

The framework must not favor development of microbial growth niches or harborage points, e.g., it must not have hollow components, also nuts and bolts (which are not smooth) must be minimized or continuously welded to the surface.

(c) Utilities

Utilities are an important part of the operating environment. Water (as well as ice and steam) must be potable and where used as an ingredient must meet all relevant

microbiological and chemical requirements. If there is non-potable water on site it must not be possible for it to mix with or be confused with the potable supply.

Air for product contact must be suitably filtered as should any gases used in processing. Boiler chemicals and lubricants shall be suitable for food processing use and kept secure when not needed.

(d) Lighting

Lighting is often underestimated in importance. If lighting is inadequate then operators will neither be able to inspect product/raw materials nor see when the plant and equipment is dirty (or clean). There are published guidelines on Lux values but basically lighting must be suitable for the plant to operate hygienically. Lights must be shielded to protect the product and environment in the event of breakage.

(e) Storage and Distribution

Storage areas must be properly planned to minimize damage and cross-contamination concerns. Consider whether you have adequate segregation, e.g., between raw and finished products, temperature and humidity control. Ensure that all storage areas are properly pest proofed. All raw materials must be stored off the floor and in sealed bags or containers. Part-used containers must be resealed after each use, and strict stock rotation (first in first out—FIFO) should be employed.

Where proper temperature control is necessary for food safety and quality, formal temperature recording and documentation will be required. There are regulatory guidelines for storage and distribution temperatures in some countries. Usually these are more stringent than what would be needed for product safety though standards (and opinions) vary, particularly with respect to chilled storage and distribution temperatures.

Specific storage areas must be provided for any chemicals that are required for use in the manufacturing area such as those used for cleaning. Separate and segregated areas will be needed for storage of waste materials which is designed to prevent the risk of product contamination. All chemicals and waste must be properly labeled and must not be decanted and stored in food containers. Separate and secure storage areas should be established for potentially hazardous non-conforming product and ingredients, for example, any product that tests presumptive or confirmed positive for pathogens.

With regard to distribution vehicles, they must be clean and sanitary/hygienic. This is especially important if you are receiving or shipping in bulk. For some categories of foods there are stringent regulatory guidelines, for example, in the case of ruminant feeds in the USA (21 CFR 589.2000). Here procedures are required to establish what was shipped in the bulk container ahead of your load. This will usually require documentation as evidence of compliance.

Much of what we have described thus far can be classed as **Sanitary (or Hygienic) Design** and these often critically important principles should be built into the company's capital projects process as **key preventative controls** (Porter, 2011).

In summary, the importance of Sanitary Design of the facility and equipment cannot be stressed enough. They must be designed (and managed) in a manner which enables them to:

- Be maintained in a clean condition and in a good state of repair such that they are not a source of contamination through build-up of soil, condensation, mold, or pathogenic bacteria.
- Avoid cross-contamination of products through the ability to control vectors such as those arising via employee traffic patterns and air flow. When a food business has both raw and cooked ready to eat microbiologically sensitive products on site this is critical. Raw ingredients and raw products must be separated from ready to eat products.
- Provide adequate facilities to enable effective cleaning activities, ideally a separate cleaning room with proper segregation between unclean and cleaned equipment such that cross-contamination is prevented.
- Operate utilities such that they are not a source or vector of cross-contamination, e.g., water and air supplies.

4.2.2 Programs

Many PRPs are systems in their own right and require many of the elements of a Quality Management system in order to operate them efficiently and effectively. We'll take a brief look at those that are usually included as HACCP PRPs.

(a) Supplier Quality Assurance

One of the key areas for initial focus alongside HACCP development is raw material safety. We must understand the hazards associated with our raw materials if we are going to make a safe product. It is particularly important to know that the supplier is controlling hazards if these cannot be controlled in our process or by consumer action. For these reasons, an effective Supplier Quality Assurance (SQA) system is one of the most important PRPs. Many industry failures (Chap. 1) are the result of a single supplier failure that carried through into many other companies' finished products.

There are a number of different elements to an effective SQA program, including having agreed specifications, auditing suppliers, and certificates of analysis. Supplier approval will depend on having confidence in the supplier's operation; that the supplier is competent at identifying and managing the hazards. It is therefore vital to develop good customer/supplier relationships—partners in the management of safe raw materials and products.

1. Raw material risk evaluation

Most companies will be purchasing a large number of raw materials and might also have some of their products produced by a contract manufacturer. It is important to be able to prioritize where to spend your time and a risk evaluation of the raw materials is an excellent use of the HACCP approach. Later (in Chap. 6) we will see an example of a raw material decision tree that can be used to help with this activity. It requires that you consider whether the raw material will undergo a hazard reduction step during your process or whether it needs to be safe when it enters your facility.

Suppliers should be asked for a description of how the raw material is processed, a Process Flow Diagram, and a site (GMP) plan. If they are also willing to supply a copy of their hazard analysis and HACCP plan it will be a real benefit but not all companies will do that. Any such information will be really helpful to the HACCP team in ensuring that they have fully identified all hazards of concern in the raw material and can determine which of the raw materials are the highest priority for on site assessment. These documents can be used to draw up a checklist of questions before the supplier audit. If your supplier is unwilling to provide detailed processing information, perhaps for reasons of confidentiality, then you must be able to assure yourself that the raw material is safe by some other means. This may be through an understanding of the raw material's critical intrinsic factors, research of past failures in the industry, good reference materials, e.g., *Microorganisms in Foods 8: Use of Data for assuring Process Control and Product Acceptance* (ICMSF, 2010), along with the structured audit of the supplier's operation.

2. Specifications

It is important that all raw materials are purchased from approved suppliers and to an accurate and up-to-date agreed specification. The specification is the cornerstone of your SQA system, detailing all the accepted criteria against which raw material quality and safety are measured. It should define clearly all the factors that you consider important to the raw material and should include limits or tolerance of acceptability/unacceptability. The document can be as lengthy or as concise as you wish, but should always include your minimum acceptance criteria.

A typical raw material specification would include the following (these issues will also need to be addressed if you are buying in a finished product):

- Details of supplier and manufacturing/supply location, i.e., not simply the head office or broker that the order is placed with. This detail may not be included if you are buying against your own specification on the open commodity market.
- A description of the raw material and its functionality.
- An ingredients list (to enable allergen assessment).
- Details of all intrinsic factors with tolerance limits, e.g., a_w , pH, salt, preservatives.
- Microbiological, chemical, or physical acceptance criteria, e.g., absence of identified hazard organisms in a specified sample size.
- Analytical and microbiological sampling plans.
- Labeling requirements.
- Storage and distribution conditions.
- Safe handling and use instructions.
- Description of pack type, size, and quantity.

3. Supplier auditing

Supplier auditing is one of the key functions in any SQA system, as it is only through on site audits that real confidence can be gained in the supplier's operation. Before auditing a supplier there are a number of questions you will want to ask.

Table 4.2 Supplier quality assurance pre-audit survey example

Iced-Delights: Supplier pre-audit survey

Company Name:

Address:

Key contacts and ownership details, number of employees, and annual turnover:

1. Production location: (for product/raw material to be purchased)

2. History: how long has the business been in operation?

3. Describe the organizational structure and where Quality fits in.

4. Building and Facilities: When was it built? Was it designed for food manufacture?

5. What other products are manufactured at the facility?

6. What allergens are used on site?

7. Is the manufacturing site certified to a formal food safety and quality system (e.g., a GFSI recognized scheme, ISO22000, ISO 9000)?

8. Does the company operate a formal HACCP system?

9. Is microbiological testing carried out on site, and does this include pathogen testing?

10. Is a third-party contract laboratory used and is it certified?

11. Does the manufacturing site use a pest control contractor? If not, what control procedures are in place?

12. Does the site operate a captive uniform policy and how are the uniforms laundered?

13. Are all raw materials and finished products stored on site or are off-site warehouses used?

14. Are complete, accurate specifications available for all ingredients, packaging, and finished products?

15. How is supplier quality assured?

16. Are written work procedures available?

17. Is there a training (hygiene related) program in place?

18. How are distribution vehicles monitored for food suitability?

19. What food regulations are considered applicable to the company’s operations?

20. Have there been any product recalls from this site or any other owned by the company?

Date completed : -----

Signature: -----

Table 4.2 provides an example of the type of pre-audit survey that might be sent to suppliers, but this list is by no means exhaustive. This information will also be important for low-risk raw materials when you do not intend to audit the supplier.

When you have constructed a program of auditing requirements, it is important to think about how audits will be carried out (Fig. 4.6). Do you, for example, have personnel who can carry out audits and are they trained and authorized appropriately? The SQA audit is critical to the safety and quality of your products and ultimately your brand reputation, so it is vital that it is carried out by competent personnel who can evaluate food safety controls and build a trusting relationship

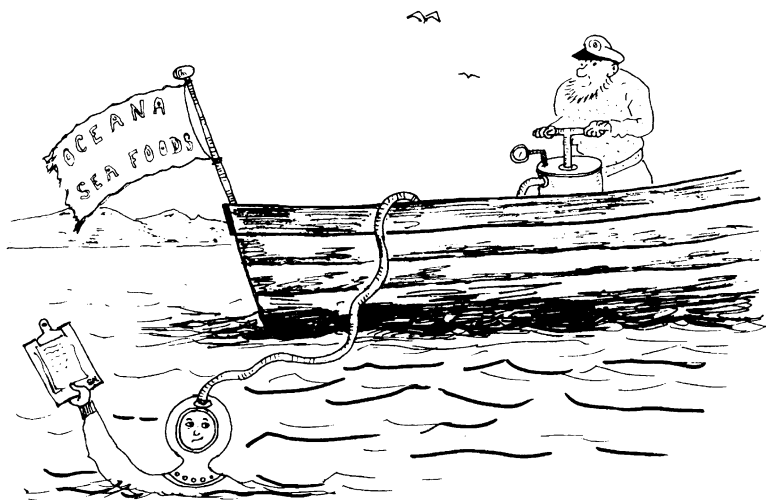


Fig. 4.6 Establishing a safe raw material supply

with your suppliers. To approve a supplier is a big responsibility which is often not fully recognized or appreciated within food companies.

We will discuss auditing in much more detail in Chap. 7, where we will be looking at auditing the HACCP system. The elements are the same for successful supplier auditing, except for supplier audits we are looking more broadly at the supplier's entire operation with HACCP as a key element.

4. Certificates of analysis

Certificates of analysis can be obtained for individual lots of raw materials to verify that these have been sampled and tested for specified criteria. You will need to check that results comply with specifications for these criteria, that the test laboratory is competent, and that the methodology and sample size is appropriate. These certificates can form a useful part of the SQA system, but the limitations of end-product inspection and testing should be remembered (Chap. 1), and they should not be the only way of verifying that the finished product is free from the hazard(s).

5. Third-party auditors and certification

If you do not have sufficient resources in terms of trained and experienced staff available to carry out your planned program of audits, then you may wish to use third-party audits as part of the program. In choosing third-party auditors, you will also need to consider the expertise and experience of the auditors. It is vital that the auditors have sufficient experience both in the technology concerned and in auditing practices. You must be confident that they will highlight any potential food safety problems and help you to maintain good relationships with your suppliers. This can be achieved by working closely with auditing providers and, for example, by going out and accompanying your third-party auditors to confirm that you are happy with their performance.

It is important to select a reputable auditing organization, and you should check whether their services have been accredited by a higher-level board, e.g., against the requirements of BS EN45011 (*General requirements for bodies operating product certification systems* (BSI, 1998)) and whether they are an accredited certification body for an external standard. GFSI benchmarked audits now provide some assurance of a competent and consistent approach but for high-risk raw materials we would advise that in addition to buying from third-party certified suppliers you go and see for yourself. If they are already certified then spend the time focusing on the food safety controls that you think are needed for **your** product.

6. *Buying from agents and brokers*

When you buy raw materials through agents or brokers, you lose out on direct contact with the supplier. This can have drawbacks when the agent has little or no technical knowledge of the raw material, but it can work if you manage the situation effectively.

You must know how your raw materials have been processed and handled at every stage, in order to establish whether the likely hazards are present. It is important that you can obtain the appropriate assurances and ideally copies of third-party certification from the agent. If it is a high-risk raw material, most companies will visit the manufacturing location to ensure that appropriate control is built into suppliers manufacturing operation.

Even with the best-planned SQA system it is impossible to be absolutely sure that your raw materials always meet the required standards for safety and quality. In order to do this more effectively it is advisable to pass on to your suppliers the requirement to be certified to a GFSI scheme or ISO22000 so that you know they have a HACCP system for food safety hazards control. This requirement can be passed right up the supply chain, so that at each stage—growers, processors, distributors, agents—there is some level of confidence in the material at that stage in the chain. Auditor competency however remains a challenge as the audits are only as good as the auditor.

Acceptance testing can be helpful. This may be visual (the material is free from foreign material) or organoleptic (does it look and smell right?). Specific tests may be done, e.g., Aflatoxin for certain feed ingredients, or microbiological testing for food ingredients which can be verification of the supplier HACCP program.

(b) Cleaning and Disinfection (Sanitation)

Hygienic operating conditions must be maintained and that will require documented programs, appropriate chemicals and tools, and adequate space in which to carry out required cleaning. Cleaning and disinfection programs are known as “sanitation” in a number of countries so for simplification, we will use that term throughout. A formalized sanitation program is one which is based on a risk assessment, is documented, and is validated as being effective and routinely

verified. What might each of these elements look like when properly implemented? The key elements that you should have in your program are as follows:

1. *A sanitation risk evaluation*

This is an evaluation of the type of residues that will need to be cleaned, together with consideration of the equipment, and process environment, including shift patterns and available down time. Considerations will include:

- **Potential microbiological risks**

- Pathogenic and spoilage microorganisms

- **Potential chemical risks**

- Allergens
- Additives and drug residues (particularly in the feed industry where variability in species intolerance is a major hazard)
- Pesticides
- Cleaning chemicals (e.g., cyanuric acid in chlorine-based manual cleaners)

- **The operating environment**

- Wet or dry

A documented evaluation should be done for each area of the plant and each piece of equipment in the process.

2. *Determination of cleaning methods*

Determination of the cleaning method is usually done together with the external sanitation services provider. Wet cleaning using chemical cleaners and sanitizers are usual for microbiological and allergen hazards. However dry cleaning has considerable benefits in terms of reducing the amount of water available to microorganisms and is nowadays regarded as a better option for plants that process dry products. It is generally easier to prevent environmental microbiological growth in dry rather than wet conditions. If dry cleaning is used, a sanitizer could follow (in countries where it is permitted) but it is not always necessary. This should be evaluated and appropriate data gathered to validate the method selected and to make adjustments as needed when setting up the program.

3. *Sanitation schedules/cleaning procedures*

Procedures and work instructions, sometimes known as Sanitary Standard Operating Procedures (SSOPs), must be properly documented for all the required daily cleaning activities as determined above. In addition, a Master Sanitation Schedule (MSS) must be established for all areas outside the regular equipment and process area cleaning. It should include overheads and light fixtures, walls and ceilings, coolers and freezers, and the external yard and perimeter. This could also be incorporated into a Master Cleaning Schedule designated to

indicate tasks which are daily, weekly, monthly, quarterly, or annual. You need to include:

- The details of equipment/area to be cleaned
- How it is to be cleaned (method)
 - This should be documented in detailed work instructions or “one point lesson” plans which could include:
 - The time (duration) allowed for the task.
 - Materials to be used, e.g.,
 - Chemicals
 - Tools
 - Chemical concentration and contact times.
 - Including any routine strength testing, e.g., with titration.
- Health and safety requirements, e.g.:
 - Safety glasses and protective clothing will be needed. Consideration should be given to how these will be kept clean such that they do not become a source of (microbiological) contamination.
- Expected outcome, e.g.:
 - Visual standards of cleanliness
 - Environmental microbiological monitoring requirements
- Corrective and preventative action in the event of a problem, e.g.:
 - Actions required (e.g., re-clean, investigate root cause, and verify that the issue was resolved).
 - Who to notify (in the event of a problem). It is beneficial to think this through ahead of time and to document requirements.
- Record keeping requirements
 - Operator sign off—as having completed the task in accordance with the work instructions
 - Reviewer sign off—to confirm (verify) that this was satisfactorily achieved
- Routine verification/pre-operations inspections
 - The person responsible should be clearly identified
 - The required method for verification should be established and documented

4. *Drain and janitorial cleaning*

A separate program should be in place for these activities with similar procedures to those described above. You need to include requirements for an up-to-date

schematic of the drains (with an indication of flow direction) and ensure that you have dedicated (color coded) equipment. The plant will recognize that contamination tends to accumulate around drains and that this is potentially a **major** cross-contamination risk if not properly controlled.

5. *Cleaning in Place (CIP) Programs*

If you are a plant that is operating a CIP system you will usually have a separate documented program. It will typically include the following:

- Diagrams of CIP systems and circuits
- Descriptions of each circuit
- List of parts that are cleaned manually together with work instructions
- Validation of hygienic design, e.g., separate circuits for raw and processed product and no dead ends

6. *Sanitation equipment and chemicals*

- Tools and equipment

You should have a program in place to ensure the integrity of the cleaning tools such that they themselves are not a source of contamination.

 - Stored clean and dry
 - Be on a regular cleaning schedule
 - Have designated containers
 - Sanitation equipment must never be used for process operations (e.g., sanitation sinks for produce washing).
- The design of the sanitation tools is important. Avoid anything made from absorbent material, also designs that could be foreign material hazards such as:
 - Reusable cloths
 - Reusable mops
 - Wire bristle brushes (unless unavoidable and then should be controlled)
 - Tools with wooden handles
 - Abrasive scrub pads (if used, these should be single use and issued on a controlled basis)
 - Any tools with crevices that could become harborage sites
- Chemicals:
 - All chemicals used must be suitable for food use and approved by the appropriate authorities.
 - A Material Safety Data Sheet (MSDS), sometimes called a hazard data sheet, must be retained on file along with a supplier continuing guarantee. All chemicals must be properly labeled and **never** decanted and stored in old or new food containers.

- Chemicals must be stored securely and in accordance with the manufacturer's recommendations. This is best done by having a locked area within the facility.

7. *Validation*

Validation of PRP programs such as Sanitation is the same as for HACCP, and third-party certification schemes such as those benchmarked by GFSI include this requirement. It is essential to establish that the programs will be effective. In a formal program evidence of this will be documented. Many companies work with their sanitation provider on this area. Validation data will include:

- Evidence that the chemicals are suitable for the tasks being carried out and are approved for use in the food industry.
- Evidence that the chemicals will be effective against hazards of concern.

8. *Monitoring and Verification of the program*

A number of routine activities will be carried out. This might include:

- Wet Cleaning:
 - Cleaner/Sanitizer concentrations checks
 - Adenosine Tri Phosphate (ATP) swabs
 - Visual pre-operations inspections (also post-cleaning if there is a time delay)
 - Microbiological and/or allergen residue checks of rinse water or of first production off the line.
- Dry Cleaning:
 - Usually entails pre-operations visual inspections
- CIP Cleaning:
 - Cleaner/Sanitizer concentration
 - Wash temperature
 - Wash contact time

For COP (out of place cleaning), the above might be appropriate plus post-cleaning ATP and visual inspection followed by a pre-op inspection.

- Environment (Microbiological) Surveillance

Microbiological surveillance programs are an essential verification activity and all but very low-risk operations will have them. Your program should include a risk-based sampling plan which takes account of the facility history, plant layout, product risk, and includes identified sampling sites, targeted microorganisms (usually *Salmonella* and *Listeria* species), or indicator organisms such as *Enterobacteriaceae*, plus the frequency and method of testing. As indicated

above, microbiological surveillance testing of first product off the line after cleaning is sometimes carried out but where this is practiced (and pathogen rather than indicator organism testing is done), all production must be placed on HOLD until the results are known. If pathogen surveillance testing is being done on food-contact equipment, a positive result would implicate anything made on the equipment following the test sample—through to the next clean and back to the previous one.

- **Audit/Assessment**

Regular hygiene audits usually form a part of the verification program. In a good program this is supplemented by a really thorough sanitation assessment occurring at least annually. It should include review of procedures and records plus a considerable amount of time in the plant inspecting equipment (including tear down of pumps and gaskets), observing the actual cleaning activities at whatever time of day, and environmental monitoring via swabbing. A review of the efficiency of the program can be done as part of the annual assessment or separately and can include sanitation costs (chemical/labor) and down time (planned or due to needed corrective actions).

Records of all the above activities will need to be reviewed routinely as part of your verification program.

9. *Training*

Left until last, but training is an essential factor for an effective Sanitation program. Your verification activities should provide some useful indicators for ongoing training needs. Like any program there needs to be training at a number of levels:

- **Sanitation Manager/Supervisor:**

This is sometimes the Quality or Production Manager's responsibility. Whoever has the responsibility for the program will need a fairly in depth level of training. They need sufficient knowledge of the types of soil to be able to develop cleaning procedures. They need to be able to understand, for example, microbiology, allergen management, chemicals mode of action, the role of validation and verification, and to be very aware of potential issues if the wrong chemical or cleaning method is used.

- **CIP Operators:**

Require a higher level of training than other operators who generally need work instruction training. All training will be validated through testing and must be documented.

(c) Allergen Control

An allergen control program can be a critical element of your company's food safety initiative if you handle multiple allergens in the facility. Improved awareness of allergens as a food safety hazard has resulted in a proliferation of precautionary labeling. Use of "May contain" type labeling limits consumer choice and the approach is now so widespread that such warnings are ignored by many. A strong

control program is the desired approach and there are a number of good reference materials available (e.g., Taylor and Hefle, 2005, FARRP, 2008, and Campden BRI, 2010), to help guide you. The best way of controlling allergen hazards is to **design them out of the product formulation** however this is not always possible. Typically allergens are controlled through:

- Avoidance of cross-contamination (with unintentional allergens)
- Labeling (of intentionally added allergenic ingredients)

Some companies struggle with conducting a hazard analysis on allergens—they are usually present or not. However, estimating the likelihood of allergens being present (based on ingredient and supplier knowledge) and plant cleanability is easier than trying to determine severity of effect. Severity will depend on the type of allergen and the sensitivity of the consumer. Given that this is difficult, most allergen management programs tend to err on the side of caution.

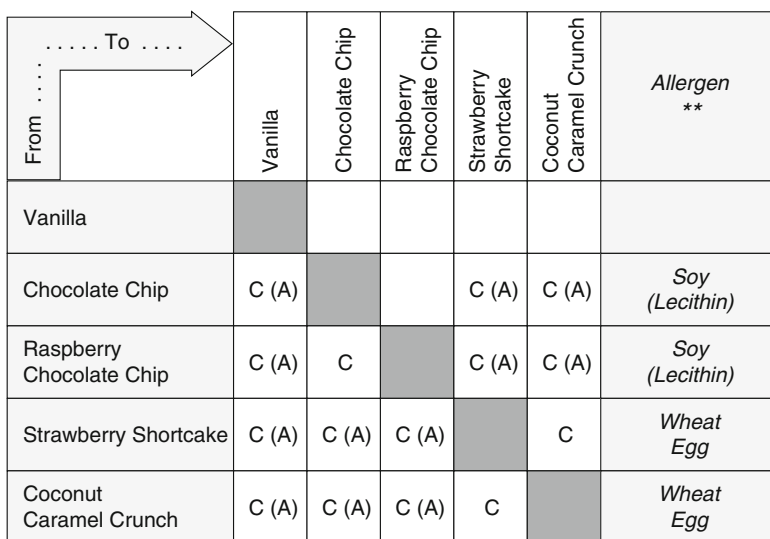
Early on in the new product development process, you should be evaluating whether new allergens are likely to be introduced to your plant. This information should be systematically evaluated by the HACCP team who will need to know:

- Is this allergen needed as a characterizing or functional ingredient (if not could it be replaced by a non-allergenic alternative?)
- Is it something that is already in use at the plant?
- Is it used on just one process line or all of them?

Hidden Allergens are what causes many manufacturers to recall products. You need to understand not only which allergens may be coming in as components of your raw materials but also what likely allergen cross-contamination risks might there be at your supplier's facility?

Cross-contamination control is critical when you have allergens in some products but not all. The allergen control program needs to be based on a systematic review of all ingredients and products. Where multiple allergens are used across a range of products, the program will usually include a production change-over matrix where the ingredient and product specifications together with the HACCP process flow diagram can be used to help establish which type of clean would be needed when scheduling production. A simple example is shown in Fig. 4.7, for ice cream made with a Vanilla base. This type of matrix can be expanded to include consideration of where in the process the allergen is added, which pieces of equipment are involved, and where in the plant are the allergens used.

Production lines should be spatially separated to prevent cross-contamination, and handling and cleaning procedures should be planned appropriately and validated as effective. Consider also what happens if personnel are switched between production lines or departments; will there be an additional risk from their protective clothing?



From To	Vanilla	Chocolate Chip	Raspberry Chocolate Chip	Strawberry Shortcake	Coconut Caramel Crunch	Allergen **
Vanilla						
Chocolate Chip	C (A)			C (A)	C (A)	Soy (Lecithin)
Raspberry Chocolate Chip	C (A)	C		C (A)	C (A)	Soy (Lecithin)
Strawberry Shortcake	C (A)	C (A)	C (A)		C	Wheat Egg
Coconut Caramel Crunch	C (A)	C (A)	C (A)	C		Wheat Egg

Fig. 4.7 Allergen changeover matrix for a vanilla-based ice cream. **All products contain dairy. Key: C = regular clean, C(A) = allergen clean, blank = scrape down is sufficient

Rework control and packaging, especially having accurate labels on products and outer cartons, is critical. This has been the root cause of numerous product recalls where the wrong label or outer case was used and resulted in allergens not being identified as present in the product. Best practice allergen control programs include the requirement for UPC bar code scanners to ensure that the right product is in the right packaging. Many companies include “contains” statements separate to the ingredients listing and in some countries (e.g., USA) this must be in plain language. This easily highlights to the consumer whether allergens of concern are present. This is slightly complicated by the fact that some countries have different allergen lists so if you are exporting you’ll need to check what the requirements are for the country of sale.

Not everyone can afford to install bar code scanners. Other types of control usually seen in a program include:

- A means to check and approve label art copy against formulation.
- A check of incoming deliveries of labels against the approved art copy.
- Procedures to issue labels to the packing line.
- Line clearance on product changeover and startup.
- Periodic line checks that the correct label is being used.

Barcode scanners are ideal for high speed lines as packaging printers have been known to mix up labels at their facility so don’t assume that all labels in a stack will be the same.

All employees should receive allergen awareness training and this should be refreshed periodically. Consider also what employees bring in as home-packed lunch (peanut butter?) and what is provided in vending machines. Hand washing will be essential as a preventative control measure.

For animal feed production, allergens are not currently regarded as being a significant hazard; however, allergenic by-products may be used as an ingredient in some feeds. Although there have been no known reports of human allergic reactions through handling of feed, it should not be disregarded. If handled by highly sensitive individuals this could potentially cause an adverse reaction, though likelihood of ingestion is remote.

Different species of animals are intolerant of numerous additives so the feed industry requires very complex production sequencing schedules in order to control cross-contamination but the concept is similar to managing allergens for the one human species.

(d) Pest Control

Like people, pests are potential vectors of microbiological contamination. It is important to establish a program that is aimed at preventing pest activity through both exclusion and elimination practices. Usually companies will have a designated person to oversee the program. That person should aim to become knowledgeable in best practices so that useful dialogue can be had with the expert contractors. Pest management programs must be documented and include target pests, methods of control, a schematic of the plant, list of chemicals used, frequency of inspection (and findings), and any training requirements.

These are the Pest Control Program key elements that you should have in your program (Wallace et al., 2011).

1. *Risk Evaluation and Preventative Measures*

Emphasis should be on the preventative approach, i.e., exclusion from entering the facility. As with sanitation, the program will be based on a risk evaluation. The principles of Pest Control are to limit food source, access, and harborage. You need to consider the external environment, likely ingress of pests into the building, and exposed product zones. Having a good culture of cleaning up spills is essential—if the pests have not got a food source they will be less attracted to the premises.

Pest control requirements should be documented in a formal pest management plan. It is really important that the on-floor practices match what the plant has documented as being important, e.g., keeping external vegetation short, managing the almost certain collection of redundant equipment that most plants have, and stacks of empty pallets. For most companies this will involve the engagement of a professional pest control operator, and a copy of his license should be kept on file along with a copy of the contract and insurance details.

The preventative measures will include the following:

- Proofing of entrances and access points
- Insect screens
- Electronic fly killing devices

- Well-maintained dry ingredients storage (sealed, no spillage)
- Controlled use of pesticides
- Use of traps
- Frequent inspections

You should have a schematic of the entire premises (including roof voids and basements) with all the pest control devices clearly marked.

2. Pest Control Chemicals

Pest control chemicals like all chemicals at the plant must be stored securely and clearly labeled. A MSDS should be kept on file confirming suitability for food premises. Care should be taken to ensure that any spillages do not become a chemical food safety hazard. As this is a food plant, all rodent baits must contain poisons that are solid (not granular) and be brightly colored to aid detection.

3. Bird Control

The plant design must discourage bird activity through appropriate building construction, regular removal of food sources (garbage areas can be a problem if not well managed), and elimination of roosting and nesting sites (drains and gutters can be fitted with screens and traps), doors must be fitted with air or strip curtains and kept closed, and use of predator bird calls is often effective. Some of this can be done retrospectively if you are in an older building.

4. Rodent Control

- Bait stations must be tamper resistant, secured to the location, and locked. You should only use poison bait in areas external to the plant—bringing poison into food processing areas is not recommended or legal in many parts of the world.
- Mechanical traps can be used in areas around entryways and regularly inspected and maintained.
- Internal traps (or sticky boards if used) should be positioned around the building according to risk, i.e., areas of frequent catches might require a higher number of traps. Usually they will be about 25 ft apart. All traps and bait stations will be numbered and marked on the plant schematic.

You will want to track rodent activity to enable identification of hot spots around the premises and to see whether there is seasonal variation. For monitoring purposes, non-toxic bait stations may be used which enables targeted and minimal use of poison. In terms of frequency of routine monitoring, a typical schedule might be weekly for internal and external traps and monthly for external bait stations as a minimum.

5. Insect Control

- Screens must be in place if doors and windows are used for ventilation but this is strongly discouraged in most types of food plant due to microbiological risk. A well-designed facility will have positive air pressure in process areas where food is exposed. Air curtains are not very effective for insects and should not be relied upon as a control device.

- Electric insect killers (EIKs) should be located outside of the exposed food production areas and if this is not possible, then well away from the exposed food areas. They should not be visible from outside the premises because the purpose of an EIK is to attract insects. Insect numbers in catch trays should be monitored for seasonal effects and infestations. Two blue bulbs plus a “sticky tube design” is recommended, though technology advances may improve over time and new recommendations made.
- Pheromone traps where used should be set up by a trained operator. Review of catch data should be included in the program as previous. All EIK and pheromone traps should be numbered and located on the schematic diagram.
- Any pesticides used on site should be recorded by name, % active ingredient, target organism, method and rate of application, area treated, license number and name of applicator, date, and signature.
- The effectiveness of the overall pest control program must be routinely (at least annually) reviewed and adjustments made.

6. *Validation Verification and Training*

These should be similar to the approach taken for the sanitation and allergen control programs.

(e) Good Laboratory Practices (GLPs) and Use of Certified Laboratories

There is a price to pay for use of bad data and many companies have found this out the hard way (Moorman, 2011). Sampling and testing plays an important role in your food safety program so you have to be sure that the results are reliable.

Laboratory certification is the independent systematic assessment and validation of a laboratory operation against a specific GLPs standard. It is normally carried out by a certification body which assesses the laboratory operation against a number of key elements, as defined in a laboratory quality standard. The quality standard may itself be based on the international standard “General Requirements for the Technical Competence of Testing Laboratories” (ISO Guide 25) or the European standard “General Criteria for the Operation of Testing Laboratories” (EN45001; EURACHEM/WELAC, 1993). The exact wording of laboratory quality standards will vary between countries and across the schemes, but the key elements normally cover the following areas:

- Organization and management of quality systems
- Audit and review
- Laboratory design and hygiene
- Sample handling
- Equipment
- Calibration (of technicians and equipment)
- Methods of analysis
- Quality control (including test sample traceability)
- Records and reports

Why is operating to GLPs important to HACCP and food safety?

The laboratory operation is a critical part of any quality system supplying information to verify that products are within specification. The results of laboratory analysis are particularly important when they are being used to validate, monitor, or verify the operation of environmental PRPs and CCPs, and thus product safety. Here, it is on the basis of results that decisions are made and actions are taken, so it is vital that they cannot be disputed.

In the case of CCP management it is essential that not only are the laboratory-based tests accredited but also any analytical testing which is carried out on the production line or in the production areas. These should be included in the scope of the certification.

Laboratory certification is also important where the company plans to use its HACCP system as part of a defense in any litigation case or if in dispute with a customer test result. In this case, you would need to provide evidence that its HACCP system was operating under control and that monitoring and verification was being carried out using assured methods. Where monitoring involves laboratory tests, independent laboratory certification gives confidence in the laboratory operation and helps to support the HACCP system and the litigation defense.

Is use of a certified laboratory necessary?

There is a strong case for laboratory certification in any organization but particularly in one operating a HACCP system for product safety. It is absolutely crucial that the results of all monitoring procedures at CCPs are irrefutable and can be trusted to demonstrate that the system is under control or can be used as the basis for corrective action decisions. Laboratory certification gives confidence in the accuracy of any results that are produced through laboratory tests and an independent system lends support to any necessary defense under litigation procedures.

In summary, there are many general benefits of laboratory certification. Specific benefits to HACCP and product safety are:

- That decisions and action are based on valid results.
- There is confidence that product safety specifications are being met.
- There is assurance that results are accurate and reliable.
- Certification will support a defense under litigation procedures.

(f) Complaints, Incident Management, and Recall Procedures

Complaints data is often the first indicator of a problem. It should be regularly analyzed and reviewed for trends. This is extremely valuable information and every complaint should be logged and investigated by the Quality Manager.

If the HACCP system fails or another unforeseen crisis occurs, e.g., to the factory building through fire or explosion, it will need to be managed in a controlled, systematic way, in order to minimize the damage to consumers and the business itself. Personnel who are trained in HACCP will be familiar with the identification and analysis of food safety hazards. This will be helpful during the management of an incident and also before this when putting an incident management system in place, in readiness for such an occurrence. One of the initial

phases in developing a program involves undertaking a business risk evaluation. This normally involves a series of questions:

- What are the potential risks to our business?
- What would be the outcome?
- What is the likelihood of the risk being realized?

An Incident Management Program will include documented procedures, a designated and trained Incident Management team, and facilities (designated Incident room, free phone lines, and administrative support) to enable an efficient and effective response when required. Trained personnel, with media-handling skills, will be necessary to reassure your customers and consumers that the situation is under control.

Lot traceability is prerequisite for effective recall. It is vitally important to be able to trace any potentially unsafe product, as with product-related incidents there is a strong chance that the product will need to be recalled from the market place. Both raw materials and finished products should be traceable. Proper lot coding will enable the amount of material retrieved during an event to be minimized. Lot traceability is another PRP that will be needed for a number of reasons, not least the ability to track potentially hazardous product through the distribution system and to retrieve it. A routine activity within a strong lot trace program will be mock trace exercises. These are typically carried out at least four times per year and should cover both raw materials and finished product. A best practice is to be able to trace within a 4 h period.

It is difficult, if not impossible, to ensure a 100 % return of product, and in a real situation the best option may be to use the media in order to inform the public.

(g) Food Defense and Bioterrorism

Food Defense and bioterrorism preventative controls continue to evolve in terms of expectations. Whilst they vary considerably around the globe, it does make sense to implement some level of program in this area. It needs to cover potential malicious contamination and sabotage, vandalism, and terrorism.

The Process Flow Diagram and hazard analysis technique can be used to help determine where contamination opportunities exist. Consider the following points:

- Is the plant secure—perimeter and buildings?
- Consider where ingredients or the product might be easily accessed.
- Where in production do people worked unsupervised?
- How do new employees get screened?
- Be aware of situations where existing employees may feel begrudged.
- Is the packaging resistant to access and will it indicate if tampering has occurred?
- Do you have a “whistle blower” (confidential) phone line where employees can feel comfortable in reporting unusual situations?

There are a number of templates and tools available (e.g., USDA, 2008, FDA, 2009) that we won't go into here but all are aimed at assessing vulnerability to terrorist attack. The systematic evaluation of infrastructure goes beyond the “gates,

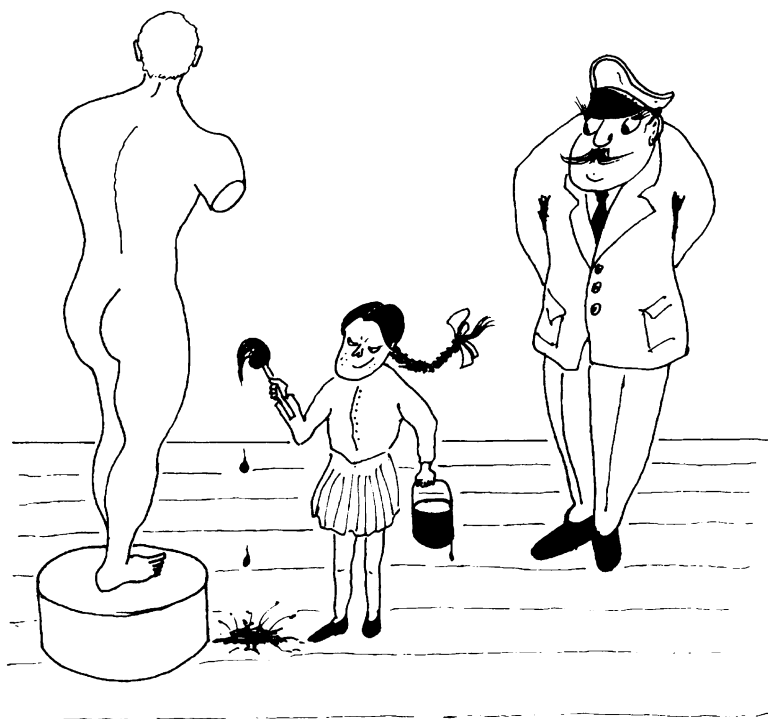


Fig. 4.8 Prediction of malicious contamination opportunities

fences, and guards” aspect of physical site security, focusing also on where in the process flow the product stream **could** be contaminated. The information generated can be managed through development of a Food Defense Plan. This document (not unlike a HACCP plan) could be used to manage identified threats in few main areas (Reeve, 2011). It can include consideration of:

- People (e.g., protection of the workforce)
- Products (e.g., protection of the products from intentional contamination)
- Assets (e.g., protection of the buildings, equipment, vehicles)
- Brand (e.g., protection of the company brand and ultimately the business)

Just like a HACCP program, Food Defense Plans require PRPs and many are the same as required for an effective HACCP program, for example, Supplier QA, and employee screening (Fig. 4.8).

(h) Preventative Maintenance Programs

A number of foodborne illness outbreaks have been the result of failure to maintain equipment or facility infrastructure (see Chap. 1). Whilst preventive maintenance programs will also be used for ensuring operational efficiencies and machine performance, the HACCP team will focus on ensuring that documented procedures are in place to assure the safety and integrity of the foods produced.

Typically a program will include:

- A master list of all equipment and areas of the facility that requires a maintenance activity. Building and equipment integrity, are an essential foundation for food safety.
- Documented maintenance schedule and procedures—for everything included in the master list.
- Spare parts inventory, with a focus on food safety.
- Lubricant program—including the type of lubricants to be used, the amount, and so on.
- Chemical control program pertaining to all maintenance chemicals—including an MSDS (material safety data sheet) for each chemical used on the site.
- Procedures for isolating equipment and the facility during scheduled or unplanned maintenance (or construction), including enhanced environmental monitoring requirements. Also, the process by which the equipment or facility are put back into use following completion of maintenance (or construction) work. The HACCP or Quality assurance team will likely be an inspector and approver of such activities.
- Calibration program—e.g., for temperature and test equipment.
- The utilities (water, steam, air) are often included in the program and will be included in the HACCP study. These might also be classified within the OPRP (see Chap. 6).
- Records should be maintained as evidence of compliance and for trend analysis in tracking performance of equipment for future decision making.

In general terms the plant needs to be well maintained such that the HACCP team isn't constantly chasing the engineering and maintenance team to get things done. All predicted maintenance should be exactly that—anticipated and taken care of—before it becomes a problem.

(i) Quality Management Systems (QMS)

This doesn't appear as a PRP in Codex (2009a) or PAS 220 (2008) but all of the activities which go on in the company to ensure that it meets its stated food safety and quality objectives are best managed within a formal QMS (Mortimore and Wallace, 2001, Wallace et al., 2011). Many companies base their internal QMS on external references—ISO9000 (2008) for Quality, ISO22000 (2005) for food safety, or increasingly, one of the GFSI benchmarked standards for food safety. ISO22000 is based on Codex HACCP principles so we will not dwell on it here. ISO9000:2000 does deserve a mention in that it is still used by many companies in tandem with ISO22000.

Quality management systems, including ISO 9000, are aimed primarily at preventing and detecting any non-conformity during production and distribution of product to the customer, and by taking corrective and preventive action to ensure that the non-conformance does not occur again. Working within a formal QMS should ensure that the product meets its specification 100 % of the time. There is obviously a danger here in that if an unsafe product is specified, the Quality System

will ensure that you make an unsafe product every time. This is where the use of HACCP as part of the formal system comes into its own—i.e., in ensuring that a safe product is both designed and manufactured according to the defined specification.

A QMS, such as ISO 9000 (or more often an internal company QMS based on ISO9000 principles), and HACCP, concerned with Quality and Food Safety Management, respectively, have much in common. Both systems require the involvement of all company employees, the approach taken is very structured, and in both cases involves the determination and precise specification of key issues. Both systems are **Quality Assurance Systems**, designed to give maximum confidence that a specified acceptable level of quality/safety is being achieved at an economic cost. Quality Control techniques, i.e., statistically valid inspection and testing, are used as a vital part of the Quality Assurance System, to monitor that the control points—quality and safety—are being adhered to. Most companies would support the idea that HACCP is a very effective way of managing food safety but only if:

- A Senior management supported Quality Policy is in place
- Calibrated equipment is used
- People are properly trained
- Documentation is controlled
- Corrective and preventative action systems are followed
- Non-conforming product is clearly identified and controlled
- The system is regularly verified through internal audit

These are all requirements of a formal QMS. In many cases, HACCP is not backed up by such disciplines and in these instances the company concerned may feel complacent in having a HACCP plan, completely unaware that it may not be working effectively.

You certainly don't have to have a company quality system certified to ISO 9000 before you start HACCP, but you should be aware of the relationship between HACCP and a QMS and how you can use the framework as a guideline for installing the procedures that will make your HACCP system secure. If you have neither HACCP nor a QMS, it is strongly recommended that, alongside the progression of HACCP, you use the QMS framework to support the HACCP implementation into the workplace, rather than do HACCP first followed by the QMS. The two are interlinked and have a real synergy. The HACCP approach can also assist in focusing on the critical quality attributes, which can help to ensure a really well-targeted QMS.

4.2.3 People

When we think about having the best performing food safety system possible, we have to recognize that we need more than a documented food safety management system.

Process × Culture = Super performance

Work done by Guerra (2005) made us think about this in terms of processes being all the systems, methods, strategies that we typically find within a company food safety and Quality Management system. If you work hard to combine that with the cultural elements of commitment, values, employee engagement, and inspiration then you have a long-term valued sustainable food safety “super” performance.

In cases where HACCP and PRPs are successfully operating the company usually has well-trained and educated employees and very strong senior management support. Arguably these are the “prerequisites” for any food company, large or small. Historically, when we refer to training as a prerequisite we generally mean at operator hygienic behavior level. Ongoing *education* of management staff and operators has more recently been recognized as the missing link and certainly a requirement for cultural change. Codex (2009a) stated objectives for personal hygiene are:

To ensure that those who come directly or indirectly into contact with food are not likely to contaminate food by:

- Maintaining an appropriate degree of personal cleanliness
- Behaving and operating in an appropriate manner

For this section on PRPs we are going to base the initial discussion on the two elements above but then expand to consider the behavioral aspects of food safety in a broader sense.

(a) *Employee Personal Hygiene*

You need to determine what standards and procedures will be needed relative to the risk of your products. We covered requirements for facilities and work wear earlier in the chapter but it warrants further discussion here.

Handwashing is one of the most effective means of preventing transfer of microorganisms through people as the vector. To ensure that employees are not only trained in **how** to wash hands properly but also **when** to wash them, they will need to be effectively trained in how to do it and educated in terms of why it is important. Adequate sinks, hot water, soap, sanitizer, and drying facilities need to be provided in order for employees to be able to follow through on the requirement. They also need to be located where needed and should be dedicated to handwashing. If hand-washing is a pleasant experience then employees are more likely to do it.

Employee facilities such as toilets should also be well equipped with handwashing facilities. They should not open directly to process areas. Changing facilities should be properly laid out to prevent cross-contamination and cafeterias and break rooms should also follow those principles. Employees need to be trained to understand and follow the requirements and why it is essential for food safety control. Again the facilities should be both hygienic and pleasant to use - this will help ensure that they are properly maintained.

Employee Health Status and requirements for employees to report any illness or symptoms of illness to their supervisor should also be clearly communicated. Anyone who is known or suspected of carrying a disease which could be transmitted through food must be restricted from food process areas. Conditions that require reporting include vomiting, diarrhea, fever, skin lesions/infections, jaundice, and discharge from ear, eye, or nose. Employees have to understand **why** this is so important for food safety.

(b) *Employee Personal Behavior*

Requirements should be clearly communicated around designated eating, drinking, and smoking areas. These will include restrictions on jewelry, requirements for nail polish and fingernails, mustaches, beards, maintenance of personal lockers, and restrictions on spitting, sneezing, or coughing over unprotected food. There are undoubtedly additional requirements not mentioned here but it comes down to having employees who understand that they are a major vector (transporter of contamination) in the plant. Visitors and contractors should follow all requirements for regular employees.

(c) *Training and Education*

Training and education are fundamentally important for food safety and should be regarded as foundational in your food safety program.

Food safety training aims to provide specific task related skills and is often more practical with learning objectives expressed in behavioral terms.

Food safety education aims to provide knowledge in the form of theoretical and conceptual information and results in the learner being stimulated to think critically, analytically or conceptually. This is essential if you really want to develop a food safety culture i.e. where the hearts and minds of your workforce are engaged and supportive.

Both training and education are important for behavior change. All food industry employees should have a general awareness hygiene training session and understand the critical role that they play. This should be refreshed periodically and both validated (to check that they understood the requirements and the end of the training session) and verified (to check that they are following the requirements on a day-to-day basis). The former can be done in a classroom setting with a quiz or test paper or more typically these days an online learning session with a test at the end. Verification needs to be done through planned observation in the process environment. An example of this would be observing whether correct hand washing protocols are being followed, rewarding employees who do it well as a positive reinforcement and taking appropriate corrective action when they are not.

The HACCP and Management teams will require education to ensure they have the necessary knowledge and expertise to be able to anticipate and identify potential hazards, to take corrective action, and to implement preventative controls as part of any overall risk management strategy. This will mean hiring the right people and having access to reputable external experts.

Much has been written on the suitability of HACCP for small businesses. We would argue that it is not the size of a business that causes difficulties but that many small enterprises do not have access to the level of technical expertise required to conduct a hazard analysis and identify CCPs, and possibly least of all to do a validation of critical limits. There are many large businesses, not just in developing markets that do not have this level of expertise either and who have just as much difficulty implementing a HACCP program. Acknowledging this and looking for external help is the best approach and can be used as way of transferring the know how into the company over time.

(d) *Food Safety Culture*

At time of writing, this is getting increased attention in terms of it being recognized as critical to ongoing food safety assurance. There are a number of definitions

“Culture is patterned ways of thought and behaviors that characterize a social group, which can be learned through socialization processes and persist through time” (Coreil et al., 2001), simply stated **“organizational culture is the way people think and act”** (Conners and Smith, 2011), or as Yiannas (2009) prefers to describe it **“Culture is the way we do things around here”**.

You may have a well-documented QMS and HACCP plan but unless you engage the hearts and minds of the company employees then you **still** have potential food safety risk. What can go wrong will go wrong and there are many examples of failure caused by thoughtless action, employees taking “short cuts,” or not following established procedure because they didn’t have time or couldn’t remember being told about it. Many companies state that food safety is their ‘top priority’ but priorities change. What you need to develop is a food safety (and quality) culture. There are some excellent references now available on this topic (e.g., Yiannas, 2009, Griffith et al., 2010a, b, Powell et al., 2011, Seward et al., 2012) and we don’t have room within this book to do more than highlight that it is an essential element of food safety success. Whilst food safety culture is about the totality of how food safety works within an organization, it could also be thought of as a pre-requirement for HACCP and food safety success. Hence it is appropriate to mention in this chapter on PRPs. There are some basic theories that might be helpful to you as you think about this. A few are described here but this is why a cross-functional food safety team is really important to support your food safety program—a Human Resource or Personnel Manager will be way more proficient in behavioral science than will the Quality Manager.

Hofstede and Hofstede (2005) described three levels of uniqueness in mental programming (Fig. 4.9).

The interesting point is that culture is a learned behavior, “It’s how we do things around here” and therefore can be changed, however change isn’t easy and doesn’t happen by accident. Culture change does not come just as a result of providing food safety training and education—or why would people smoke, drink too much, drive too fast? Training and education are key components but culture change needs more

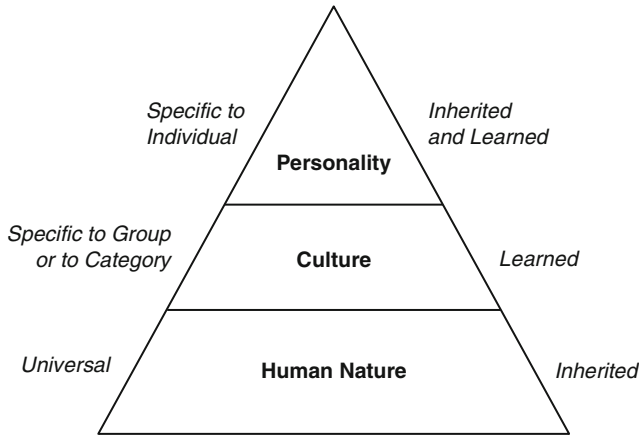


Fig. 4.9 Three levels of uniqueness in mental programming (adapted from Hofstede and Hofstede, 2005)

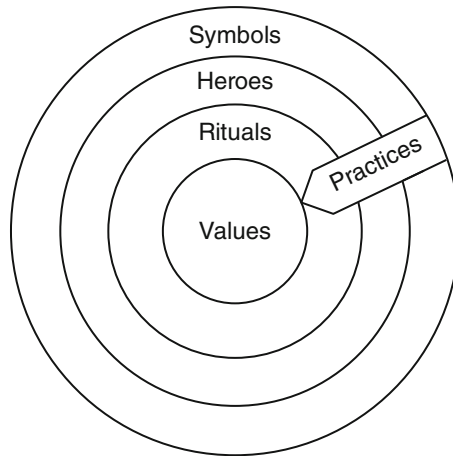


Fig. 4.10 Manifestations of culture at different levels (adapted from Hofstede and Hofstede, 2005)

than that. It needs **real** commitment from the top to the bottom of an organization, it needs stories of failure that really hit home, it needs to relate to the individual employees, and it needs **constant** reinforcement and layering of information through effective communication. It is worth considering the various layers of a culture (Fig. 4.10), both within organizations and individuals—the more we understand the theory, the more we can lean into it in terms of approach.

Symbols are words, gestures, objects that are recognized by those who share the culture. They are visible. Other aspects lie below the surface and are less obvious. Examples include corporate logo, national dress.

Heroes are those who are prized and serve as role models for behavior. Consider who is your role model or food safety hero? Louis Pasteur or your CEO?

Rituals are those behaviors that are shared by a culture, e.g., the way of greeting, paying respect to others, and which play a big role in how business is done. Rituals also include the way language is used. National cultures can impact on business when not understood. For example the ritual of shaking hands which in some countries like the Middle East means that “serious negotiations are formally beginning” but in other countries this means that agreement has been reached, i.e., negotiations are at an end. This might be one of the reasons that GMPs vary so much from country to country. Symbols, heroes, and rituals associated with a National culture will naturally vary.

At the core are the **values**. They relate to preferences such as good versus evil, ugly versus beautiful, forbidden versus permitted, and dangerous versus safe. They are acquired early in our lives and are learned from our parents initially, followed by schools and work. In companies these are the business ethics/integrity. Sometimes an individual’s personal values are said to not be a “fit” for an organization. This is where you need to agree on and work to integrate the food safety values for your company.

Practices can cut across the layers—some come through inherited behaviors or traditions. Some develop as a result of past issues and concerns and some relate to fashion and can be transient. Some practices exist because they have never been challenged. The practice of using melamine to supplement protein in animal feed in China had never been an issue. It was a known common practice. The good news is that new practices can be learned and can run across all layers. As a HACCP team you can “walk the talk,” i.e., practice and be a champion for the defined PRP practices such as hand washing, uniform control, reinforcement of hygienic behaviors, and sharing of technical knowledge.

The HACCP team will be catalysts for food safety culture development and as such need to be equipped with the knowledge and leadership skills to do so. As technical people, we aren’t necessarily expert in this area so we need to reach out to our colleagues who understand behavioral science. This is usually the Human Resource or Personnel function who can be called upon to partner with the HACCP team to assess resource needs, plan the food safety communication approach, facilitate training and education activities, help with behavioral observation, and change management. Of course we also need to engage with other functions across the company, not least the manufacturing function for their leadership at the facilities. Also, the company senior leadership team for constant and visible leadership.

What is clear is that development of a food safety culture is not solely the responsibility of the Quality Assurance department. One thing to remember—*employees don’t care **what** you know until they **know** that you care*. This is an old saying but as stated earlier a strong food safety culture requires that the hearts and minds of all employees in the company are fully engaged.

4.3 Validation and Verification of PRPs

PRPs, just like HACCP, do need to be properly verified and maintained. This includes validation of their effectiveness as preventative control measures and verification to confirm ongoing implementation. As shown earlier, the Sanitation program is a good example of this—it needs to be validated when being set up, i.e., to confirm that the procedures and chemicals will have the capability to effectively clean, and verification to confirm that what was set out as the procedure is being followed on a day-to-day basis. Many companies will do the verification via audit or set up control points to provide additional focus. Can you verify whether your company or your suppliers have a food safety culture? We think that to some extent, yes you can—by looking at the practices, symbols, and rituals in a food safety sense. Tangible factors such as visual cleanliness, the state of the operating environment in terms of structure and equipment, how well maintained is the external perimeter and the site overall, and less tangible but visible, do managers hold employees accountable for adherence to laid down food safety protocols or do they ignore lack of adherence to hygienic behavior, are food safety performance goals in place, is data collected and used for action, are food safety rules established and communicated, and so on.

4.4 Key Points Summary

PRPs are clearly an essential element in the task of developing simple, effective highly focused HACCP systems. In fact this has always been so and the very term “prerequisite program” symbolizes the formalization of elements of GMP and good hygienic practice.

- PRPs are as important for effective food safety control as HACCP is in many cases.
- Increasingly, the **essential** food safety support programs are known as Operational PRPs, a term which came from ISO22000 (2005).
- Appropriate and properly implemented PRPs can ensure that the HACCP plan is focused on the truly critical control points.
- PRPs are needed prior to and during the implementation of HACCP but HACCP can be used to prioritize PRP improvement efforts.
- Hazard assessment is needed in order to establish which food safety hazards are controlled through PRPs, OPRPs, and CCPs. This means that HACCP skills are needed when establishing or upgrading your PRP program.
- Food Safety culture is **an essential foundation**. Without this the systems will not be sustainable.
- PRPs need validation and verification to ensure that control is effective.

Further guidance can be found in the many excellent PRP publications, a number of which target a very specific area, for example, hygiene, sanitation, allergen management, pest control, metal detection. General texts also exist and are helpful

in providing a good overview. These include *Good Manufacturing Practice: A Guide to its Responsible Management* (IFST 2007), ISO/TS 22002-1:2009 *Prerequisite Programmes on Food Safety: Part 1 Manufacturing*, (ISO2009, formerly PAS 220)—*Prerequisite programs on food safety for food manufacturing* (BSI 2008), PAS222—*Prerequisite programs for food safety in the manufacture of food and feed for animals* (BSI 2011), and Sperber (1998). The ISO and PAS documents provide details of the PRPs that support HACCP as required by ISO22000 (2005).

Chapter 5

Designing Food Safety

Whenever a company is designing a new food product it is important to ask if it is possible to manufacture it safely. Effective HACCP systems will manage and control identified food safety issues on an ongoing basis but what they cannot do is make safe a fundamentally unsafe product. **The most effective way to ensure safe food is to design out the likely hazards.**

Safe design might first seem a relatively straightforward operation; however, when we look at all the necessary elements to achieving safety, the complexity of getting this right starts to emerge and we can see that there are several elements that need to be effectively designed for food safety, and which will need to operate within a supportive food safety culture (Fig. 5.1).

Figure 5.1 illustrates that HACCP cannot work in isolation. It needs to be accompanied by safe design control procedures and prerequisite programs (PRPs), and supported by a range of essential activities which go into making up a culture of food safety. This will include management commitment as demonstrated by investments in the operating environment, programs, people and training, a continuous improvement approach, and a strong documented quality management system.

The “safe product/process design” element is particularly aimed at the safe design of individual products being produced within the safety management framework of HACCP systems and PRPs and this will be the main focus of this chapter. However it is important to also consider the safe design of prerequisite programs in that we need to consider the safe design of the food process equipment and the facility where products will be produced, handled, and/or packed. Many of the necessary elements for safe equipment and facility design will overlap with PRPs; however it is useful to also consider the facility in this chapter to provide a complete picture of the safe food system. We have already considered HACCP system structure design in Chap. 2 and will follow through on HACCP application and implementation in Chaps. 6 and 7.

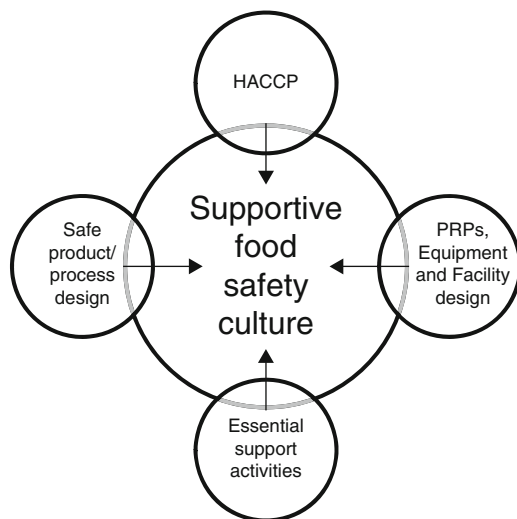


Fig. 5.1 Designing food safety programs

5.1 Product Safety Design

It is essential that food safety is designed into a product at the development stage and this should be the responsibility of the product development and HACCP teams working together. Ideally HACCP teams will include a member(s) from the product development team whose responsibility includes informing them about new product/process ideas at an early stage. There is no point in new product prototypes being shown to marketing departments or to customers if there are inherent safety risks which cannot be controlled. Lack of early cross functional food safety assessment lengthens the overall timeline for new product development if reformulations or process changes are found to be needed during a later HACCP study. Not only could this be embarrassing for the commercial teams but development ideas which have not had early food safety risk assessment could be responsible for foodborne illness in the marketing or customer buying departments through consumption of unsafe samples made in the development kitchen. The presence of product development specialists on the HACCP team is not only essential for bringing information about new developments to the team's attention but also ensures that the philosophy of and requirement for safe design are taken back to the product development team, where they become a cornerstone of future developments. As stated earlier, the most effective way of preventing foodborne illness is to design out as many of the likely failure modes as possible. The product development team needs to fully embrace this philosophy.

Several factors must be considered when designing food safety into a product, and the HACCP team and other relevant specialists must be involved at the outset. In this section we will consider the product formulation and process technologies,

along with the importance of ensuring raw material safety. We will also discuss the establishment of a safe and achievable shelf-life and provide an example of how this information may be organized into a formal product safety assessment record.

5.1.1 Designing Your Recipe Formulation

Most companies will be manufacturing or packing a specific type of product within a particular sector of the food industry and so will have detailed knowledge and experience of their likely hazards and appropriate control measures. Often new product development will be around (simple) variations to an existing range of products, in which case it is tempting to assume that the same controls will be suitable for control of food safety hazards. However it is important to note that this will not always be the case and to remember that changes to product formulation have been the cause of previous food safety incidents (see also Chap. 1).

A good example of a catastrophic product development error is associated with an outbreak of botulism in the UK in 1989. This outbreak (Shapton, 1989; O'Mahoney et al., 1990) involved the change from a standard hazelnut yogurt formulation to a low calorie version, and both the yogurt manufacturer and the hazelnut puree supplier were at fault in their product formulation safety design. The puree manufacturer should have understood what was making the puree safe in terms of the product's intrinsic safety factors and process. By taking out the sugar and replacing with artificial sweetener, questions should have been asked about the impact of the changes on safety, e.g., what was preserving the puree and preventing the growth of spore-forming organisms such as *Clostridium botulinum* and did this new formulation change that. The yogurt manufacturer should also have been asking questions about the safety of his or her new raw materials very early in the redesign. However, no change to the heat process of the hazelnut puree was put in place by the puree manufacturer, so an inherently unstable and unsafe product was produced and supplied to the yogurt company, where it was simply mixed into the yogurt and resulted in 27 cases of botulism and one death (Shapton, 1989; O'Mahoney et al., 1990). Whilst this example happened more than 20 years ago, it remains a useful lesson to those involved in the product development process of the need to review safety for all new developments, no matter how simple they may seem at first.

The important point is the need to review in detail each change to a product formulation and consider both what new hazards might be introduced and what impact the proposed change has on overall formulation safety. From the above example it is important to remember that changes can also result in removal of existing control measures as well as introducing potential new hazards.

Often hazards are being controlled by a combination of formulation controls within the recipe and other control measures. Chapter 3 introduced some of the ways that product formulation is used to control microbiological hazards, e.g., pH and acidity, organic acids, addition of preservatives, and water activity. It is important that HACCP and product development teams understand the intrinsic

recipe factors being used to control safety within food products and review the impact of proposed recipe changes on these control systems.

The other key element to consider is whether the proposed new formulation will mean that there are new significant hazards that need to be controlled. This will require appropriate knowledge within the HACCP team to evaluate the potential for new hazards and may mean that additional specialist expertise has to be brought in, for example when product developments move into areas of limited experience for the specific food business or when a completely new product or process type is being considered.

5.1.2 Designing Safe Processes

Most food companies (human or animal foods) will have well-established manufacturing processes in operation and these may involve a variety of technologies, such as heating, cooling, fermentation, etc. Often these processes will have been used for many years and their safety, therefore, is taken for granted. However, when starting out with HACCP or any certified formal quality management system, gathering evidence that your processes have been confirmed as safe (i.e., that you have documented proof of it) is a key requirement. We will see the importance of validating process safety where CCPs are involved in Chap. 7 and it is best practice to start building up a dossier of evidence that processes used to control significant hazards are valid and effective across the normal operating conditions. This may be done with reference to legislative or literature values, and will also always require local on-site testing and monitoring to demonstrate that the intended process parameters are met.

For proposed new processes where there is limited knowledge and experience, the safety of each application needs to be researched and validated in the same way before the proposal can be implemented. Again, it may be necessary to bring additional specialist help into the product development and/or HACCP teams to help with understanding the implications of the findings and assist with the safety evaluation.

5.1.3 Safe Raw Materials for Safe Product Design

Hazards are brought into our facilities by people, through the environment (dust on air, etc.) and through raw materials. Product safety starts with knowledge about the safety status of raw materials that we use. Whilst control of raw materials is normally via supplier quality assurance procedures as part of PRPs, it is important first to understand the likely hazards that specific raw materials might present so that appropriate controls can be built in. This might be through supplier quality assurance or it might be through processing controls in the food operation,

depending on what is appropriate for the specific hazard. For example, raw ingredients such as raw meat will almost always carry a risk of contamination with microbial pathogens and these will need to be controlled at some stage before consumption of the final product; however it would be unrealistic to require that all microbial pathogens of concern were absent from the raw meat on delivery due to the absence of processing steps in primary production. Nevertheless, where no control for specific significant hazards can be built into the food process then the raw materials must be safe at the point of delivery and this will require control measures to be part of the raw material supply chain. In this case the supplier assurance procedures must be able to demonstrate that control measures have been applied. See Chap. 4 for further discussion of supplier assurance as part of prerequisite programs.

5.1.4 Establishing a Safe and Achievable Shelf-Life

When you are designing your products, you will need to consider the shelf-life that you and your customers would like for each product, and then go on to establish whether or not this proposed shelf-life is safe and achievable. Criteria that can influence your product's shelf-life include:

- Raw materials
- Process technology used
- Product intrinsic factors
- Type of packaging
- Conditions during storage, distribution, and retail
- Customer storage and handling

The shelf-life will be limited by factors that cause the product to become unsafe or deteriorate, and these will be influenced by the criteria listed above. Rancidity of fats can cause revulsion when consumed, but these are normally associated with spoilage rather than safety. As we are concentrating on safety in this text, we will consider here only factors that cause the product to become unsafe. As with the other aspects of product safety design, you need to ensure that you have the correct expertise available to take shelf-life decisions. For example, if you are a small manufacturer of high-risk products, you may wish to consider the use of external experts to help with shelf-life determination.

What Factors Could Cause the Product to Become Unsafe?

The main factors that can cause products to become unsafe during their shelf-life are pathogenic microorganisms. We have already discussed microbiological pathogens as hazards and have looked at intrinsic factors as control measures in Chap. 2. The Pathogen Profiles Appendix may also be helpful in deciding whether

the product is likely to provide an environment favorable to pathogen growth. Pathogenic microorganisms may be present in your product from the raw materials, or from contamination during processing. These may be able to grow, depending on the intrinsic factors and packaging, along with the storage, distribution, and handling conditions to which the product is subjected.

If you consider that a pathogen is likely to be present in your product, and that it will not be prevented from growth by the product's intrinsic factors, then you will need to investigate the degree of growth that is possible in the product. This, along with knowledge of the infectious dose for the organism in question, can be used to evaluate whether the product will become potentially unsafe for consumption and under what circumstances. It is important to note that if pathogens with a low infectious dose are likely to be present (i.e., the mere presence of them is a significant hazard) at the start of shelf-life, and the product is not likely to be cooked thoroughly by the consumer, then the product is potentially unsafe and should be redesigned. A good example of this is *Salmonella* in low-moisture foods, particularly those that are minimally processed, e.g. peanut butter, flour, spices. Technologies are available which can be used to improve safety, such as irradiation, steam sterilization, and heat treatments, but this is a change in traditional practice for many of these categories and more research is needed. This is an area that in recent years has been the subject of discussion regarding the role and responsibility of industry versus the consumer. In the past, we might have said that the consumer was responsible for thoroughly cooking raw foods (i.e., the kill step). However, there have been a number of outbreaks in the raw products category (such as vegetables and ground meats for barbeque cooking) which might lead us to consider that there are very few foods where the consumer should have that responsibility—perhaps raw grains or meats and even then we have to consider known likely consumer use such as consumption of raw homemade cookie dough or meats preferred rare. Companies producing products that have traditionally been considered as 'raw' but which may be consumed without proper cooking are challenged with this particular scenario.

How Do You Know When Pathogens Reach Unsafe Levels?

Information on growth potential in foods, and with varying proportions of inhibitory intrinsic factors, can be found in the scientific literature. This can give you a good idea of the likely situation in your product but should not be relied on absolutely for a safe shelf-life. Mathematical modelling of pathogen growth in various concentrations and combinations of intrinsic factors can also be carried out. A number of computer models have been developed which can also be used or accessed but these do require microbiological expertise for interpretation and your HACCP team may need additional expert help depending on the existing team makeup.

The theoretical safe shelf-life obtained from literature values or mathematical modelling should be confirmed in practice for the product in question. This can be done through examination of the product for each microorganism of concern

throughout and beyond the proposed shelf-life. Product samples should be held under the expected storage and handling conditions, and it is prudent to build in an element of abuse, e.g., elevated temperature storage, to reflect possible product mishandling.

Where the microorganism(s) of concern may not be present all the time, or may be present at very low levels, it is more appropriate to carry out product challenge testing to evaluate potential for growth. Here each individual pathogen is inoculated into the product, which is then held at the expected storage and handling conditions. As for standard shelf-life examination, the product is tested at various intervals throughout and beyond the proposed shelf-life and an element of abuse should be built in.

It is important to note that shelf-life should always be confirmed on product samples which have undergone the same treatment as all product which goes on sale. This means that any shelf-life proposed through theoretical studies, or through examination and challenge of development samples, must be verified on product which has been manufactured on production lines at the factory, and under the normal manufacturing conditions.

5.2 Prerequisite Program Design

As with all other parts of the food safety program, it is important that prerequisite programs (PRPs) and, where appropriate, OPRPs, are carefully designed to ensure that they will control the necessary issues every day. Chapter 4 provides a detailed breakdown on some of the key PRP elements and it is not proposed to repeat the detail here. However, it should be remembered by all food businesses that the development and/or review of PRPs is an opportunity to strengthen the level of control they provide for food safety. This means that it is not sufficient just to accept existing systems that have been in place for some time, without asking the question: “Can we do this better?” The HACCP system is an approach to continuous improvement and this will also be the case for its supporting systems.

Additional detail to help in strengthening PRPs can be found in a range of other publications such as food safety and prerequisite audit standards, e.g., standards meeting the Global Food Safety Initiative requirements (GFSI, 2011) or specific prerequisite standards such as the ISO (2009) publication, *Prerequisite Programmes on Food Safety: Part 1 Manufacturing*, ISO/TS 22002-1:2009 (formerly PAS 220:2008), or other books and guides, e.g., Sprenger (2012).

5.3 Equipment and Factory Design for Product Safety

Linked to PRPs for providing the general hygienic operating conditions necessary for safe food production is the concept of hygienic/sanitary equipment and factory environment design. This is clearly essential in all product handling areas and will

also be important in other ancillary areas of a food facility, particularly with regard to areas where food handling personnel have access. Modern food processing facilities are normally designed with a good level of hygienic/sanitary standards; however many of us are challenged with operating out of facilities which were built long before the concepts of sanitary design were being developed. It is important to keep up to date with developments in best practice and knowledge on the behavior of hazards in food-handling environments. HACCP techniques can really help with understanding the impact on product safety if the product does encounter environmental contamination, i.e.: What is making the product safe and very importantly, what would cause it to be unsafe?

Hygienic design considerations might be product specific since there will be particular considerations for different product sectors and links in the food supply chain (see also Chap. 8). This might include the need for specific environmental standards and equipment or, for example, for segregation/zoning of different processing areas in certain product/process types.

As discussed in Chap. 4, segregation of areas (sometimes called zoning) is a common control measure to manage the hygienic/sanitary standards in food facilities. This involves building in a gradient of product protection systems and procedures, with the highest degree of hygiene used where the product is most vulnerable to contamination, e.g., after cooking but before packing. This type of system is common in the production of perishable ready-to-eat products. It is important to recognize that for some products the mere presence of a pathogenic microorganism at low numbers can cause severe illness, even mortality. Control of *Salmonella* in low-moisture foods requires a zoning approach to prevent cross-contamination of the finished product. Design of food facilities for high care zones needs to be carefully thought through at the site planning stage as it will be much more difficult to build in appropriate controls as an afterthought in a completed building. Specific considerations when designing segregation zones will include traffic patterns for product, equipment, and personnel, the need for dedicated changing areas and/or “air locks,” the need for dedicated equipment for production and maintenance, and the need for positive air pressure and appropriate drainage and waste management design.

For both the facility environment design and equipment design, perhaps the most important aspect in a food operation is ensuring that all areas, plant, and equipment can be effectively cleaned and disinfected. Inability to clean due to inappropriate surfaces, “dead-ends” or areas in pipework, equipment that cannot be dismantled fully or successfully cleaned in place, etc. will mean that food debris and microorganisms start to build up and this could cause safety implications via product contamination.

Further supporting information on hygienic design of food facilities and equipment can be found in other publications such as Campden BRI Guideline No 39, *Guidelines for the Hygienic Design, Construction and Layout of Food Processing Factories* (CCFRA, 2003), Shapton and Shapton's *Principles and Practices for the Safe Processing of Foods* (1998), and Holah and Leileveld's *Hygienic Design of Food Factories* (2011). Additional helpful guidelines can be found via Web sites run

by expert groups, such as the European Hygienic Engineering and Design Group (<http://www.ehedg.org/>), which offers a range of guidelines with particular reference to hygienic equipment design, or the US Grocery Manufacturers Association, which provides checklists for *Facility Design* and *Equipment Design for Low Moisture Foods* (<http://www.gmaonline.org/resources/research-tools/technical-guidance-and-tools/>).

5.4 Product Safety Assessment

Most companies nowadays use the modular approach to HACCP system design (see Chap. 2). In addition to HACCP plans it is essential that all companies ensure that the safety of individual products has also been properly assessed. In modular systems, the HACCP plans usually cover a **process**, which means that a number of different products are included within each module. It is also important to consider each individual product through a form of product safety assessment. This is intended to pick up any product-specific hazards and can be used to document recommendations to the HACCP team. Product safety assessments may be carried out either before HACCP plan development, where all existing product varieties will be assessed, or after HACCP implementation, when new varieties are added to a product range. In the latter case it is particularly important to ensure that the existing HACCP plan is still valid for the new product.

Throughout this book we are using a fictitious example of ice-cream manufacture to illustrate the design and implementation of HACCP systems. This example assumes that the manufacturer is a medium-sized company producing a number of different varieties and operating to acceptable food industry standards. The products are packed in family-sized and individual tubs for retail sale. Here, at the development and safety design stage, we again refer to the case study and specifically, a chocolate-chip ice-cream product which will be managed by the modular HACCP plan outlined in Chap. 2.

The Product Development personnel can be assisted by the HACCP team in establishing the product criteria early on in the design of a new product. This will often involve the drafting of a development specification.

5.4.1 Development Specification

In many cases the product safety assessment will be based on a development specification, such as the example given in Fig. 5.2 for chocolate-chip ice cream.

In most cases the suppliers of the raw materials will be known and outline or full specifications may be available. This is important as the next step in the assessment is the evaluation of likely raw material hazards.

5.4.2 *Product Concept Safety Considerations*

A product safety assessment may be carried out and documented in a number of ways, but usually comprises consideration of:

- Target audience and food sector
- Raw materials
- Legal issues
- Recipe and intrinsic factors
- Process conditions and cross-contamination issues
- Distribution and final customer/consumer handling

(a) *Target audience and food sector*

Most foods are targeted at the general public but not all. If producing for certain segments of the population such as infants, children, or the elderly, you may need to capture this in terms of there being a need for heightened controls. For example, products designed for young children will have the additional concern of choking hazards; for the immunocompromised consumer, a higher degree of environmental hygiene might be needed. Also consider the food sector. Food service and catering operations will be different to retail. Products being used in commercial kitchens may be subject to abuse through more frequent handling, but conversely, you may be able to ensure more consistent user practices by working with your customers and providing handling instructions and training. With retail products, the consumer at home is the target and more difficult to educate in terms of safe handling practice as we've discussed earlier.

(b) *Raw material evaluation*

Considerations of ingredient sensitivity during the design of a new product can assist in targeting the SQA activities to work with new suppliers at an early stage. A number of issues are likely to be discussed, for example:

Sensitivity status:

- Why is the ingredient considered “sensitive”?
- What (specifically) are the microbiological hazards of concern?
- What likely chemical and physical hazards exist?

The team should review literature for guidance and also for indications of outbreaks or events in the raw material categories that they are using. They should also expect their raw material suppliers to be knowledgeable about the safety of what they are producing.

Supplier control:

- What is the approval status of the factory or the agent?
- What is the specification status—has the supplier signed off to indicate agreement?
- Are certificates of analysis required? If so, is the testing laboratory approved/certified?

- Have previous audit reports been considered? Evaluate any third-party reports as well as any that you have generated yourself in previous years.
- Are there any shelf-life criteria associated with the ingredients that would impact your product?

Bearing this in mind, let's now look at the ingredients and packaging for the ice-cream case study. Table 5.1 shows how the information may be organized as each ingredient is evaluated.

(c) *Legal constraints*

These may not strictly relate to product safety, but it is important to be aware of relevant legislation, particularly if exporting for distribution and sale in other countries:

- Are you making any claims about the product? This may be important if the company is planning to reduce salt or sugar in the formulation. It could be a very early indicator to the HACCP team that important intrinsic safety factors are likely to change.
- Consider ingredient usage concentrations, e.g., whether there are any maximum usage restrictions. This will be the case with chemical preservatives and other additives.
- Review product compositional requirements. In some countries there are formal standards of identity for certain categories of foods.
- Understand the regulatory position with regard to processing requirements, e.g., pasteurization. Ensure that this is the same in the country of manufacture versus where it will be sold. Irradiation is a good example where there are differing requirements by country.
- Review microbiological criteria—especially if exporting to a country which has differing regulatory requirements and test protocols.
- Chemical criteria—same as above, i.e., specifications may vary across national borders. An example may be antibiotic residues in dairy products, and also use of chemicals such as ethylene oxide which is still permitted in some countries but banned by many.
- Use of technologies—such as biotechnology. Here the regulatory and consumer acceptance may vary and this is also worth a team review and discussion.
- Labeling requirements differ across countries and this is important too for food safety criteria such as allergen communication.

(d) *Recipe/intrinsic factors*

It is important for the team to be really clear on what is making the product safe—and of course, what therefore might make it unsafe in terms of the intrinsic formulation safety factors. As a processor, you need to be really expert in your food category, so this is an area for the team to spend some time on. Consider the criteria outlined in Chap. 3 such as a_w , pH, chemical preservatives, and organic acids.

Basically at this stage the team needs to answer the question: Which intrinsic factors control the product safety and at what levels?

Table 5.1 Chocolate-chip ice cream—raw material hazard considerations

Raw material	HACCP team notes
Skimmed Milk Powder (SMP)	
Salmonella	When we consider SMP, there is an associated risk of salmonella from historical data; however, the ingredient will undergo a heat process which is lethal to vegetative pathogens. There is no cross-contamination risk at this facility as there is already full segregation of the raw materials before pasteurization from the post-process area, and from other sensitive raw materials such as chocolate chips. This raw material therefore does not require a heightened level of control at the SQA stage for this hazard though the team acknowledges the importance of strong hygiene protocols at their plant.
Allergens (Dairy)	The product must be labeled.
Foreign material	Foreign material is not normally associated with SMP because the milk is filtered before drying and powder is sieved and passed over a magnet immediately before bagging. If foreign material were present it will be due to an equipment malfunction though that should be considered.
Antibiotic residues	Antibiotic residues may carry through to the final product and will not be removed by the heat process. So, as part of SQA, the raw milk supply into the dairy must be monitored.
Cream	
Vegetative pathogens (e.g., <i>Salmonella</i> , <i>Listeria</i> , <i>E. coli</i>)	This hazard is most likely to occur through post-process contamination, e.g., through poor tanker hygiene. However, for the same reasons as SMP, there is no requirement for a heightened level of control at the supplier. The control must be in place at the Iced-delights facility.
Foreign material	There is an in-line filter in place at the supplying dairy.
Antibiotic residues	As per SMP.
Allergen (Dairy)	The product must be labeled.
Liquid sugar	
	No hazards were identified.
Milk chocolate chips	
Salmonella	For chocolate chips there is a hazard of Salmonella being present, which is recognized from historical data in chocolate. The chocolate chips will be added to the ice cream after the heat process, and the consumer will eat the product without any further preparation. This leads us to the decision that a high level of control is required with this raw material, and we should focus SQA resource here accordingly.
Chemical—pesticide residues	These hazards could occur at the growing and raw material storage stages. However, this would be routinely controlled through the prerequisite SQA program.
Allergens (Dairy)	The product must be labeled.

(continued)

Table 5.1 (continued)

Raw material	HACCP team notes
Water	
Protozoa	As an ingredient in this product there would be minimal risk from bacteria due to the heat process. The temperatures may not be sufficient for protozoan parasites such as <i>Cryptosporidium</i> but the risk is considered to be minimal due to the quality of the mains water supply and no history in the region.
Chemical, e.g., toxic metals, pesticides, nitrates	As an ingredient, control of the supply is critical as these hazards may not be processed out. However, this would be routinely controlled through the prerequisite SQA program.
Vanilla flavor	
Microbiological	The processing by the supplier will eliminate any risk of either microbiological or physical hazards.
Physical	
Stabilizer (lecithin)	No hazard identified other than acknowledging that this is soy lecithin and needs to be considered as an allergen in some countries (labeling control).
Plastic tubs and film	
Chemical (plasticizers and additives)	The SQA process must ensure that all chemical constituents are legal and within chemical migration limits for a high-fat ice-cream product.
Waxed cartons, waxed lids, plastic lids	No hazard identified.

(e) Process conditions

Having understood the intrinsic safety factors, it is equally important to be expert in your process:

- Does the process affect the safety intrinsic factors?
- Does the process make the product safe and why?
- Are any hazards likely to be introduced due to the process? Think here about not only the new product but also any existing products in the facility.

(f) Cross-contamination

We considered this in Chap. 4 and the HACCP team need to draw on their expert knowledge of the plant and process activities here:

Are there any obvious risk factors from or to existing products, packaging, and the process environment? Allergen control in addition to pathogen contamination would be an appropriate consideration.

(g) *Intended shelf-life*

Think about all the data gathered together so far as you answered the questions above. It is likely that the Product Development team will be conducting shelf-life studies and will build in some simulated abuse as part of the study. The HACCP team needs to understand:

- How susceptible is the product to food safety failure (or spoilage—whilst not food safety, this can be an indicator of abuse through the shelf-life of the product) if and when it was abused during the course of its intended shelf-life?
- What governs the shelf-life, i.e., are the limiting factors sensory attributes or microbiological deterioration?

(h) *Distribution*

This builds on the previous considerations; once the team has a detailed knowledge of the intrinsic safety factors, and the shelf-life criteria, it will be easier to consider the distribution stage of the product life cycle. Basically the team needs to understand whether the product is susceptible to damage or abuse. If you are producing a product that will be further processed or packed at another location and therefore perhaps transported in bulk, then this is a really important step in the process to consider.

(i) *Customer/consumer-intended and unintended use*

Similar to above:

- Could additional hazards be introduced?
- Is control necessary for any hazards at this stage?
- Although not normally considered as a food safety hazard, could packaging cause health and safety hazards, e.g., injury while opening cans?
- Basically, do you understand all the potential uses of the product, e.g., in different recipes, etc.? This is a really important element, particularly if there are known “unintended” uses for the product, e.g., consumption of raw cookie dough that is designed to be cooked, or the preference for meats that are not fully cooked through.

This information could be recorded in report format or using a simple table, as in the following example (Table 5.2).

When you have established the safety of your individual product designs, and decided on the likely shelf-life, you can move on to look at how safety will be controlled from day to day during manufacture. This is through the establishment, implementation, and maintenance of an HACCP plan for the process, which we will begin to consider in Chap. 6, along with the operation of PRPs and management programs within a hygienically designed facility.

Table 5.2 Product safety assessment: Chocolate-chip ice cream

Example						
PRODUCT chocolate-chip ice cream				FORMULA		DATE 5-11-96
Stage	Considerations	Criteria	Likely hazard	Control measures	Is control possible?	Validation of control
Concept	Targeted at general population including high-risk groups. Domestic use	Frozen product to be eaten without any further process	Vegetative pathogens with low infective dose	Pasteurization, filtration, supplier assurance	Yes	Whilst it is pasteurized at the facility, there will be many ingredients added post pasteurization that must be made safe by the supplier
Ingredients	Sensitive ingredients and supplier control:					Careful control at supplier —effective supplier management (including audit of processing site for hygiene assessment and microbiological test facilities)
	SMP	Dried } Pasteurized, chilled }	Vegetative pathogens (<i>Salmonella</i>) Allergen (Dairy)	SQA	Yes	Supplier's microbiological tests and antibiotic monitoring procedures
	Cream		Antibiotic residues	SQA	Yes	Verify that antibiotic monitoring procedures satisfactorily covered during SQA audits
	Chocolate chips	Ready to use	<i>Salmonella</i> Allergen (Dairy)	SQA	Yes	As above: Careful control at supplier → effective supplier management (including audit of processing site and microbiological test facilities)
	Water	Mains	Chemicals, heavy metals, etc.	Supplier control	Unknown	Legal obligation
						Ensure proactive relationship with water authority

	Stabilizer	White powder	No hazard identified though white powders that look the same could be substituted by mistake	Labeling in plant	–	–	Controlled labeling of all ingredients must be in place in the factory
	Packaging	Plastic tubs and film	Plasticizers and additives	SQA	Yes	Supplier testing results	Ensure that product suitability testing has occurred and is documented as complying with legal requirements
Legal	Ingredients/product	Thermal process control recipe	Food safety		Yes	Regulations as per manufacturing country	Check compliance
Recipe/ intrinsic factors	a_w , pH, chemical preservatives, organic acids	None that will control product safety. Insufficient sugar to prevent microbial growth totally	No—product is frozen	–	–	–	–
Process	Process conditions	Pasteurization failure	Survival of vegetative pathogens	Correct heat process	Yes	Required	Ensure that the effectiveness of the heat process is validated for this formulation. Critical limits will need to be established
		Poor temperature control during ageing	Spore outgrowth	Effective temperature control and stock rotation	Yes	Audited on a monthly schedule. Calibrated temperature recording already in place	None

(continued)

Table 5.2 (continued)

Example					FORMULA		DATE 5-11-96		Page 1 of 4
PRODUCT chocolate-chip ice cream									Recommendations to HACCP team
Stage	Considerations	Criteria	Likely hazard	Control measures	Is control possible?	Validation of control			
	Contamination	Air filtration failure	Introduction of pathogens	Effective filtration	Yes	Required	Check filter size and performance criteria. Microbiologically filtered air necessary		
Post-factory	Shelf-life	Product consumed beyond shelf-life	No hazard identified	—	—	—	—		
	Customer abuse	Temperature abuse	Unlikely—sufficient abuse for growth will render product inedible	—	—	—	—		
		Contamination with serving spoon	Unlikely—only low numbers; will not grow in freezer	—	—	—	—		
			Slight risk perhaps from leaving spoons in water between servings which would be a cross-contamination concern	None possible	No	—	The product is targeted to the domestic market rather than catering; therefore hazards associated with mass servings are unlikely to be realized. Revisit if a “catering” version is launched		

Signed: J. Smith (Position) Development Manager Date: 21-02-12

5.5 Key Points Summary

As we have seen, food safety design requires that you think about a diverse set of systems, procedures, and resources in order that you achieve both a practical and effective food safety management system. The most effective way of assuring food safety is to design it in. There is some complexity here in achieving an effective and best practice system/operation and it is important that all the elements described above are considered when designing for food safety, or when reviewing effectiveness of the existing product and supporting PRP designs.

- Safe design of products, processes, facilities, and management systems and procedures is essential for delivering safe food products to the consumer.
- Key elements of a Food Safety Program include Safe product/process design, HACCP, and prerequisite programs, supported by a culture of supportive management practices. Careful design and planning are essential to the effectiveness of all these elements.
- Product safety design includes consideration of how recipe formulation can control hazards and this needs to be reviewed when changes to existing products or product range extensions are proposed. Establishment of a safe and achievable shelf-life needs to be achieved as part of product safety design.
- Safe process design needs to be confirmed by validation that the process can control all relevant significant hazards.
- Safe raw materials and knowledge of the safety status of all incoming goods are essential when designing food safety systems and controls.
- A formal and methodical approach to product safety assessment for all food products provides the discipline needed to assure that all products can be managed safely within the framework of the food safety program. This is particularly important for businesses operating modular HACCP systems to ensure that all individual product variants are safe.
- All food processing and handling facilities need to be designed to facilitate hygienic/sanitary conditions. Working together with strong PRPs, these provide the basic foundations needed for the manufacture of safe food.

Chapter 6

How to Do a HACCP Study

Having understood how to design safety into product formulations and process environments, we are ready to look at how to carry out the HACCP study. In this chapter we will be identifying and analyzing the potential hazards associated with products during processing and exploring the options for their control. In doing this, we will be looking at a number of useful techniques that will help the team to structure their approach. We will then move on to the identification of the Critical Control Points (CCPs) and start to build up the information required in the HACCP plan—critical limits, monitoring procedures, corrective action, and responsibility. This covers the requirements of HACCP principles 1–5. We will continue to use the fictitious example ice cream product and will look at the construction of a modular HACCP plan for an ice cream manufacturing business.

6.1 What Is the HACCP Plan?

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

The HACCP plan is a formal document that pulls together the key information from the HACCP study and holds details of all that is critical to food safety management. The HACCP plan is developed by the HACCP team and consists of several components—the two essential documents are the Process Flow Diagram and the HACCP control chart, and these may be accompanied by other necessary support documentation. It is normal practice to include a product/process description, and, if a Product Safety Assessment (PSA) has been documented for individual/groups of products (Chap. 5), then these may be filed together. Details of record keeping and verification procedures may also be included, although these could be held

separately within the company quality management system. You will also find it helpful to retain all preparatory documents used by the team, which illustrate the hazard analysis and CCP identification thought processes, although this level of documentation need not be part of the formal HACCP plan.

6.1.1 The Process Flow Diagram

In preparation for the application of HACCP principle 1, a comprehensive Process Flow Diagram needs to be developed. This is a stepwise sequence of events through the whole process, giving a clear and simple description of how the end product is made. It is an essential part of the HACCP plan that enables the team to understand the production process and, very importantly, is the basis for the hazard analysis. It should include details of all ingredient handling procedures and follows the process through to the consumer. Consumer actions may also be included, depending on the terms of reference drawn up by the team (Sect. 6.2).

At the end of the HACCP study all CCPs identified are normally highlighted on the Process Flow Diagram, thus tying it together with the HACCP control chart. The Process Flow Diagram is also useful in providing an overview of the process and control of food safety to customers and regulatory inspectors.

6.1.2 The HACCP Control Chart

The HACCP control chart (or worksheet) contains details of all the steps or stages in the process where there are CCPs. It is normally documented as a matrix or table of control parameters, and contains details of the hazards and control measures associated with each CCP, along with the control criteria and responsibilities.

In order to develop a HACCP system we use the (Codex, 2009b) HACCP principles and follow a number of steps. Whilst we chose to break down the approach to developing a HACCP system into four key stages, Codex defines a logic sequence for application of the principles. This closely aligns with what we have described as Key stage 2, but does not include consideration of the Preparation and Planning (Key stage 1), Implementation (Key stage 3), and Maintenance (Key stage 4) of the overall system. For completeness, the Codex Logic system steps are included here (Table 6.1) alongside the Key stage 2 approach (Fig. 6.1).

Table 6.1 Logic sequence for application of the Codex HACCP principles (Codex, 2009b)

Logic sequence for application of HACCP	
Step 1	Assemble HACCP team
Step 2	Describe Product
Step 3	Identify Intended Use
Step 4	Construct Flow Diagram
Step 5	On-site Confirmation of Flow Diagram
Step 6	List all Potential Hazards, Conduct a Hazard Analysis, and Consider Control Measures
Step 7	Determine CCPs
Step 8	Establish Critical Limits for each CCP
Step 9	Establish a Monitoring System for each CCP
Step 10	Establish Corrective Actions
Step 11	Establish Verification Procedures
Step 12	Establish Documentation and Record Keeping

We covered the assembly of a HACCP team in Chap. 2. One of the first things that the team needs to do is to consider the terms of reference or “scope” of the study. This is usually done before going on to describe the product and its intended use.

6.2 Define Your Terms of Reference

When your team is ready to start its first HACCP study, it is important to agree on the terms of reference or scope before they begin. It is essential that the correct focus is established to prevent the team being overwhelmed with unnecessary detail.

HACCP was originally designed as a food safety management tool, and food safety should be the initial focus. However, as this is a very wide area in itself, the team must decide first where to start, and also, just as important, where the study will end.

There are a number of questions to help with these decisions:
Do you want to cover all types of hazards initially (i.e., microbiological, chemical, and physical) or just one type, e.g., microbiological?

Experienced teams usually look at all types of hazards at once, and this is certainly better from the time management point of view. However, an inexperienced team may find it easier to limit the number of hazard types in the initial study. The process can be revisited again afterwards to look at the other hazard types.

This approach may also be necessary if specialists, e.g., the microbiologist, are only available at certain times.

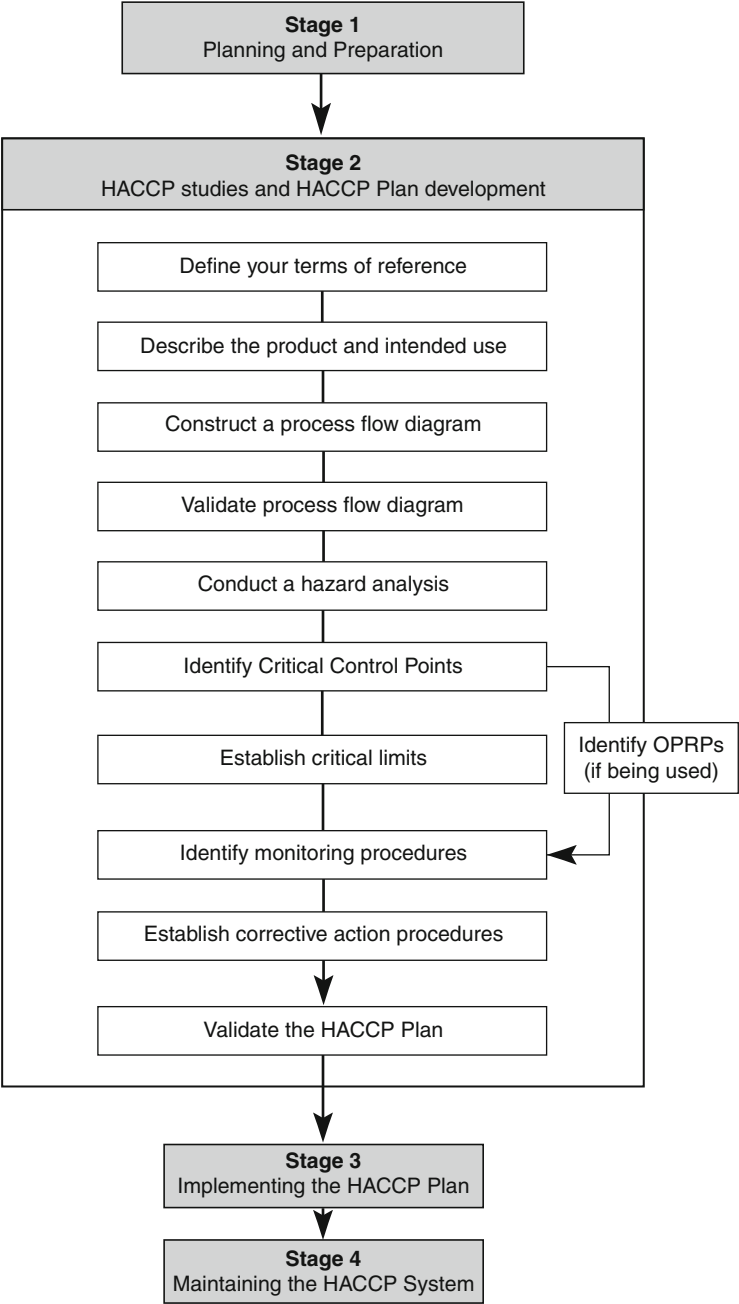


Fig. 6.1 HACCP Key stage 2—HACCP studies and HACCP plan development

Will the study cover a whole process or one specific part, and is this for one or a group of products? That is, what are the start and end points?

This will depend largely on how you have organized your HACCP system. You will have to consider the length and complexity of the process, and whether it divides logically into separate process modules. It is worth emphasizing that, when process modules are fitted together, all process steps must be covered to ensure that no hazards are missed. It is particularly important to investigate what happens to the product when it moves from one process area to the next.

You will want to consider whether this is a farm to fork approach. Could or should any primary producers be included, for example, if the majority of your raw materials are sourced directly from the agricultural producer (e.g., meat or dairy products), and also whether the HACCP study should continue through distribution, retail, and consumer handling once it leaves your direct control? To answer the former question you will need to determine whether the suppliers have the capability to draw up and implement their own HACCP plans. To answer the latter question you will need to consider whether your product is safe at the end of production, i.e., all hazards have been controlled, or whether the product needs special handling. Is it a perishable product that could potentially be rendered unsafe by improper handling, or are you actually relying on consumer action to control any hazards, e.g., in a raw meat product?

When you have answered the above questions you will be able to define your terms of reference for the HACCP study (Box 6.1).

Box 6.1 Case Study—Iced Delights: Ice cream Manufacture
Terms of reference

This HACCP study considers biological, chemical, and physical hazards throughout the entire ice cream manufacturing process.

Biological hazards include vegetative pathogens such as *Salmonella*, *E. coli*, and *Listeria* and toxin-formers such as *Staphylococcus aureus*. Chemical hazards could be associated with the raw materials, e.g., pesticides, aflatoxins, antibiotics, and allergens, or with contamination during the process, e.g., allergens cross-contamination.

The team considered that a wide range of physical hazards would affect the safety of these products, as they are likely to be consumed by small children who may be susceptible to choking on large items.

As the ice cream is to be sold as frozen retail tubs and its safety is unlikely to be affected by storage and distribution, the HACCP study stops at the dispatch stage. The team had decided on a modular approach covering all products produced at the factory.

At this stage in the HACCP process, the Iced Delights team also finalized the structure of their modular HACCP system (Fig. 6.2). The shaded boxes in this figure are the modules that will be covered in detail in our worked example.

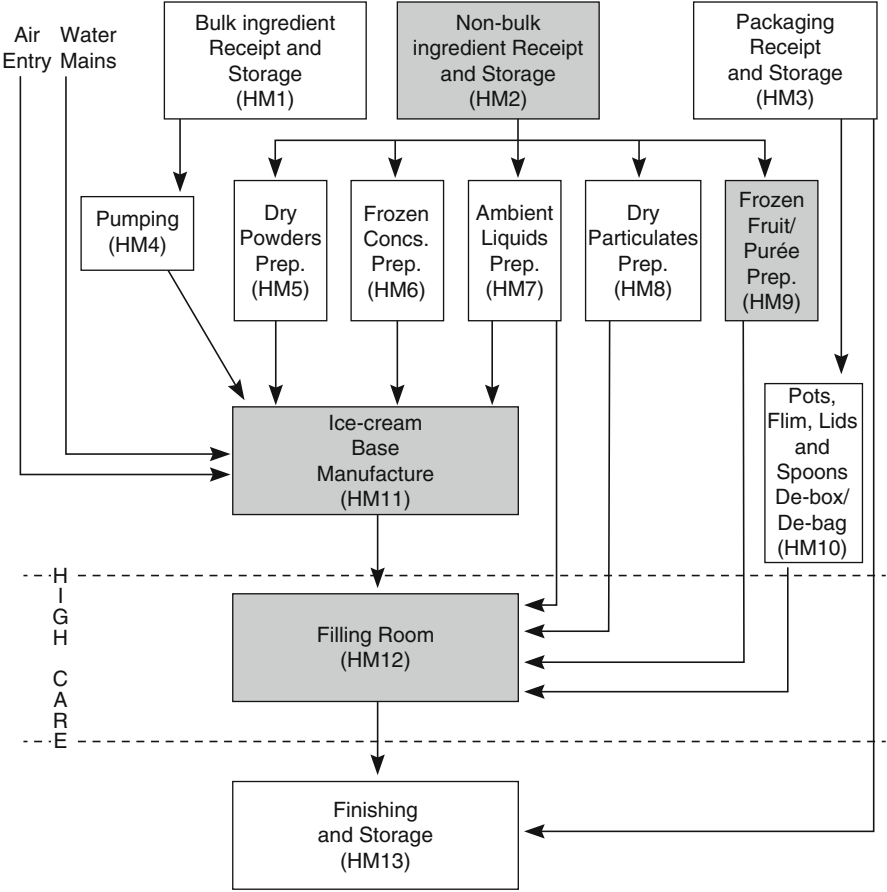


Fig. 6.2 Ice cream modular HACCP system structure (HM: HACCP Module)

6.3 Describe the Products and Their Intended Use

At this stage a product description may be constructed for two reasons. Firstly, it is essential that the team is fully familiarized with the products and process technologies to be covered by the HACCP plan. Secondly, the product description acts as an introduction and point of historical reference to the HACCP plan (Box 6.2). The information that the team captured during the PSA (Chap. 5) will be an excellent starting point.

Physical

- Fruit stalks
- Nut shells
- Metal

Chemical

- Allergens: dairy, nuts, wheat gluten (in shortcake and cookie dough), lecithin (in chocolate)
- Packaging chemical migration issues
- Antibiotics in cream and skimmed milk powder
- Aflatoxin in flour (cookie dough) and nuts
- Adulterants (Melamine in dairy components)

Key control measures:

- Supplier quality assurance activities (specifications, supplier approval)
- Process control steps
- Cross-contamination prevention
- Temperature control
- Labeling

6.4 Constructing a Process Flow Diagram

6.4.1 *Types of Data*

The Process Flow Diagram is used as the basis of the hazard analysis and must therefore contain sufficient technical detail for the study to progress. It should be carefully constructed by members of the team as an accurate representation of the process and should cover all stages from raw materials to end product or the end of the process module, as defined in the HACCP study terms of reference. The following types of data should be included:

- Details of all raw materials and product packaging, including format on receipt and necessary storage conditions.
- Details of all process activities, including sampling and any other routine manual interventions¹ and the potential for any delay stages. It is important that this lists all the individual activities rather than becoming a list of process equipment.

¹ Whilst previous convention was to exclude inspection and sampling activities from process flow diagrams, experience has shown that it is useful to indicate where sampling and other interventions take place from the perspective of identifying where cross-contamination risks may occur.

- Temperature and time profile for all stages. This will be particularly important when analyzing microbiological hazards as it is vital to assess the potential for any pathogens present to grow to hazardous levels.
- Details of any product reworking or recycling loops.
- Storage conditions, including location, time, and temperature.
- Distribution/customer issues (if included in your terms of reference).
- Not typically included in a Process Flow Diagram but in developing it the team can certainly consider and highlight types of equipment and design features that may need to be called out. For example, whether there are any cracks and crevices or dead-end areas where product might build up and/or that are difficult to clean?

It is also useful to draw up a floor plan with details of segregated areas (Chap. 4) and personnel traffic patterns. While it is possible to indicate both process flow and floor plan on the same diagram, HACCP teams usually find it helpful to keep these as two distinct diagrams in the HACCP file.

6.4.2 *Style*

The style of the Process Flow Diagram is the choice of each organization and there are no set rules for presentation. However, it is often felt that diagrams consisting solely of words and lines are the easiest to construct and use. Engineering drawings and technical symbols are used by some companies but, because of their complexity, these may cause confusion and so are not advised. Whichever style of presentation is chosen, a key point is to ensure that every single activity is covered and in the correct order. For large, complex processes, where the modular approach is being used, it is normal practice to prepare a separate diagram for each operation. Where this is done, it is important to show exactly how each diagram fits together and the team must ensure that no stages have been missed out, particularly transfer stages and rework.

6.4.3 *Verify as Correct During Manufacture*

When the Process Flow Diagram is complete (Fig. 6.3) it **must** be verified by the team **prior** to the hazard analysis stage. This involves team members watching the process in action to make sure that what happens is the same as what is written down, and may also involve going in during the night shift or

HM2: Non-bulk ingrediens – Receipt and Storage

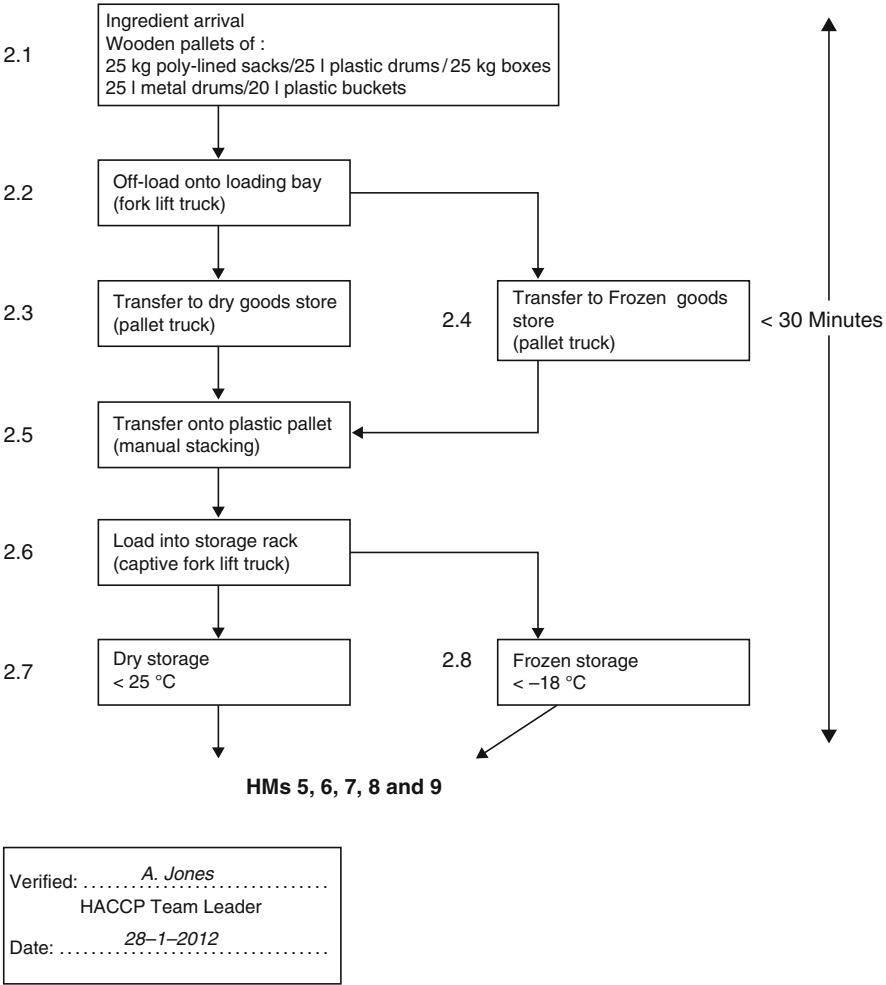


Fig. 6.3 (continued)

weekend shift to ensure that any alternatives are included. It is essential to establish that you have got it right as the hazard analysis and all decisions about CCPs are based on these data.

Figure 6.3 outlines the Process Flow Diagrams for our modular HACCP plan ice cream example.

HM9: Frozen Fruit/Fruit Purée Preparation

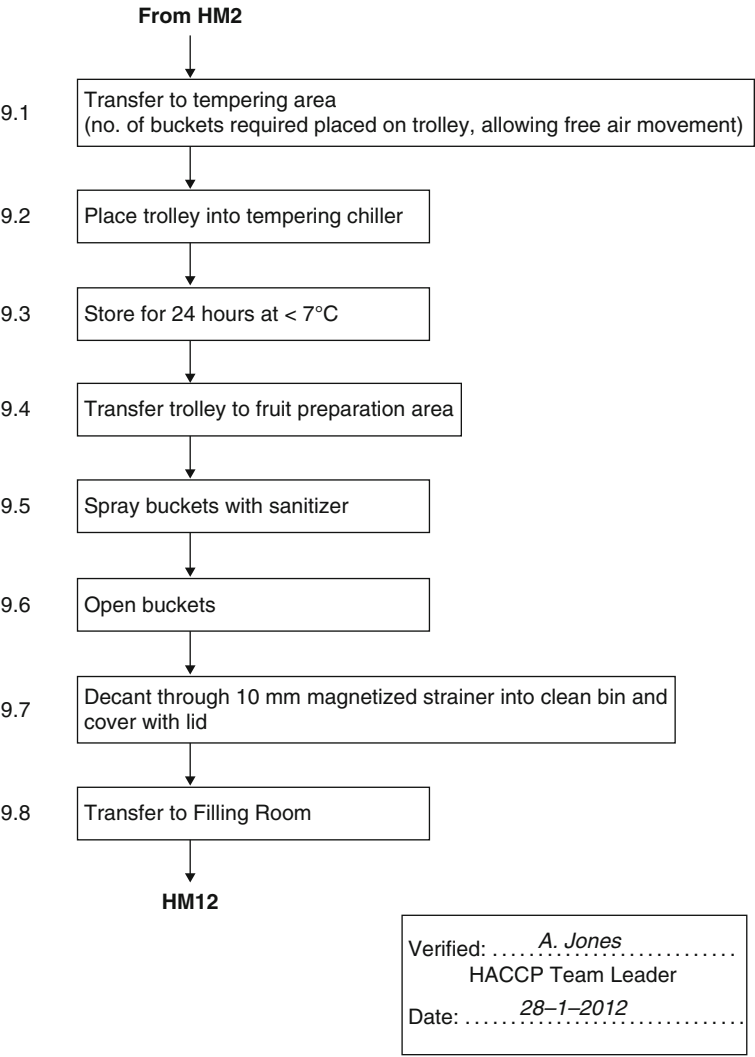


Fig. 6.3 (continued)

HM11: Ice-cream Base Manufacture

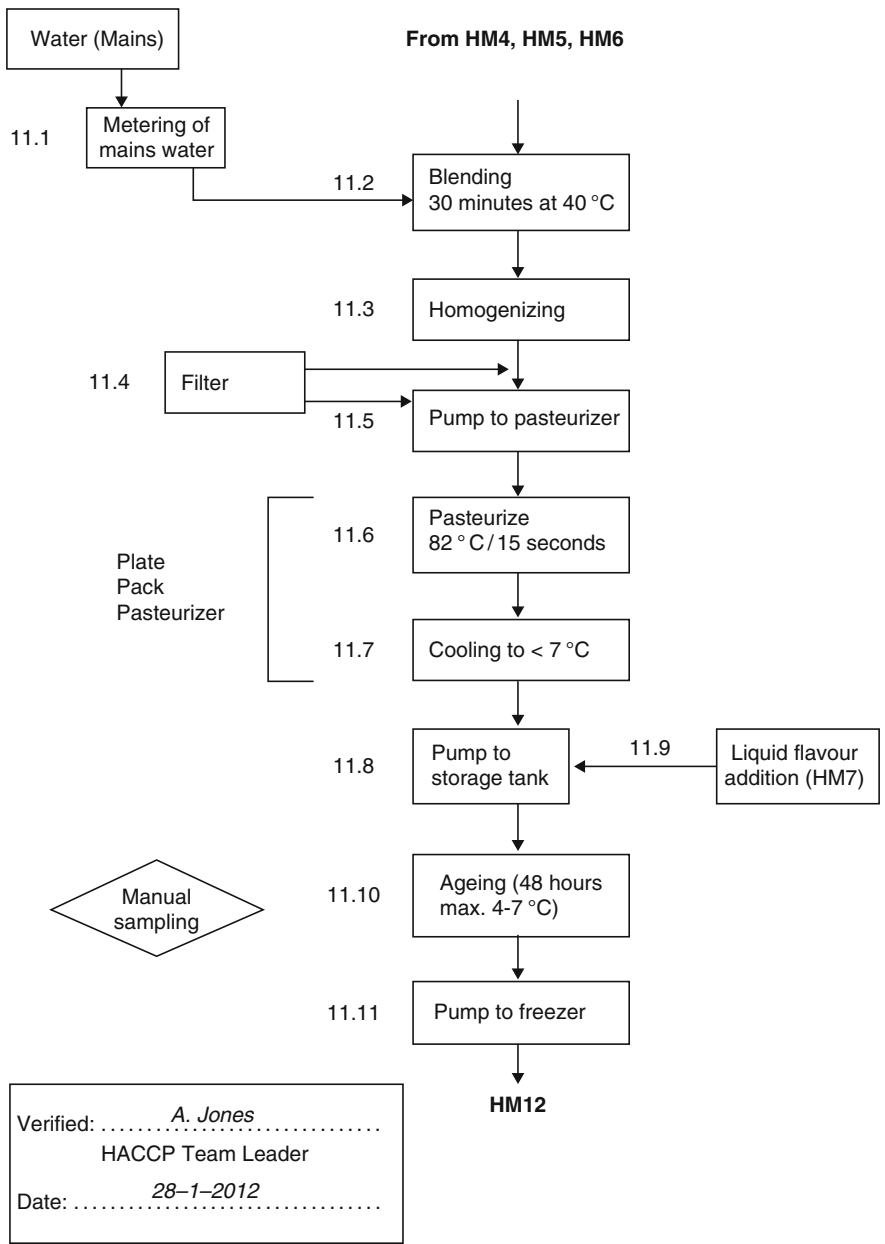


Fig. 6.3 (continued)

HM12: Filling Room (ambient temperature < 10 °C)

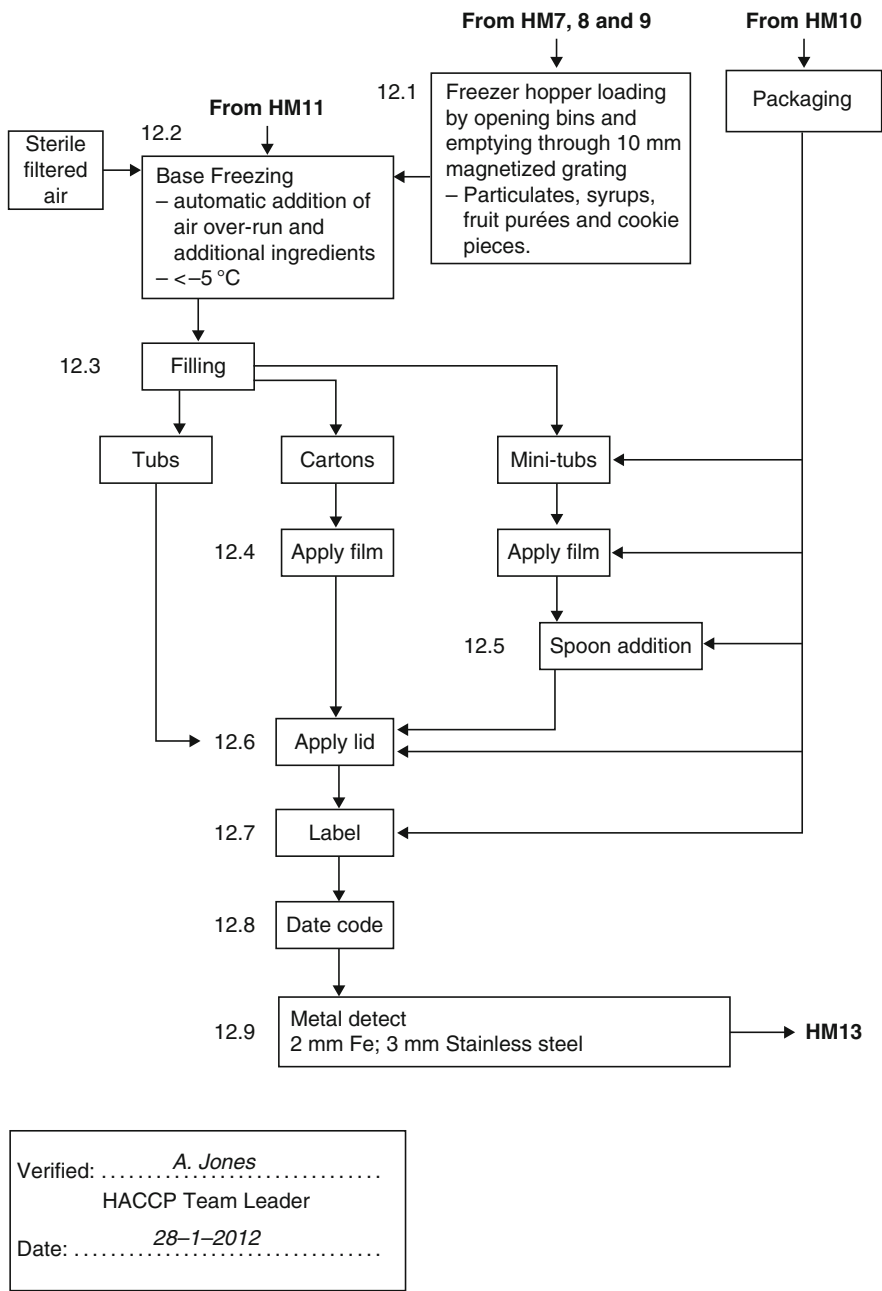


Fig. 6.3 Case study process flow diagrams—ice cream manufacture

6.5 Carrying out the Hazard Analysis

When the Process Flow Diagram has been completed and verified, the team can move on to the next stage of the HACCP study, the hazard analysis, as described by HACCP principle 1. This is one of the key stages in any HACCP study and what makes the difference between a really useful food safety management program or a paper exercise. The team must ensure that **all potential hazards** are identified and considered. Hazard analysis involves the collection and evaluation of information on hazards and conditions leading to their presence, in order to decide which are significant for food safety and therefore should be addressed in the HACCP plan. Several resources and techniques are available to the team to assist in this task, as described in the following sections. However, before starting out on the hazard analysis, all team members must be clear on the meaning of the word “hazard.” Remember, a “hazard” is normally considered to be a factor that may cause a food to be unsafe for consumption. Hazards can be of biological, chemical, or physical nature (Chap. 3).

HAZARD:

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

A biological, chemical or physical agent that is reasonably likely to cause injury or illness in the absence of its control (NAMCF, 1997)

The wording is similar yet NACMCF reminds us that it is during the process of analyzing hazards that we need to think about likelihood of occurrence **“in the absence of it’s control,” i.e., without the influence of existing control measures and prerequisite programs (PRPs)**. During hazard analysis we determine how critical to food safety those control measures and PRPs are.

6.5.1 The Structured Approach to Hazard Analysis

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)

A structured approach to hazard analysis helps to ensure that all conceivable hazards have been identified. It really is crucial that you do not miss any hazards and this will be helped by having input from a wide range of disciplines in your team, working from a comprehensive and validated process flow diagram.

When your team is new to hazard analysis, it is usual to ensure that all potential hazards are identified before moving on to discuss significance and possible control measures. More experienced teams may wish to discuss control measures already in place or required improvements at the same time as conducting the hazard analysis, as it may save time, but—some words of caution—make sure that you do not miss

Table 6.2 Hazard Analysis Chart

Process step	Hazard and source/cause	Likelihood	Severity	Significant Hazard		Control measure
				Y	N	

any hazards out. It is sometimes found that personnel get into deep discussions about the merits of different control measures and that the hazard identification stage either loses momentum or loses its way completely. When this happens, hazards may easily be missed, so it can be better to ensure you have identified them all first before moving on to discuss control options.

It is normal practice to record all hazards in a structured manner against the process steps where they occur or using a Hazard Analysis Chart. An example of a Hazard Analysis Chart is shown in Table 6.2. It is also extremely important to document the source or cause of each hazard, as this helps in identifying the most appropriate effective control measure. The documentation produced is then used as the basis for the hazard analysis and discussion of control measures. The use of such documentation helps to structure the thinking and discussions of the team, and therefore helps to ensure that all potential hazards are included.

At each stage in the process flow diagram, the specific hazards and their causes or sources should be identified. This can be done either formally, through a structured brainstorming session, or informally, as part of a general discussion. Brainstorming is one of a number of standard problem-solving techniques that can be applied successfully to HACCP and is particularly useful at the hazard identification step for a number of reasons:

1. Brainstorming naturally promotes lateral thinking as team members build on each other's ideas. Where team members are analytically or scientifically trained, lateral thinking and new ideas may be repressed and brainstorming helps to overcome this.
2. Where the group members are too close to the process and how it has always been done then it can be difficult to challenge what is known or understood, and

this leads to assumptions being made and ongoing beliefs being accepted. Structured brainstorming helps to cut through these issues, allowing team members to “think the unthinkable.”

3. Brainstorming overcomes the belief that there is always one correct solution to every problem, which can lead individuals into searching for the one correct answer, and in doing so overlooking alternative, less apparent solutions.

Brainstorming is an approach where all team members offer their ideas. An individual is usually allocated the position of scribe to ensure that all ideas are recorded and a time limit may be set to keep the pressure on. Brainstorming is often carried out as a facilitated quick-fire session and team members can say whichever hazards come into their heads. It is successful because other team members are able to think laterally and build on the ideas previously suggested. Ideas are never praised, criticized, or commented on during the brainstorming session because this may influence contributions about to be made.

6.5.2 Questions to Be Considered

The following includes some questions to help with hazard identification based on those put together by the NACMCF (1997); however, the list is not exhaustive, and you may have some additional ideas. Remember to refer to your individual PSA information, the product description, and your own in-depth knowledge of the process environment and, particularly where using the modular approach.

(a) Prerequisite programs (see Chap. 4)

This is an extremely important area for discussion that was covered in much more detail in Chap. 4 where we said that PRPs are used to manage the environment (facility and people) and that operational prerequisite programs (OPRPs) were those PRPs where, if a failure occurred, it was highly likely that a food safety hazard would be present. The team needs to consider whether the required PRPs are in place. How extensive are they? Can they be shown to effectively control any day-to-day hazards within the work environment? Are adequate verification procedures in place to ensure that they are working? **How likely is the product to be cross-contaminated in the manufacturing environment?** To assess this properly, the team needs to be out in the facility, looking hard not just at the facility infrastructure (floors, walls, overheads, equipment) but also observing practices and asking questions of operators in terms of what really happens day to day.

Sanitary/hygienic design is a really important element of the PRP and the root cause of numerous failure events when inadequate. Consider whether there are any hazards directly associated with the facility layout or internal environment? Is segregation adequate between raw and ready-to-eat product? Is positive-pressured filtered air necessary? Do traffic patterns for personnel, raw materials, equipment, and waste cause any cross-contamination hazards?

Consider microbiological, chemical, and physical safety issues. Are there any stages where contamination could build up or where microorganisms might grow to dangerous levels?

Can the facility and the equipment be effectively cleaned? Are there any additional hazards associated with particular equipment? Can the equipment be effectively controlled within the required tolerances for safe food production?

(b) Raw materials

This has been considered already as part of the PSA. Raw materials are a major source of hazards in to your facility so use the data already gathered to confirm that there is a common understanding amongst the team. For large companies the PSA is often done at the head office where the product development team and corporate HACCP team might be located. In these cases the PSA is a very helpful approach to communicating hazards associated with raw materials to the plant-based HACCP team.

Ensure that the team fully understands: What hazards are likely to be present in each raw material and are these likely to be of concern to the process and/or finished product? Are any of the raw materials themselves hazardous if excess amounts are added? You need to really understand your raw materials as a potential source of contamination that is coming into your facility.

(c) Intrinsic factors

Do the product's integral factors (pH, a_w , etc.) effectively control all microbiological hazards likely to be present in the raw materials or that could enter the product as cross-contaminants during the process? Remember there are different types of microorganisms that react in different ways—what will control one might not control another. Which intrinsic factors must be controlled to ensure product safety? Will microbiological hazards survive or will they grow in the product?

(d) Process design

Will microbiological hazards survive any heating step in the process or is there a kill step that will destroy all pathogens? Does the use of reworked or recycled product during the process or in any of the raw materials cause a potential hazard? Consider carefully all forms of microbiological hazards, including spore formers and toxins producers. Is there a risk of recontamination between process stages?

(e) Personnel

Could personnel practices affect the safety of the product? Are all food handlers adequately trained in food hygiene? Do you have adequate hand washing facilities? Are uniforms captive to the facility? Consider where jewelry, medications, personal cell phones, and other personal items are stored and permitted. Are occupational health procedures in place such as reporting illness and injury? Do all employees understand the purpose and significance of both the PRP and the HACCP system, along with how their role affects the process?

(f) **Packaging**

How does the packaging environment influence the growth and/or survival of microbiological hazards? For example, is it aerobic or anaerobic? Does the package have all the required labeling and instructions for safe handling and use, and can these be easily understood? Is the package damage-resistant and are tamper-evident features in place where required? Is coding sufficient to allow product traceability and recall?

(g) **Storage and distribution—what could go wrong?**

Could the product be stored at the wrong temperature and will this affect safety during the shelf-life? Can the product be traced through the distribution chain in a timely manner, and effectively withdrawn from the market place in the event of a food safety issue?

(h) **Customer and consumer usage**

Could the product be abused by the customer or consumer causing it to be unsafe? Are there any **known** consumer practices (e.g., consuming raw cookie dough) that need to be considered?

(i) **Customer and consumer complaints**

Are there any identifiable trends in customer or consumer complaint data? Does this suggest uncontrolled or inadequately controlled hazards in the process?

(j) **Industry sector events**

What have other similar industries experienced? You should research foodborne illness events in the same product and raw material categories as yours. Why did the events occur? Could they have been prevented? How do your systems compare?

6.5.3 Ensuring Sufficient Detail

Some HACCP plans are weak and add little value due to the fact that the team has generalized too much. The team needs to be very thoughtful and specific about the likely hazards. For example, rather than stating “Biological” or even “Pathogens” at a process step the team needs to think in terms of likely **specific** pathogens such as the non-sporeformers; e.g., *Salmonella* spp., *E. coli*, and *Listeria monocytogenes*; the toxin producers such as *S. aureus*; and the spore formers such as *Clostridium perfringens*, *Clostridium botulinum*, and *Bacillus cereus*. Only by getting more specific will the team be able to properly determine the cause of the hazard:

Is it . . .

- **Presence** of the hazard in the raw material or product
- **Growth** (and potential toxin formation) of microorganisms during the process
- **Cross-contamination** with the hazard during processing and handling
- **Survival** of microorganisms through failure of the process step (that was designed to eliminate or reduce to an acceptable level)

Table 6.3 Ice cream case study, freezing stage—hazard brainstorming

Hazard	Cause
<i>Metal Blades from bag-opening knives</i>	<i>Operator lack of care</i>
<i>Jewelry from operators</i>	<i>Through de-bag operators not following personal hygiene policy</i>
<i>Crawling insects</i>	<i>Open top on choc-chip hopper allows entry of debris from overhead structure. As a PRP preventative control measure a cover was identified as being needed to design out the hazard</i>
<i>Condensation from overhead pipes</i>	
<i>Rivets from equipment</i>	
<i>Rust from equipment and overheads</i>	
<i>Flying insects in process area</i>	<i>Insects flying into open hopper (see above)</i>
<i>Polythene from ingredients bag</i>	<i>Poor operating practice at debagging</i>
<i>Pathogenic microorganism on dust in the air</i>	<i>Filter malfunction</i>
<i>Cross-contamination</i>	
<ul style="list-style-type: none"> • <i>Microbiological (vegetative pathogens, e.g., <i>L. monocytogenes</i>) due to residues/debris in the freezer</i> 	<i>Poor freezer cleaning procedures</i>
<ul style="list-style-type: none"> • <i>Chemical (allergens)</i> 	<i>Allergen cross-contamination through inadequate cleaning</i>
<ul style="list-style-type: none"> • <i>Cleaning chemicals left in base of tank</i> 	<i>Inadequate inspection pre-start-up</i>

Also, only by being specific, will the team be able to identify what the really appropriate preventative control measures are. In the case of physical and chemical hazards the same approach can be taken. Instead of stating “foreign material ingress” at a process step, consider the specific (and real) concern based on knowledge of the plant and process. Reference activities or pieces of equipment and then consider specific and appropriate control measures.

As an example, at the freezing stage of the Process Flow Diagram for ice cream, which includes the addition of the particulates such as chocolate chips, the Iced Delights team identified the hazards and their causes shown in Table 6.3 through brainstorming.

Following the brainstorming session, the team should analyze all the hazard ideas but must be careful that no idea is rejected, unless all team members are confident that there is no risk in the process under study.

6.5.4 Severity and Hazard Significance

“Would you rather eat moldy grain and face the chronic low-probability of risk of liver cancer, or would you rather eat nothing at all and face an acute prospect of starvation?” (Sperber, 1995)

Within the HACCP study we need to take a logical, practical approach to risk evaluation. At the end of the hazard identification step, the team will have a list of potential hazards that might occur in the raw materials and during the process. Risk evaluation involves the evaluation of the potential hazards on this list, to establish

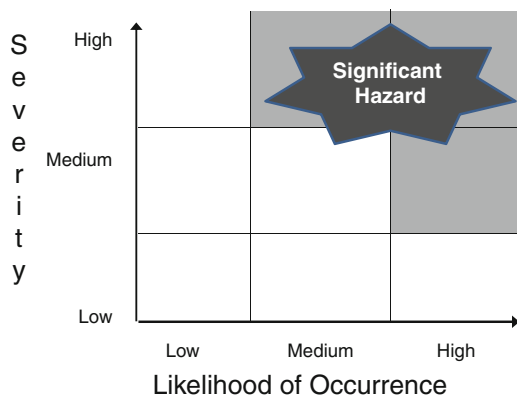


Fig. 6.4 Determination of hazard significance

Risk evaluation categories—key for Fig. 6.4

Likelihood of occurrence	High	Highly probable. Known history in the sector.
	Medium	Could occur. Minimal history within the sector but has happened.
	Low	Unlikely to occur. No known examples.
Hazard severity	High	Life threatening or long-term chronic illness (e.g., infection, intoxication, or anaphylaxis), chronic effects or death.
	Medium	Injury or intolerance. Not usually life threatening.
	Low	Minor effect. Short duration.

the realistic significant hazards that the HACCP system must control. Some useful definitions are:

RISK:

The probability or likelihood that an adverse health effect will be realized (Mortimore and Wallace, 1998)

SIGNIFICANT HAZARD:

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)

A hazard that is likely to occur and that would cause an adverse health effect in the absence of control (Mortimore and Wallace, 1998)

Significant hazards are determined by evaluating their likelihood of occurrence and the severity of the potential effect if they should occur. This is a risk-based judgment performed by the HACCP team and many teams find it helpful to divide “likelihood” and “severity” up into smaller risk evaluation categories to assist in determining significance (Fig. 6.4).

In the scheme illustrated in Fig. 6.4, those hazards with a medium or high likelihood of occurrence and a medium to high severity of effect are considered as being significant.

Table 6.4 Structured risk evaluation

Hazard/source	Likelihood of occurrence			Severity of outcome			Comment
	High	Medium	Low	High	Medium	Low	
For example, presence of Salmonella in raw chicken	✓			✓			Severe outcome if not controlled by the cooking process

ICMSF *Microorganisms in Foods 8: Use of Data for assuring Process Control and Product Acceptance* (2011) has three slightly different classes—moderate, serious, and severe.

Sometimes only two classes are used—low and high—in which case hazards that could cause harm to the consumer, whether life threatening or not, would be classed as high and, similarly, hazards that could occur although there is minimal history would also be classed as high. Here the significant hazards would be those with both high likelihood and high severity.

Whatever wording is chosen, a significant hazard is one with **both** a high likelihood of occurrence (in the absence of control—as per the NACMCF (1997) definition) **and** a severe outcome, as shown in Fig. 6.3. These are the hazards that must be controlled by the HACCP system.

As an extension to this way of thinking, you could also consider the likelihood of detection should the control measure fail (i.e., what procedures can be used to monitor that control is in place and is effective as planned). This is not a requirement of the HACCP process but would help to build in additional measures to strengthen the systems overall.

It is also helpful to use a structured approach to documenting the significance evaluation, thus providing a documented commentary on the evaluation of high, medium, or low risk. This could be incorporated into the Hazards Analysis Chart shown in Sect. 6.5.1 (Table 6.2) to form a hazard analysis and risk evaluation chart or table. An example of this is shown in Table 6.4.

Some teams prefer to carry out risk evaluation as a team discussion in a less structured way, noting at the end their findings on which hazards have been

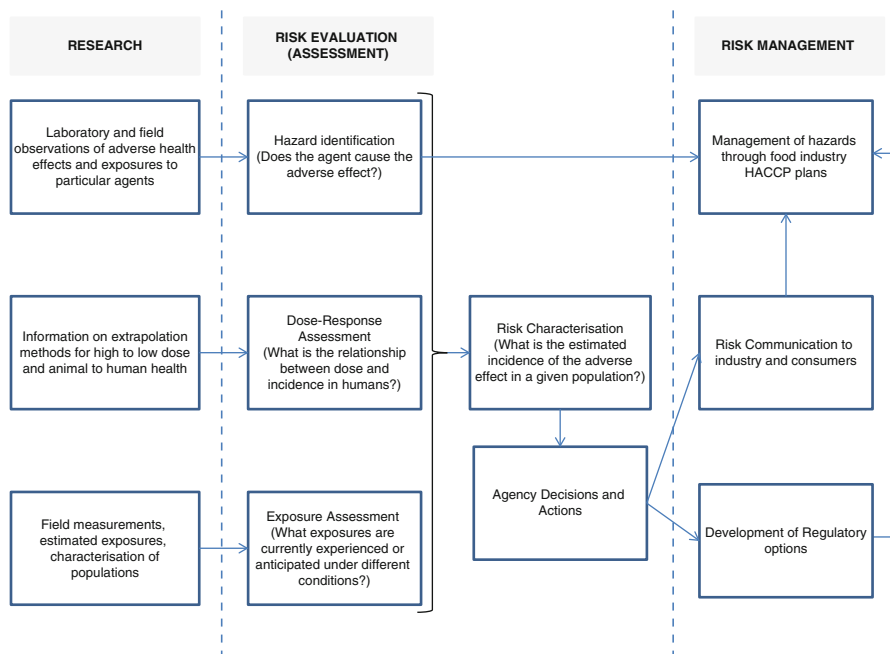


Fig. 6.5 Formal risk evaluation and its link to practical risk management (adapted from National Research Council, 2008)

considered realistic and significant. Whichever approach is taken, a number of questions will need to be asked during the analysis about the potential hazards and about the facility and its processes and systems.

Let us briefly consider formal (quantitative) versus practical (qualitative) evaluation of risk. There has been substantial confusion about risk evaluation regarding the responsibilities of food companies and national/regulatory agencies, i.e., who does what? Whilst food industry HACCP teams will almost always be considering risk in terms of hazard significance in their operation (as detailed above), it is worth taking a few moments to consider how this fits with more formal quantitative assessment of risks to public health that are carried out at national/international levels. The formal process of risk evaluation is based on research information and involves a set of interlinked steps (Fig. 6.5).

- **Hazard identification**

With some similarities to hazard identification done by HACCP teams, this involves considering research information to establish if an agent causes an adverse effect to public health.

- **Dose-Response Assessment** (Also known as **Hazard Characterization**)

This considers qualitative and quantitative estimates of the nature, severity, and duration of the adverse effect relative to the amount or numbers of the hazard

consumed. It is known, for example, that the presence of a low number of *Salmonella* in a high-fat product will be a potential problem. For other organisms (e.g., *S. aureus*) much higher numbers are usually needed.

- **Exposure assessment**

This is the evaluation of the degree of intake likely to occur when a product containing the hazard is consumed. This can be difficult to establish, particularly for microbiological hazards, where numbers may be affected by handling practices after production in perishable products, or where the organism is irregularly distributed, i.e., non-homogeneous. Biomarkers have been used to gauge levels of some exposures, such as lead and dioxin.

These three sets of assessments are then considered together as part of:

- **Risk characterization**

This is the estimation of the adverse effects likely to occur in the population, i.e., the nature and magnitude of human risk.

This type of quantitative risk assessment technique is often used in the field of chemical toxicity. These are detailed studies based on knowledge of likely total exposure to specific chemicals in the food chain, and often experimental effect data, e.g., from studies on mice or rats, are extrapolated to potential effects on humans. Similarly, quantitative risk assessment has also been carried out for microbiological hazards, where historical information on likely microbial or toxin intake in illness outbreaks has been used to estimate the potential adverse effects for particular microorganisms in foods. This is often really a semiquantitative risk assessment, since the number of different factors affecting human susceptibility to infections makes precise evaluation difficult. For example, susceptibility is affected by a number of host-specific factors, such as age and nutritional status, food factors, such as fat content and acidity, and organism factors, such as dose and virulence of the pathogen (Notermans et al., 1995).

Formal quantitative risk evaluation is normally carried out at governmental or international agency level rather than in individual food businesses. Depending on the agency decisions based on this evidence, there is likely to be communication of the risks to industry and, where relevant, to consumers. There may also be development of specific regulations which apply to the food industry.

Because of the problems associated with obtaining meaningful data at business level and having local expertise to deal with it, quantitative risk assessment is not normally the first choice of the company in HACCP team. Instead, for practical purposes, qualitative risk evaluation is more commonly used. This involves forming a judgment on risk, based on knowledge of the product/process and likely occurrence/severity of the hazard, and understanding of the likely use or abuse of the product before consumption to provide an estimate of the degree of harm or adverse health effects that may be caused by an uncontrolled hazard in a food product. In other words, the process requires that the team identify the significant hazards that **must** be controlled by the HACCP system. It should be stressed that, to form this judgment correctly, the team must include an

appropriate level of experience and expertise. This is specialist knowledge and help should be sought from outside the company if not available in house. Even if you do have expertise it can be a really good idea to have an external review and confirmation of the findings. Inexperienced teams would be wise to recognize their limitations and as indicated earlier bring in additional resource where necessary as validation of their own findings.

6.5.5 Reference Materials: Where to Find Them and How to Use Them

A wealth of reference material is available to assist you in identifying and analyzing the hazards in your process.

The members of your team are the first important resource with their collective and multidisciplinary experience of the process and product technology under study. With their different backgrounds and focus areas, team members will be able to gather much of the information and insights needed. The team as a whole should discuss the significance of each of the individual issues identified and ascertain the risk or likelihood of each hazard occurring.

In areas where the team expertise is limited it is important to know where information and advice can be obtained. It is essential that further expertise is secured when required as incorrect evaluation and predictions could have food safety implications.

Chapter 3 gives detail on a wide range of biological, chemical, and physical hazards, along with preventative control measure options. Although this list of hazards and control measures is not exhaustive, it can be a good starting point for the team and can be used to spark off other ideas during a hazard brainstorming session.

Examples of hazards in different product and raw material types can easily be found in the literature in the form of books, epidemiological reports, and research papers. Here again information can be found on the likely behavior of particular hazard types during the process along with possible controlling options. When using literature data to assist with hazard analysis it is vital that the team is able to interpret this data and evaluate the significance to the process under study. Information may also be found through the Internet, in hazard databases, and through the use of mathematical models. Legislation may also help where it highlights particular concerns with specific product types. Again, it is important to be able to interpret the significance of any data found.

If you do not have sufficient expertise available there are a number of organizations and resources where you may obtain support. These include industry trade associations, research associations, universities, regulatory enforcement authorities and external expert consultants, also your suppliers of raw materials and key customers' technical personnel. Check out www.cdc.gov, www.food.gov.uk, www.hpa.org.uk, and www.csiro.au as examples of what is available from the many reputable information sources on the Internet.

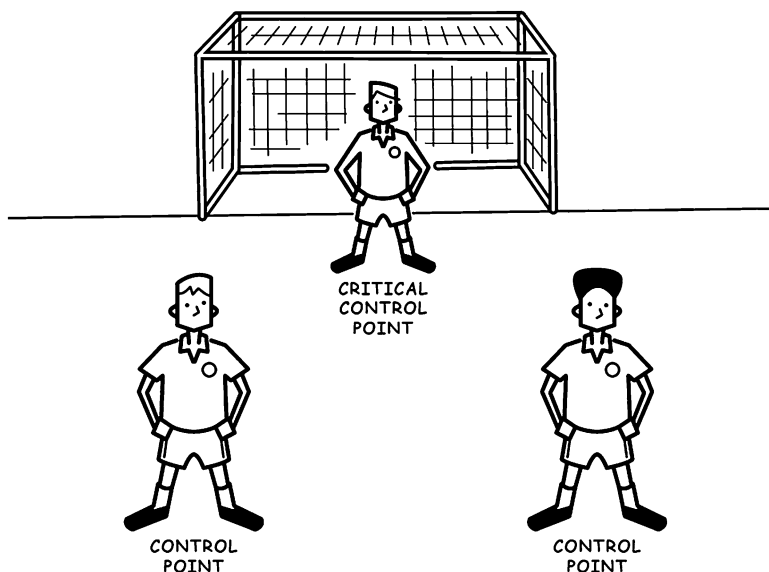


Fig. 6.6 Ensure you have efficient defenses

6.5.6 Identifying Control Measures

When all potential hazards have been identified and analyzed, the team should go on to list the associated control measures (also sometimes known as preventative measures or controls). This is particularly important for the significant hazards but it is useful to consider control measure options for all hazards identified. The control mechanisms for each significant hazard and are normally defined as those factors that are required in order to prevent, eliminate, or reduce the occurrence of hazards to an acceptable level for food safety.

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)

CCPs are essential for product safety, as they are the points where control is effected. However, the CCP itself does not implement control. Instead it is the action which is taken at the CCP that controls the hazard, i.e., the control measure. Examples of control measures can be found in Chap. 3, but as a reminder they include:

- Product intrinsic safety factors (Chap. 5)
- Process controls, e.g., heat kill step, sifting, sieving, metal detection (Chap. 3)
- Environmental controls, e.g., temperature-controlled storage, prevention of cross-contamination such as filtered air and water, chemical control (Chap. 4)
- Supplier control (Chap. 4).

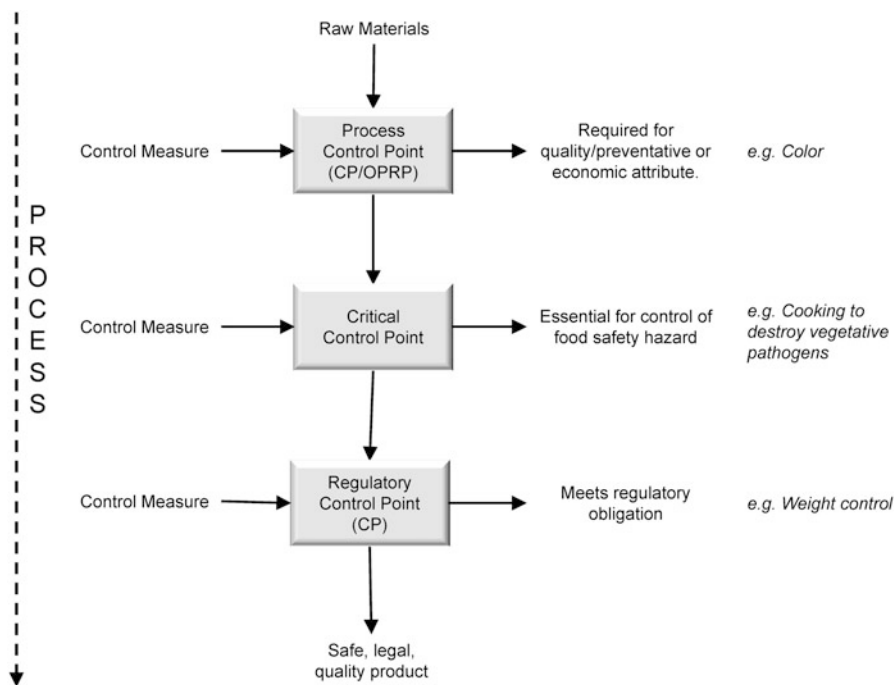


Fig. 6.7 Control measures and control points

Some companies implement additional hazard control points in their processes. These are normally upstream from the CCP for the particular hazard under consideration and are designed either to protect the process and process equipment (Fig. 6.6). Examples are found in bulk operations where each unit of the process may have a hazard-controlling step such as metal detection or magnets. Although hazards are controlled at these points, they are not genuine CCPs as they are not the steps where control *must* be applied for product safety. These additional control points are often described as **preventative** or **manufacturing** control points, or simply **Control Points (CPs)**, and their purpose is to give the process a greater degree of control and often serve to limit the amount of product produced when a failure occurs, i.e., cost effective.

Figure 6.7 shows the various types of additional control points that you might have in your process, including those that may be needed for product attributes, such as color or flavor, and for regulatory compliance. However, as the scope of this book is HACCP and product safety, we will focus on the control measures for significant food safety hazards.

Control measures must always relate to the hazard that they are there to control. They must also be validated as being capable of control at all times.

When evaluating control measures at the control points, it is necessary to consider what you already have in place and what new measures may need to be put in place. This can easily be done using your process flow diagram and/or Hazard

Table 6.5 Hazard Analysis Chart for raw materials

Chocolate-Chip Cookie Dough Ice Cream						
Raw materials	Hazard and source	Likelihood of occurrence	Severity of effect	Significance Y/N	Control measure	Rationale
Skin milk powder (SMP)	Salmonella from supplier cross-contamination	M	H	Y	Pasteurization and post-process control.	Dry powders are always a concern with regard to Salmonella. External history of events in this sector. Need to know about supplier capability.
SMP and cream	Antibiotic residues	L	M	N	Incoming goods testing. Supplier surveillance.	Government oversight of this issue and low likelihood of occurrence given protocols in place.
	Allergen	H	H	Y	Labeling.	
Pasteurized cream	Vegetative pathogens (Salmonella, <i>Listeria</i> , <i>E. coli</i>) through post-process contamination	M	H	Y	Pasteurization and post-process control.	Need to know about supplier capability.
Process air (for incorporation into the ice cream)	Pathogen cross-contamination	M	H	Y	Filtration.	This air is food contact and has to be considered as an ingredient.
Liquid sugar	No hazard identified					
Milk chocolate chips	Salmonella (no kill step in chocolate process)	M	H	Y	Supplier control is highly necessary.	No subsequent step in process. Totally reliant on supplier. Whilst cocoa receives a kill step, chocolate does not and other ingredients in the chocolate may be the source.
	Allergen (dairy)	H	H	Y	Labeling.	
	Metal	L	M	N	Metal detection.	Supplier control and own plant.

(continued)

Table 6.5 (continued)

Chocolate-Chip Cookie Dough Ice Cream						
Raw materials	Hazard and source	Likelihood of occurrence	Severity of effect	Significance Y/N	Control measure	Rationale
Cookie dough	Presence of <i>Salmonella</i> , <i>E. coli</i> , <i>Listeria</i> in raw cookie dough	M	H	Y	SQA and use of heat-treated flour in the formulation.	This has occurred (though rarely) and is a significant issue in that the ingredient is added post-pasteurization. Design control specified use of heat-treated flour.
	Allergen (gluten, egg)	H	H	Y	Labeling.	Supplier control and own plant.
	Metal	L	M	N	Metal detection.	In this manufacturing region the incidents of protozoa in water are rare and there is strong government oversight. However, the team wanted to demonstrate that it was considered.
Water	Protozoa (<i>Giardia</i> , cryptosporidium)	L	H	N	Controlled through the water company and on-site filtration.	
	Heavy metals	L	H	N		
Vanilla flavoring	None likely to occur					
Stabilizer—soy lecithin	Allergen (soy)	H	H	Y	Labeling.	Soy lecithin is regarded as an allergen in some countries.
Packaging—plastic tubes and film	Chemical and plasticizer additives	M	M	N	SQA specifications.	This is a high-fat product but hazard can be controlled at the design stage by specifying appropriate food grade packaging. Taint should be considered but this is not a food safety hazard.

Table 6.6 Hazard Analysis Chart for process steps

Ice cream manufacture HACCP Module 2 (HM2)						
Non-bulk ingredients—receipt and storage						
Process step	Hazard and source	Likelihood of occurrence	Severity of effect	Significance Y/N	Control measure	Rationale
2.1 Ingredient arrival	No hazard identified				–	
2.2 Offload onto loading bay	Chemical contamination: migration of exhaust fumes through packaging. Susceptible high-fat materials, e.g., cookie pieces, nuts, choc-chips	L	L	N	Vehicle engines to be switched off on docking. Introduce new third-party drivers' code to site security rules.	This is a taint issue and is unlikely to be truly hazardous. However, a detectable off-flavor may cause the consumer to feel unwell and perceive a greater risk. The additional control measures identified here would become part of the ongoing GMP program and managed through Standard Operating Procedures (SOPs).
2.3 Transfer to dry goods store	No hazard identified				–	
2.4 Transfer to frozen goods store	No hazard identified				–	
2.5 Transfer onto plastic pallet	No hazard identified				–	
2.6 Load into storage rack	No hazard identified				–	
2.7 Dry storage	Pest ingress during storage	M	L	N	PRP pest control program and good dry storage control is necessary.	
	Growth of mold if stored wet.	M	L	N		Chronic illness from aflatoxin.

(continued)

Table 6.6 (continued)

Ice cream manufacture HACCP Module 2 (HM2)						
Non-bulk ingredients—receipt and storage						
Process step	Hazard and source	Likelihood of occurrence	Severity of effect	Significance Y/N	Control measure	Rationale
2.8 Frozen storage	No hazard identified			–	–	The fruit has a low pH so food safety is not a high concern but spoilage is. Also, temperature abuse may lead to fruit texture deterioration.
Ice cream manufacture HACCP Module 9 (HM9) Frozen fruit/purée preparation						
From HM2						
9.1 Transfer to tempering area	No hazard identified				–	
9.2 Place trolley into tempering chiller	No hazard identified				–	
9.3 Store for 24 h at <7 °C	No hazard identified				–	
9.4 Transfer trolley to fruit preparation area	No hazard identified				–	
9.5 Spray buckets with sanitizer	No hazard identified				–	Cross-contamination of the fruit/purée with sanitizer is not considered to be a hazard due to the small quantities used and the low risk of transfer right through the bucket, even if damaged.

9.6 Open buckets	No hazard identified	H	M		Y	Planned preventative magnet pull strength calibration and cleaning program	–	Metal is usually regarded as a significant food safety hazard if likely to occur and in the absence of control, i.e., the properly functioning magnet, the team felt that this was an appropriate response.
9.7 Decant through 10 mm magnetized strainer into clean bin and cover with lid	Metal carry-through due to magnet malfunction (e.g., magnet not cleaned regularly)	H						The team felt that metal was the most severe of the likely foreign material hazards but if the strainer was damaged then this could be a concern. Historically this type of breakdown does occur.
	Foreign material carry-through due to strainer damage	H	M		Y	Planned preventative maintenance		
9.8 Transfer to filling room	No hazard identified							
↓								
HM12								
Ice cream manufacture HACCP Module 11 (HM11)Ice cream base manufacture								
From HM4, 5, and 6								
↓								
11.1 Metering of mains water	No hazard identified						–	*The possibility of product contamination with high levels of pathogens/toxins should be considered, depending on equipment design and cleanliness. Here, an effective prerequisite cleaning program is in place, verified before each use by ATP hygiene monitoring of surfaces and rinse waters.
11.2 Blending of ingredients	No hazard identified*						–	
11.3 Homogenizing	No hazard identified*						–	

(continued)

Table 6.6 (continued)

Ice cream manufacture HACCP Module 2 (HM2)						
Non-bulk ingredients—receipt and storage						
Process step	Hazard and source	Likelihood of occurrence	Severity of effect	Significance Y/N	Control measure	Rationale
11.4 In-line filtration	Carry-through of foreign material due to filter malfunction	L	M	N	Planned preventative maintenance—filter in place and intact	The likelihood of foreign material being present and of a size that is injurious to health is considered to be remote. Therefore this is not a significant hazard though there would be equipment damage (pasteurizer) if controls failed.
11.5 Pump into pasteurizer	No hazard identified*				–	
11.6 Pasteurize	Survival of vegetative pathogens through not achieving correct heat process (time and/or temperature)	H	H	Y	Correct heat process achieved	This is a known area of risk for this product category.
11.7 Cooling to -7°C	Cross-contamination with pathogens—leakage from raw side of plate pack due to damage and/or inadequate pressure differential	H	H	Y	Correct pressure set up; planned preventative maintenance	

11.8 Pump to storage tank	No hazard identified*						–	
11.9 Add liquid flavor	No hazard identified						–	
11.10 Aging	Outgrowth of spore-forming pathogens due to temperature abuse	L		H		N	Temperature maintenance <7°C. Maximum storage 48 h	Not likely to occur due to short time at this stage.
	Introduction and growth of pathogens due to a sampling intervention at this step	M		H		Y	Specific hygiene operating procedure	Note that sampling has not been shown as a process step but is considered at this stage. This might be an OPRP.
11.11 Pump to freezer	No hazard identified*						Good hygiene practices and temperature maintenance, etc.	
↓								
HM12								
Ice cream manufacture HACCP Module 12 (HM12)Filling room								
From HM7, 8, 9, 10, and 11								
↓								
12.1 Freezer hopper loading—particulates, syrups, fruit purées, and pieces—by opening bins through magnetized grating into freezer hopper	Metal carry-through due to magnet malfunction	L		M		N	Planned preventative maintenance—magnet pull strength calibration and cleaning program. Later metal detector.	Some ingredients have not been through a magnetized grating or metal detector prior to this step.
	Foreign material carry-through due to grating damage	L		M		N	Planned preventative maintenance. Later metal detector.	

(continued)

Table 6.6 (continued)

Ice cream manufacture HACCP Module 2 (HM2)						
Non-bulk ingredients—receipt and storage						
Process step	Hazard and source	Likelihood of occurrence	Severity of effect	Significance Y/N	Control measure	Rationale
12.2 Base freezing—automatic addition of sterile-filtered air over-run and particulates/syrups	Introduction of pathogens in contaminated air	H	M	Y	Effective filtration and planned preventative maintenance.	The possibility of product contamination through poor cleaning of the freezer should also be considered here
	Cross-contamination due to poor cleaning	M	H	Y	Very specific cleaning program.	This might be an OPRP.
12.3 Fill tubs/cartons	Hazardous foreign material ingress from environment or filling heads	L	M	N	Planned preventative maintenance and redesign. Later metal detector.	With effective prerequisite and preventative maintenance the risk is small but the team decided to install a cover over the filler to design out the issue with regard to the environment. A later metal detector will address equipment foreign material.
12.4 Apply film (cartons/minitubs only)	Inability to identify product tampering (malicious contamination) in distribution	L	H	N	Visual inspection with a vision control system.	Include Biosecurity consideration in food defense plan.
12.5 Air filtration	Pathogens cross-contamination due to filter failure.	M	H	Y	Preventative maintenance	This might be a CCP or OPRP
12.6 Spoon addition (minitubs only)	No hazard identified					
12.7 Apply lid	No hazard identified					

12.8 Label	Allergen hazard not identified	H	H	Y	Nuts, eggs, dairy and gluten, etc. all need to be labeled. Bar code scanner in place.	The major allergens within the present range are the presence of nuts. Therefore the possibility of wrongly labeling the product presents both a food safety and a legal noncompliance risk.
12.9 Date code	Inability to trace and recall product	L	H	N	Correct date coding.	There is not strictly a food safety hazard here, more the ability to minimize the effect if a CCP fails. It is vital to be able to trace and recall all products concerned. Therefore it will be appropriate to manage this as part of a quality management system. If a serious event occurred the company could suffer widespread publicity and cost. Additionally, lot traceability is likely to be a legal requirement in many countries. Lot coding also limits the amount returned in the event of failure.
12.10 Metal detect	Metal contamination not identified due to equipment malfunction	H	M	Y	Effective metal detection—calibrated metal detector suitable for product dimensions. Planned preventative maintenance.	

Analysis Charts as a guide, and taking into account the **source or cause** of the specific hazard.

Remember that more than one control measure may be required to control a hazard that occurs at different stages of the process. For example, the potential for contamination with *Listeria monocytogenes* before and after cooking in a ready-to-eat product. For contamination before cooking the heat process might be the control measure, while environmental hygiene controls would be required to prevent contamination after cooking. Similarly, more than one hazard might be effectively controlled by one control measure, e.g., two microbiological pathogens by a heat process, or physical hazards such as glass and metal through use of sifting.

In order to make safe products you must understand how to control the hazards and risks associated with both your raw materials and the process steps. The raw materials should, ideally, contain no hazards (unlikely), or any hazards likely to be present must be controllable by the process or prerequisite Supplier QA program (Chap. 4).

The completed Hazard Analysis Chart shows the hazards and control measures identified by the team for some of the raw materials (Table 6.5) and process modules (Table 6.6) being studied in our ice cream example.

6.6 Making Food Safety Decisions

Significant hazards have to be controlled. Raw material hazards might be controlled by the supplier but process-related hazards need to be controlled in your own plant by the most appropriate methods. There are several tools available which help with the decision process in terms of which of the controls are **critical** for food safety—the CCPs.

6.6.1 Where Are the Critical Control Points?

HACCP principle 2 requires that CCPs are identified. But you need to know how to find them. A CCP is a point, step, or procedure where a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

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)

CCPs can be found by using your thorough knowledge of the process and all the possible hazards and measures for their control. The information established during the hazard analysis should allow the identification of CCPs through the expert judgment of the team and specialist advisers.

However, the location of CCPs using judgment alone can be unfocused; may lead to disagreement within the team, and sometimes results in more points being managed as CCPs than are really necessary or, worse, in essential CCPs being missed. There is always the tendency to err on the side of caution, but designating

too many points as CCPs, rather than correctly identifying the real CCPs, may mean that you lose credibility and commitment as there will always be some points where you are prepared to negotiate a deviation. For example, if a metal detector failed at a raw material stage, you could switch it off and rely on the one at the end of the line, which, as long as the sensitivity is appropriate, would lead to potential increase in the amount of substandard product that is later rejected but with minimal compromise on food safety.

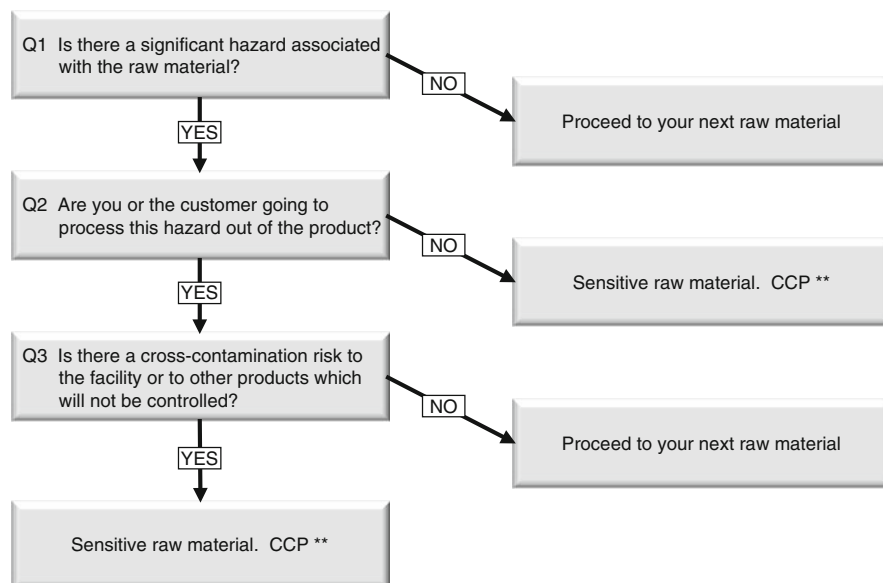
On the other hand, too few CCPs would be even more disastrous and could cause the sale of unsafe food. It is important that control is focused where it is **essential** for food safety and so care should be employed to ensure that the CCPs are correctly identified.

To assist in finding where the correct CCPs should be, a decision tree tool is available (Fig. 6.9). A decision tree is a logical series of questions that are asked for each significant hazard. In the case of the CCP Decision Tree this is for each significant hazard at each process step. We have also developed a decision tree for raw materials to help identify where control of raw materials is critical (Fig. 6.8) to the food safety of your product. How a decision tree works is that the answer to each question leads the team through a particular path in the tree and to a decision whether or not a CCP is required at that step. Using a CCP Decision Tree promotes structured thinking and ensures a consistent approach at every process step and for each hazard identified. It also has the benefit of forcing and facilitating team discussion, further enhancing teamwork and the HACCP study.

Several versions of CCP Decision Trees have been published (Codex, 1993, 1997, 2003, 2009b; Campden BRI, 2009; Mortimore and Wallace, 1994, 1998; NACMCF, 1997) and these have slightly different wording, although they display a common approach to CCP location.

6.6.2 Use of CCP Decision Trees for Raw Materials

In establishing the level of control required for each of your raw materials, it is important to think about how they will be handled and processed. The same raw material may require different levels of control for two different products, e.g., herbs going into a cooked product may require less emphasis on microbiological control at the raw material stage than the same herbs being used as a garnish on a ready-to-eat product. For many companies, testing the high-risk raw materials (ideally at the supplier), with receipt of a Certificate of Analysis (COA), upon delivery has been the primary control measure, even at times being seen as the CCP. This isn't ideal and relies on a solid and statistically valid sampling plan but as indicated earlier, testing is not an assurance of food safety, i.e., a negative test result does not mean that the food is safe. Understanding where a high level of control is needed for the safety of your products is a better approach and allows the SQA focus to be on that smaller list of suppliers who require a detailed level of scrutiny



** High level of control required at the supplier and therefore this is a priority for supplier approved activities. Following the hazard analysis you are likely to find that this raw material must be managed as a CCP at the supplier.

Fig. 6.8 Raw material decision tree (Mortimore and Wallace, 1994, 1998)

including on-site assessments. In order to assist in identifying the level of control needed a question-decision tree has been developed (Fig. 6.8).

We'll start by explaining this raw material decision tree. By following the sequence of questions in the decision tree you will gain an understanding of the level of control required for each of your raw materials. Work through the decision tree as follows.

Q1 Is there a significant hazard associated with this raw material?

This first question may be obvious but it focuses the mind on identification of all food safety hazards associated with the raw material under consideration. If no hazards are identified, then you should move on to the next raw material, but if hazards are identified you should consider Question 2 for each one.

Q2 Are you (or the customer) going to process this hazard out of the product?

If the answer to this question is no, then you could potentially have the hazard in your finished product if you do not implement effective control at the raw material stage. This is therefore a very sensitive raw material and must be subjected to a high level of control, probably as a CCP in the supplier's process. If, however, the answer to this question is yes, then you should go on to consider Question 3. Question 2 also prompts you to consider the customer (or consumer) use of the product. Recent events

such as the consumption of raw cookie dough (Powell et al., 2010) have indicated that you also need to be thinking about known **unintended** uses of the product at this stage (see Chap. 5).

Q3 Is there a cross-contamination risk to the facility or to other products which will not be controlled?

This question investigates whether the hazard could be carried through to your products by direct cross-contamination or via contamination of the facility. This is particularly important in a facility where several different products are being made, as there may be a lethal step built in to control the hazard in its intended product but not to other products it might cross-contaminate. If the answer to this question is no, then you should move on to the next hazard or raw material. If the answer is yes, then control of the sensitive raw materials is essential for food safety, and it is likely that control will be a CCP in the supplier HACCP system. Alternatively you could consider a redesign of your facility such that segregation is possible and the response to this question becomes “no.”

Using the Raw Material Decision Tree will allow you to target Supplier QA resource at the raw materials that are most critical to your operation and products. These raw materials should then be managed through your prerequisite SQA system and to a high degree. Best practice is when a supplier becomes a true partner in food safety management with frequent open communication of issues and test data. Table 6.7 shows how use of the raw material decision tree has structured the identification of hazards for the ice cream case study.

Table 6.7 Chocolate-chip cookie dough ice cream—raw material decision matrix

Raw material	Q1	Q2	Q3	CCP?	HACCP team notes
Skimmed Milk Powder (SMP)					
Salmonella	Y	Y	N	No	When we consider SMP, the answer to Q1 is Yes because of associated risks of salmonella. However, the answer to Q2 is also Yes as this ingredient will undergo a heat process which is lethal to vegetative pathogens. There is no cross-contamination risk at this facility as there is already full segregation of the raw materials before pasteurization from the post-process area, and from other sensitive raw materials such as chocolate chips. This raw material therefore does not require to be managed as a CCP at the SQA stage for this hazard.
Allergen (Dairy)	Y	Y	N	No	Labeling is considered as the process step where the allergen hazard is controlled. Dairy is currently in all products made at the plant.
Cream					
Vegetative pathogens (e.g., <i>Salmonella</i> , <i>Listeria</i> , <i>E. coli</i>)	Y	Y	N	No	This hazard is most likely to occur through post-process contamination, e.g., through poor tanker hygiene. However, the answer to Q2 is Yes and Q3 No, for the same reasons as SMP.

(continued)

Table 6.7 (continued)

Raw material	Q1	Q2	Q3	CCP?	HACCP team notes
Allergen (Dairy)	Y	Y	N	No	Labeling is considered as the process step where the allergen hazard is controlled. Dairy is currently in all products made at the plant.
Liquid sugar	N	–	–	No	No hazards were identified.
Milk chocolate chips					
Salmonella	Y	N	–	Yes	For chocolate chips there is a hazard of Salmonella being present. The chocolate chips will be added to the ice cream after the heat process, and the consumer will eat the product without any further preparation. This leads us to the decision that a high level of control is required with this raw material, i.e., it will be a product CCP, and we should focus SQA resource here accordingly.
Allergen (Dairy)	Y	Y	N	No	Labeling is considered as the process step where the allergen hazard is controlled. Dairy is currently in all products made at the plant.
Air	Y	Y	N	No	Filtered in the plant.
Cookie dough					
Vegetative pathogens (e.g., <i>Salmonella</i> , <i>Listeria</i> , <i>E. coli</i>)	Y	Y	–	Yes	This must be managed by the supplier. The cookie dough is added after the heat kill step.
Allergens (wheat, egg)	Y	Y	N	No	Allergens can only be “process controlled” through label identification. The cross-contamination risk at the plant is managed through sanitary design and cleaning.
Water					
Chemical, e.g., toxic metals, pesticides, nitrates	N	–	–	No	As an ingredient, control of the supply is critical as these hazards may not be processed out. However, this would be routinely controlled through the prerequisite SQA programme.
Stabilizer (lecithin)	Y	Y	N	No	Allergens can only be “process controlled” through label identification. The cross-contamination risk at the plant is managed through sanitary design and cleaning.
Allergens (soy)					

6.6.3 Use of CCP Decision Trees for Process Steps

The questions in the tree should then be asked for each hazard at each **process** step, including receipt and handling of raw materials as they arrive at your facility.

If you have used the previous decision tree for raw materials you will already know where specific CCPs are required to control incoming raw materials **before** they reach your site, i.e., the CCP is at the supplier.

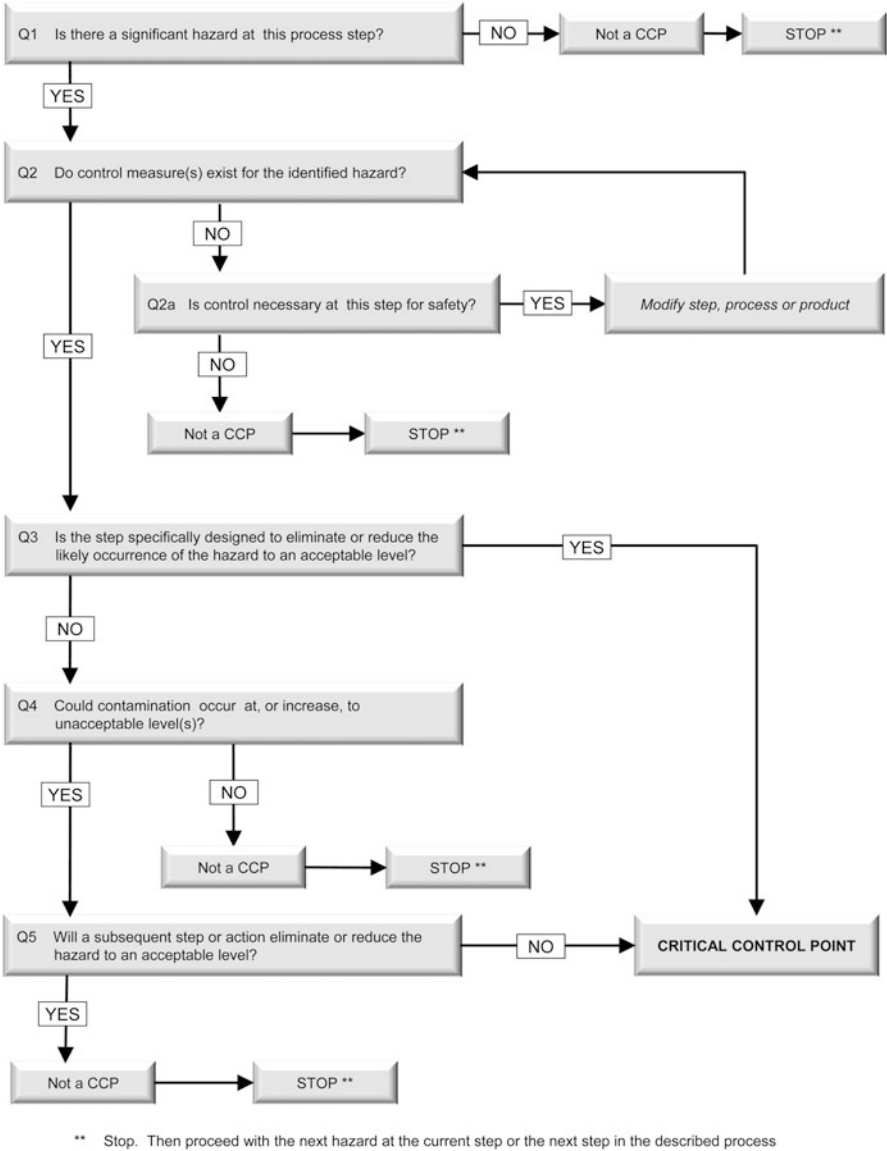


Fig. 6.9 A CCP Decision Tree (adapted from Codex, 2009b)

You will find that it helps to focus on raw materials first at the development stage and should pick these up again with the CCP Process Step Decision Tree (Fig. 6.9) where they arrive as incoming goods at your facility.

Q1 Is there a significant hazard at this process step?

This first question will seem obvious but it helps to focus the team’s minds on the specific process step in question. This is an additional question to that published

within Codex (2009b) and is particularly useful if there is a time delay between carrying out the hazard analysis and determining CCPs. Sometimes a “hazard” identified during brainstorming turns out not to be a significant hazard when reviewed here. Based on the Hazard Significance diagram (Fig. 6.4), consider those hazards with a medium or high likelihood of occurrence and a medium to high severity of effect as being significant. Typically companies will classify anything with a HH, MH, or HM combination as “significant.”

Also at this point, the team should consider what is happening in the environment around that process step and whether there are any hazards specifically related to cross-contamination of the product. Again, this may have been done at the hazard analysis stage but this question allows the team the chance to review and focus. In terms of significance, for microbiological hazards, significance is most likely to be after any pathogen reduction steps. For allergens, the team should consider cleanability of equipment and the ability to effectively segregate. If there are these types of hazards then the team should also consider whether the hazard could be designed out, e.g., through upgrading the working environment or by acquiring some new equipment. The team may continue through the CCP Decision Tree as normal for these types of hazards (i.e., move on to Q2) or, where using the OPRP concept, they could utilize another type of decision tree tool to determine whether they should be managed via an OPRP (see Sect. 6.6.3).

Q2 Do control measures exist for the identified hazard?

Here you need to consider the control measures you already have in place along with what could be implemented, and this is most easily done by referring to your Hazard Analysis Charts. If the answer to this question is yes, then you should move straight on to Question 3.

If, however, the answer is no and control measures are not and could not be put in place, then you must consider whether control is necessary at this point for food safety (Q2a). If control is not necessary here then a CCP is not required and you should move on to the next hazard and start the decision tree again. However, make sure that if you are answering no here because there is control later on and that you actually pick up the later point as a CCP. An example of how this question loop works is for metal detection. Metal detection might not be required for safety at some of the early process steps although they may be associated with a metal hazard. It would, of course, be essential to have a metal detector at the finished-product stage.

If members of the team have identified a hazard at a process step and there are no possible control measures at that or any following step, then you must carry out a modification to build in control. This may involve either the process step, the process itself, the product, or the introduction of a new procedure such that food safety control is possible. For example, if *Salmonella* is likely to be present and your heat process is not sufficient to destroy the organism, then you will need to look at increasing your heat process or building in some other control method. It should be noted that a process step can only operate as a CCP if control measures can be introduced. When the necessary modifications have been established you should ask Q2 again and progress through the tree.

It is important that any necessary changes highlighted at this stage by the team, to the step, process, product, or procedures, are agreed and implemented before the product goes into production. Here you may need to ensure that senior management fully accept the team's findings and provide the required back-up for the change(s) to be implemented. It is useful to create an action list here for any necessary changes and this can be checked through at the implementation stage to make sure the actions have been completed.

Q3 Is the step specifically designed to eliminate or reduce the likely occurrence of the hazard to an acceptable level?

The key thing to remember when asking this question is that it is the **process step and not the control measure** that is being questioned. If team members incorrectly consider the control measure, then they will always answer yes (since control measures are always designed to control hazards), and additional, unnecessary CCPs will result. This question was originally developed to accommodate process steps that are specifically designed to control specific hazards. What the question is really asking is whether the step itself controls the hazard. For example, milk pasteurization at 71.7 °C for 15 seconds is specifically designed to control vegetative pathogens, while ambient storage of raw materials is not specifically designed to control hazards such as pest infestation.

You should consider carefully your hazard analysis information along with the Process Flow Diagram to answer this question, and remember—it is just as important to consider mixing steps, where it may be critical to get the product formulation right, as it is to consider the main processing steps. If the product is not properly mixed, then your intrinsic control mechanisms may not be effective, and a poorly mixed product may have detrimental effects on other processing steps, e.g., the heat process.

If the answer is yes, then the process step in question is a CCP and you should start the decision tree again for the next process step or hazard. If the answer is no, move on to Q4.

Where there is debate over whether or not the process step is “specifically designed” to control the hazard, it is worth noting that an alternative route through the decision tree should ultimately give the same answer.

Q4 Could contamination occur at or increase to unacceptable level(s)?

This question requires your hazard analysis information along with the team's combined experience of the process and processing environment (see Chap. 4). The answer should be largely obvious from the hazard analysis but make sure that you have covered the following issues:

- Is the immediate environment likely to include the hazard(s)?
- Is cross-contamination possible via personnel?
- Is cross-contamination possible from another product or raw material?
- Could composite time/temperature conditions increase the hazard?
- Could product build up in dead spaces in the equipment and increase the hazard?
- Are any other factors or conditions present that could cause contamination to increase to unacceptable levels at this step?

Where there is uncertainty about what constitutes unacceptable levels of a particular hazard, it is important that the team should seek expert advice before making a decision. However, if a completely new process is under study, it may not be possible to obtain a definite answer. Here the team should always assume that the answer is yes and proceed appropriately.

When considering how contamination could increase to unacceptable levels, it is important to understand the possible additive effect during the process for each particular hazard. This means that you may need to think not only about the current process step but also whether any subsequent steps or holding stages between steps could cause the hazard to increase. For example, a number of steps being performed at ambient temperature might give the opportunity for a low initial contamination level of *Staphylococcus aureus* to grow to toxin-forming levels and become hazardous to health.

If the answer to Q4 is yes, i.e., contamination could occur at or increase to unacceptable levels, move on to the next question. If the answer is no, go back to the beginning of the decision tree with the next hazard or process step. This is also where the OPRP controls will be acknowledged (see later).

Q5 Will a subsequent step or action eliminate or reduce the hazard to an acceptable level?

This question is designed to allow the presence of a hazard or hazards at a particular process stage if they will be controlled later in the process. In this way it minimizes the number of process steps that are considered to be CCPs and focuses on those steps that are crucial for product safety.

If the answer to this question is yes, then the current process step is not a CCP for the hazard under discussion but the subsequent step/action will be. For example, correct consumer cooking will control some of the microbiological hazards present in a raw meat product. Similarly, metal detection of finished products at the packing stage will detect metal contamination that may be a hazard associated with the raw materials or an earlier process stage. If the answer is no, then the current process step must be a CCP for the hazard being considered.

Although this question allows the number of CCPs to be minimized, this may not be appropriate in all cases. In the above example of metal detection, the only CCP that is absolutely critical is metal detection at the finished product stage. However, from a commercial point of view, the early detection/control of metal or any other hazard where there is a high degree of risk will be advisable and additional preventative control points may be built in. When this is done it must be made clear that the purpose is to establish additional control in order to minimize product losses.

When working through the decision tree you may find it helpful to designate members of the team as question master and scribe. The team will find it much easier to vocalize (say it out loud) hazards and process steps as they progress through the decision tree, e.g., at Q3: "Is the (insert process step under consideration) step specifically designed to eliminate or reduce the likely occurrence of (insert hazard under consideration) to an acceptable level?" This will ensure that the discussions are structured and that the team does not become side-tracked. It is often also helpful to construct a question-and-answer matrix for each process step

where a hazard has been identified. This could be done on a flip chart so that all team members can see it. Alternatively, this could be an extension to the Hazard Analysis Chart. This is what we did in Tables 6.7 and 6.8.

Before moving on to look at how CCPs are controlled, we will now follow through the Process step CCP Decision Tree for the ice cream HACCP case study

Note: You will notice in Table 6.8 that we have highlighted some environmental cross-contamination issues relating to significant hazards within the table. Whilst PRPs normally cover general contamination issues relating to the processing environment and its management, these were considered significant due to the potential severity with this product group in combination with likelihood of

Table 6.8 Process step decision matrix—ice cream manufacture

Process step—hazard	Q1	Q2	Q2a	Q3	Q4	Q5	CCP	HACCP team notes
HACCP Module 2: non-bulk ingredients receipt and storage <i>No significant hazards identified</i>								Recognized as a routine PRP.
HACCP Module 9: frozen fruit/purée preparation								
9.7 Decant through 10 mm magnetized strainer into clean bin and cover with lid—metal carry-through due to magnet malfunction	Y	Y	–	N	Y	Y	No	Metal detection later on in process.
Foreign material carry-through due to strainer damage	Y	Y	–	N	Y	Y	No	The team considered that it was unlikely that such a robust strainer would be damaged but decided to err on the side of caution and recognize that this can happen (i.e., answered “Yes” at Q4). They concluded that this needs to be on a preventative maintenance program and regular inspection schedule. There are magnets and metal detection later on in the process.
HACCP Module 11: ice cream base manufacture								
11.6 Pasteurize—survival of vegetative pathogens	Y	Y	–	Y	–	–	Yes	Pasteurization is specifically designed to kill vegetative pathogens.
11.7 Cooling—cross-contamination with pathogens due to a fault in the equipment	Y	Y	–	N	Y	N	Yes	This type of hazard is commonly associated with plate-pack pasteurizers.

(continued)

Table 6.8 (continued)

Process step—hazard	Q1	Q2	Q2a	Q3	Q4	Q5	CCP	HACCP team notes
11.10 Aging—Introduction of pathogens (Salmonella) through manual sampling intervention at this step. Environmental cross-contamination	Y	Y	—	N	Y	N	(Yes)	The team is concerned about the presence of pathogens that could be introduced at this step through cross-contamination. A specific procedure will be required which could be a CCP or might be considered for effective management as an OPRP. The team should have in-depth discussions and could utilize the OPRP Decision Tree (see later) to help with the structured debate.
HACCP Module 12: filling room								
12.2 Base freezing—introduction of pathogens through environmental cross-contamination with contaminated food contact air	Y	Y	—	N	Y	N	(Yes)	Concerned about the presence of microorganisms rather than growth in this frozen product., The team will have in-depth discussions in order to determine whether to manage this cross-contamination hazard as a true CCP or whether an OPRP would be an effective management approach.
Environmental cross-contamination with allergens through poor cleaning	Y	Y	—	N	N	N	(Yes)	Similar to above with this allergen cross-contamination hazard. This specific piece of equipment could be managed as a CCP or it might be managed as an OPRP.
12.7 Allergens not identified at labeling step	Y	Y	—	N	N	Y	Yes	Labeling is a CCP and is the final allergen control in terms of consumer alert. Note: The answer to Q4 could have been “Yes” in which case this still becomes a CCP.
12.9 Metal detect—metal contamination (not identified) due to equipment malfunction	Y	Y	—	Y	—	—	Yes	This is the final opportunity for control of metal before distribution and sale to the consumer.

occurrence. Using the decision tree brings us to the conclusion that a high level of control is required for these issues, i.e., they come out as CCPs. However, since they are managed by programs rather than at the specific process step, it becomes logical to consider whether they might better be managed as OPRPs. We will, therefore, come back to look at how that might work in the next section.

Keeping to CCP identification for the moment, you should continue to work through the decision tree (Fig. 6.9) for each hazard present at each process step until all CCPs have been determined. When this has been achieved the team should highlight the CCPs on the Process Flow Diagram and move on to building up the HACCP control chart.

6.6.4 Operational PRPs

As we have stated previously, Codex (2009a, b) does not mention OPRPs. However, due to their requirement in ISO 22000 (ISO, 2005) the term and the approach is becoming more widespread in its use and is, therefore, included here.

We introduced the term OPRP in Chap. 4 and stated that identification of OPRPs occurs during the hazard analysis stage. Whilst this is normally done at hazard analysis, we are placing this section after CCP identification because it is important to understand CCPs first in order to fully grasp the OPRP concept.

The OPRP concept provides that OPRPs can be considered as an **essential** program for managing significant hazards and are, in a way, the missing link between the day-to-day good hygienic operating conditions and CCPs. CCPs manage hazards at a process **step**, whereas OPRPs are programs that are designed to manage hazards across multiple process steps since they are about control of people and/or the process environment.

Let's refer to the relevant definitions that are either in Codex (2009b) or ISO 22000 (2005) which are the primary international references:

PRP

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 22000, 2005)

OPRP

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 product(s) or in the process environment (ISO 22000, 2005)

These definitions are quite different and we've underlined the words and phrases that we think are the key to understanding and using this approach.

It might be helpful to liken these two definitions with those related to specific control measures and CCPs in HACCP:

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)

Critical Control Point: A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level (Codex, 2009b)

PRPs are to OPRPs what control measures are to the CCPs. In other words OPRPs, like CCPs, are **essential** for food safety, i.e., you would not run the plant without assurance that they were in place and operating effectively. PRPs are about basic good hygienic operating conditions aimed at **preventing the introduction of hazards or conditions** which would allow their proliferation. With an OPRP we think about a process or program being used to control introduction of contamination via a direct product vector where subsequent steps will not eliminate or reduce the hazard to an acceptable level. This is usually after the pathogen reduction step in the case of microbiological hazards. Hazard analysis should be used to identify likely sources and vectors of microbiological hazards throughout the process—not only at the process steps but also through general process areas and which may arise through routine and non-routine activities, e.g., product sampling interventions or unclogging a blocked pipe. For any area that you may want to define “GMP” as a control measure for a hazard, try to be more specific—this can be done during the Hazard Analysis stage. At every process step consider the sources and vectors of environmental contamination (this can also be done for some chemical hazards such as allergens). Consider:

- **Sources:** Sources could be people, pests, wooden pallets, raw materials. They can also be microorganisms which are established in niches and harborage sites. Use knowledge of past history in your plant, insights from failures in other companies, and conduct extensive environmental microbiological sampling to understand the risk profile of your facility.
- **Vectors:** Ways that the contamination will transfer from the source to the product. There can be direct transfer from the source of the microbiological contamination to the product, or indirect, i.e., from the source to the product via an environmental vector which acts as a transient or temporary source of contamination. Examples here would be the use of high pressure water hoses where the water acts as a vector to transfer the microorganisms in niches or harborage sites, or hands that are soiled from going to the bathroom, taking out garbage, touching the nose or mouth, i.e., where the hands act as the transfer vector of contamination. In both these cases the water or the hands can be a direct product vector, i.e., when they land on or touch products directly. An indirect vector example would be where the water or the hands land on or touch food contact equipment that will become the temporary source.

To conduct a thorough risk assessment, you will need to look way beyond the actual process steps to include the general plant operating environment. Consider all current control options and determine whether additional ones are needed. Use both visual observations and talk with production operators. The relationship between the source, the transfer vectors, and the product needs to be assessed and fully understood by all employees in the facility. Figure 6.10 shows this

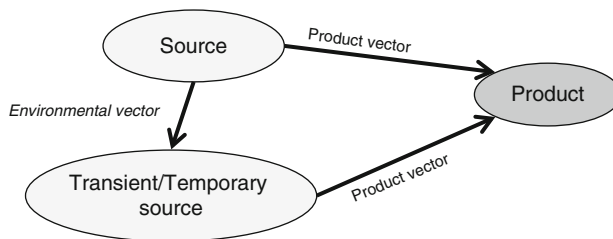


Fig. 6.10 Relationship between sources and vectors of (Microbiological) contamination (Holah, et al., 2012)

diagrammatically. An OPRP is likely to be needed as an essential preventative control where you have these factors in play.

Some examples of OPRPs might be the requirement for HEPA filtration and positive air pressure in a high-risk (post-pathogen reduction) production area or the allergen sequencing (production scheduling) program in a plant that has multiple allergens. OPRPs require a higher degree of scrutiny than PRPs. If there was a failure in the PRP for a period of time, the likelihood of an immediate food safety event would be low, however, with an OPRP, a failure would be highly likely to result in a food safety event, i.e., the plant would not be prepared to run without these programs being strictly adhered to (Chap. 4, Fig. 4.4). For those who find the decision processes helpful, we are including two examples for identifying OPRP's. The first one can be used in parallel to the CCP Decision Tree and is described in Fig. 6.11.

OPRP-Q1 Is there a significant risk of cross-contamination to the product at this process step?

Refer to the Hazard Analysis Chart and any instance where cross-contamination is highlighted as a concern. Cross-check that all likely cross-contamination hazards have been captured by using the process flow diagram (just as you would for the CCP determination) and go back into the plant to look at what is happening around each of the steps.

- What are the likely means of cross-contamination—think about sources and vectors:
 - Environment (e.g., air flow, water, dust)
 - People (where are they in relation to the product, where do they come from, what have they been handling, where else do they work in the plant)
 - Raw materials (e.g., are they on pallets that came from the supplier, how clean is the external packing, what steps) are taken in terms of hygiene before they come into contact with the product
- How exposed is the product at this point?
- What would happen if it became contaminated?

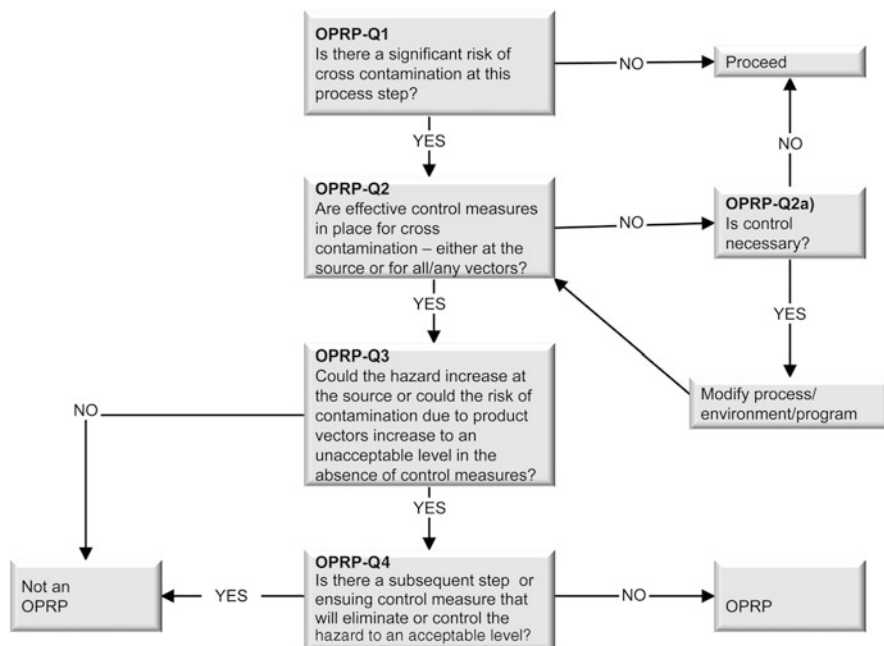


Fig. 6.11 Operational PRP decision tree

Pay particular attention to any intervention into the process flow once the product is considered safe, e.g., post-pathogen reduction step. Also, where the product is exposed to the environment (post-pathogen reduction step).

OPRP-Q2 Are effective control measures in place for cross-contamination—either at the source or for all/any product vectors?

Look at the PRPs that you have in place. This is often where companies need to make changes. If control measures are not in place move to OPRP-Q2a. If they are in place then move on to OPRP-Q3.

OPRP-Q2a Is control necessary? If it isn't then proceed, but if you do need to improve your control at this stage—either the environment itself or to enhance or implement a program, then this is the time when the team can discuss and agree on what needs to be done.

OPRP-Q3 Could the hazard increase at the source or could the risk of product contamination due to vectors increase to an unacceptable level in the absence of control measures?

Look at the CCP Decision Tree work (at Q4) and cross reference to what the team thought about this. Remember that this is not just specific to the actual process steps but everything that happens around them including transfer and holding stages. Look specifically at the hygienic design of the equipment and the plant environment—are there likely niches and harborage sites for microbiological hazards.

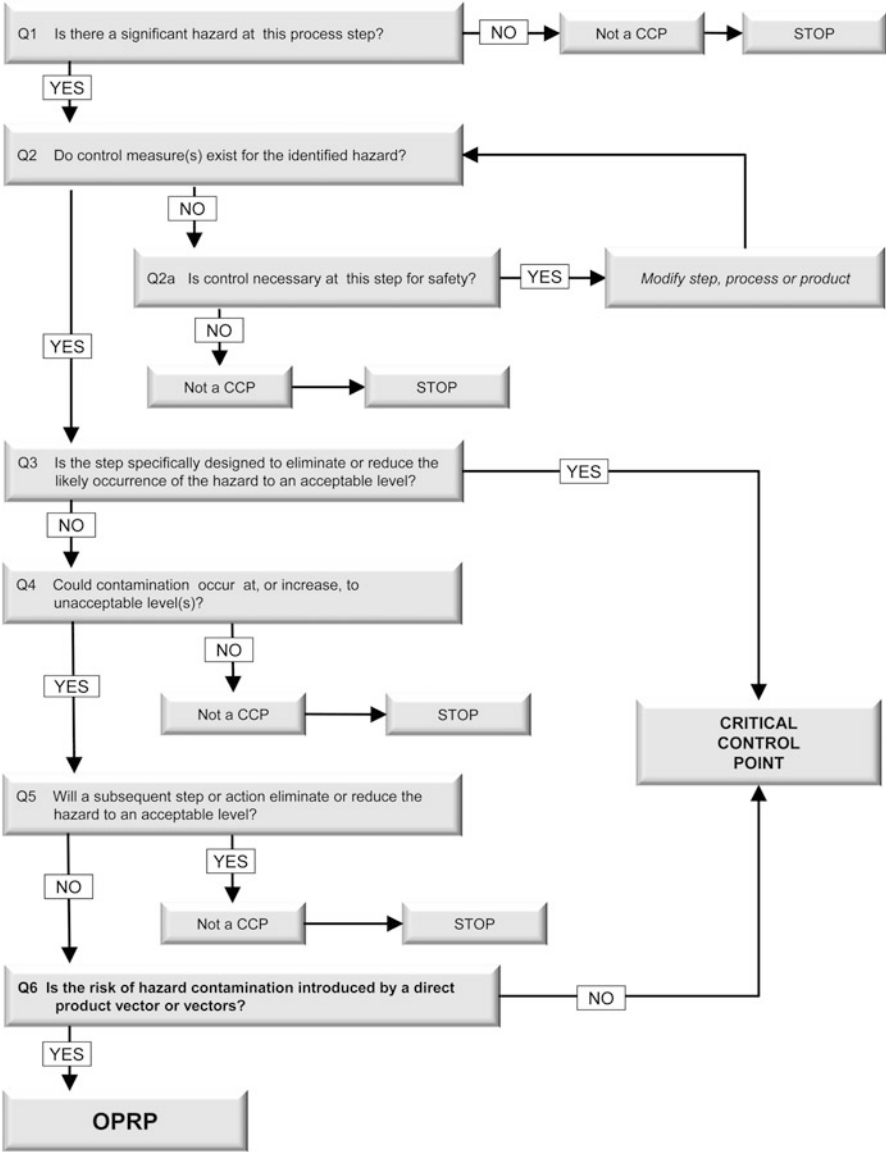


Fig. 6.12 A combined CCP/OPRP decision tree

OPRP-Q4 Is there a subsequent step or ensuing control measures that will eliminate or reduce the hazard to an acceptable level?

Cross refer to the CCP Decision Tree (Q5).
In discussion with colleagues, we present a second example second example of an OPRP decision process (Fig. 6.12). This one is an adaptation of the CCP

Decision Tree. It has an additional question (Q6) which in response to a “no” answer at Q5, simply prompts the HACCP team to consider whether the hazard is introduced by a direct product vector. If yes, then the hazard could be managed by an OPRP, if no, then it must be managed as a CCP.

Either OPRP decision tree may be useful but, as for CCPs, knowledge and experience is needed to determine which hazards could be managed by OPRPs. The decision trees are only tools and if you choose not to use OPRPs then skip this next section of the book.

It is important to focus on the points and programs which are truly critical to product safety, and this means that their number is usually kept to a minimum, specific to each unique process and facility, in order to direct attention accurately on the essential controlling factors. The Iced Delights HACCP team used the OPRP Decision Tree described in Fig. 6.11 for their environmental cross-contamination hazards and decided to manage those hazards as OPRPs within their overall food safety program—Table 6.9.

If you are having difficulties in telling the difference between CCPs, PRPs, OPRPs, and process control points, you should ask yourselves this simple question:

If I lose control at this step is it likely that a health hazard will occur?

If the answer is yes, and you have a specific process control at that step, then the point must be managed as a CCP, and an effective control measure must be identified. (It may, of course, also be a regulatory control point.) Similarly, if the control is through a broader program then it will likely be managed as an OPRP.

The effective operation of all CCPs and, where used, OPRPs is essential to the safety of the product.

6.7 Building Up the HACCP Control Chart

As we saw in Sect. 6.1, the HACCP control chart is one of the key documents in the HACCP plan, holding all the essential details about the steps or stages in the process where there are CCPs. This information could be documented separately elsewhere, but most companies find it easier to hold it all together in one matrix, such as the example shown in Table 6.10.

6.7.1 *What Are the Critical Limits?*

When you have identified all the CCPs in your process, the next step is to decide on their safety boundaries. This is **HACCP principle 3**. You must establish the criteria that indicate the difference between safe and unsafe product being produced so that the process can be managed within safe levels. The absolute tolerance at a CCP, i.e., the division between safe and potentially unsafe, is known as the critical

Table 6.9 OPRP decision matrix—ice cream manufacture

Process step—hazard	OPRP-Q1	OPRP-Q2	OPRP-Q2a	OPRP-Q3	OPRP-Q4	OPRP	HACCP team notes
11.10 Aging—Introduction of pathogens (Salmonella) through manual sampling intervention at this step. Environmental cross-contamination.	Y	N				Yes	The team is concerned about the presence of pathogens that could be introduced at this step through cross-contamination. A specific procedure is not currently in place but will be required. This would not normally have been considered as a CCP so the heightened control that managing as an OPRP provides is appropriate and adds considerable value.
12.2 Base freezing—Introduction of pathogens through Environmental cross-contamination with contaminated food contact air.	Y	Y	–	Y	N	Yes	Concerned about the presence of microorganisms rather than growth in this frozen product. The team decided to manage this cross-contamination hazard as an OPRP because the utilities program is not specific to this process step but needs to be highly visible within the company food safety management program.
12.2 Environmental cross-contamination with allergens through poor cleaning.	Y	N				Yes	The team was concerned that cleaning was problematic in certain areas (e.g., nut filler hopper). Use of duplicate and dedicated equipment could be a part of the Allergen Control PRP but that this particular activity would be managed more closely. This is not currently in place so needs to be purchased.

limit. If the critical limits are exceeded, then the CCP is out of control and there is a high probability that a hazard will exist.

Critical limits:
A Criterion that separates acceptability from unacceptability (Codex, 2009b)

Critical limits may meet (or exceed) national/international regulations, company safety standards, or scientifically proven values. As it is an absolute value it will be a single value, i.e., it cannot be a range. A critical limit is like the edge of a cliff—you are on it or over it, there is no range of uncertainty.

(a) How do you set the Critical Limits?

Since the critical limits define the boundaries between safe and potentially unsafe product, it is vital that they are set at the correct level for each criteria. The team must therefore fully understand the criteria governing safety at each CCP in order to set the appropriate critical limit. In other words, you must have detailed knowledge of the significant hazards, along with a full understanding of the factors that are involved in their prevention or control. Critical limits will not necessarily be the same as your existing processing parameters.

Each CCP may have a number of different factors that need to be controlled to ensure product safety, and each of these factors will have an associated critical limit. For example, cooking has long been established as a CCP that destroys vegetative pathogens. Here the factors associated with control are temperature and time. The critical limits associated with industrial meat cooking, for example, are that the center temperature achieves a minimum of 70 °C for at least 2 min. In cases such as this, where numerical critical limits are required the critical limit will be an absolute value and not a range.

In order to set the critical limits, all the factors associated with safety at the CCP must be identified. The level at which each factor becomes the boundary between safe and unsafe is then the critical limit. It is important to note that the critical limit must be associated with a measurable factor that can be monitored routinely by test or observation. Some factors that are commonly used as critical limits include temperature, time, pH, moisture or *a_w*, salt concentration, and titratable acidity.

Table 6.10 The HACCP control chart

CCP no.	Process step	Hazard	Control measure	Critical limits	Monitoring			Corrective action	
					Procedure	Frequency	Responsibility	Procedure	Responsibility

As team members you will have an in-depth knowledge of the hazards and control mechanisms of the process, and you should have an understanding of the

safety boundaries. However, in a number of cases this may be beyond your in-house expertise and it is again important to know where you can obtain information and advice. Possible sources of information are as follows:

- Published data—Information in scientific literature, the Internet, in-house and supplier records, industry and regulatory guidelines (e.g., Codex, ICMSF, FDA, IDF), and trade associations
- Expert advice—From universities, consultants, research associations, plant and equipment manufacturers, cleaning chemical suppliers, microbiologists, toxicologists, and process engineers.
- Experimental data—These are likely to support critical limits for microbiological hazards and may come from planned experiments, challenge studies where product is inoculated, or from specific microbiological examination of the product and its ingredients.
- Mathematical modeling—Computer simulation of the survival and growth characteristics of microbiological hazards in food systems.

(b) Types of Critical Limit

The factors or criteria that make up the critical limit will be related to the type of hazard that the CCP is designed to control and the specific control measure in place. They may involve numbers—either minimum or maximum values for the given criteria but never a range—for example, maximum pH 4.5 to prevent growth of *Listeria monocytogenes*, minimum temperature/time combination for HTST milk pasteurization 71.7 °C for 15 seconds.

- Chemical limits

These may be associated with the occurrence of chemical hazards in the product and its ingredients or with the control of microbiological hazards through the product formulation and intrinsic factors. Examples of factors involved in chemical limits are maximum acceptable levels for mycotoxins, pH, salt, and a_w , or the labeling or absence of allergens.

- Physical limits

These are often associated with the tolerance for physical or foreign material hazards. However, they can also be involved in the control of microbiological hazards, where the survival or death of the microorganism is governed by physical parameters. Examples of factors associated with physical limits are absence of metal, intact sieve (sieve size and retention), and temperature and time.

- Procedural limits

These are more difficult but usually will be associated with procedural control measures. For example, “debagging (sanitary) operating procedure followed at all times” may be a critical limit where the control measure to prevent packaging materials entering the product stream is a specific debag procedure. Similarly, the critical limit might be “continued approved status” where the control measure is

effective supplier assurance for particular hazards. Where these control measures are part of PRPs, particularly OPRPs, it would be **critical** that the prerequisite elements were working correctly.

- Microbiological limits (or Food Safety Objectives?)

These should normally be avoided as part of the HACCP system. This is because microbiological factors can usually only be monitored by growing the organism of concern in the laboratory, a process that may take several days. The monitoring of microbiological limits would therefore not allow you to take instant action when the process deviates. Instead you might have several days' production quarantined in storage, without knowing where the hazard is present. This is further complicated by the fact that microorganisms are rarely distributed homogeneously throughout a batch, and therefore may be completely missed (remember the limitations of inspection and testing as discussed in Chap. 1). It may be possible to use microbiological limits for positive release of raw materials, but only if the material is homogeneous and a representative, statistically valid sample can be taken.

Microbiological measures are best kept for verification purposes, i.e., where you perform additional tests to ensure that the HACCP system has been effective, as the time scale involved does not create operational difficulties. One exception to this general rule is where rapid microbiological methods can be implemented as part of PRP verification, but even these need to be truly rapid, i.e., minutes rather than hours, to be effective. An example here is ATP bioluminescence, which can be used to demonstrate the effectiveness of cleaning procedures, and the polymerase chain reaction techniques, which are increasingly used as an early warning for microbiological hazards.

When your team have established appropriate critical limits for all CCPs, they should be added to the HACCP control chart as in the example in Table 6.11.

6.7.2 *Validating Your Critical Limits*

It is impossible to discuss critical limits and CCPs without reference to validation. Validation is mentioned in Codex (2009b) as being part of verification (principle 6). However, the team needs to consider validation along the way and in particular as they determine CCPs and define the critical limit.

VALIDATION:

Obtaining evidence that the elements of the HACCP plan are effective (Codex, 2009b).

There are several important tasks to complete before implementing the HACCP plan. Firstly, the HACCP plan elements need to be validated to establish if the control mechanisms you have specified are actually suitable for control of the specific significant hazards that are likely to occur in the process. This is validation, defined by Codex (2009b) as "*obtaining evidence that the elements of the HACCP plan are effective.*" This step is designed to ensure that both the controls will work and that all relevant significant hazards have been identified and addressed.

Table 6.11 Ice cream manufacture—HACCP control chart

HACCP Plan No. HP001				Iced Delights HACCP control chart				Date: March 28, 2012	Supersedes: April 01, 2009
HACCP Module Ingredients:				Iced Delights HACCP control chart				Approved by: Marge Inovera (HACCP team leader)	
CCP no.	Process step	Hazard	Control measure	Monitoring			Corrective action		
				Critical limits	Procedure	Frequency	Responsibility	Procedure	Responsibility
I.1	Chocolate Chips	Salmonella	Effective supplier control. Agreed specification (maximum acceptable levels)	Continued approved status (Audit passed) Absent/50 g					
I.2	Cookie Dough	Salmonella, E. coli	Effective supplier control. Agreed specification (Heat-treated flour) Agreed specification (maximum acceptable levels)	Continued approved status (Audit passed) Absent/50 g					
HACCP Module 11: Ice Cream Base Manufacture									
11.1a	Pasteurizing	Survival of vegetative pathogens	Correct heat process, Operational Limit 82 °C/15 seconds	79.4 °C/ 15 seconds					
			Automatic divert	Divert working					
11.1b	Cooling	Cross-contamination with pathogens	Correct pressure differential	Constant pressure					

(continued)

Table 6.11 (continued)

HACCP Plan No. HP001				Iced Delights HACCP control chart				Date: March 28, 2012		Supersedes: April 01, 2009
								Approved by: Marge Inovera (HACCP team leader)		
CCP no.	Process step	Hazard	Control measure	Critical limits	Monitoring			Corrective action		
					Procedure	Frequency	Responsibility	Procedure	Responsibility	
		due to leaks in plate pack								
	HACCP Module 12: Filling Room									
12.2	Metal detecting	Metal not detected	Effective metal detection	All product passes through a working metal detector						
12.7	Labeling	Allergens not identified	Bar code scanner	All product passes through a working bar code scanner						

At a basic level, this means: **will the controls outlined in the HACCP plan be effective in ensuring food safety?** As you establish critical limits, you need to validate that they will ensure control of the hazards of concern and also that you can adequately achieve the critical limits using the equipment in your facility.

The critical limits can be validated by reference to literature (confirming that, for example, 79.4 °C for 15 seconds is effective to control *Salmonella*) and also through laboratory collaborative studies and capability studies in the plant. Great care must be taken here and it is advisable to use a subject matter expert who can determine whether literature information applies to the specific product/process in question at your facility.

In terms of whether your process is capable of operating to the critical limits, it is at this point that many companies will carry out process capability studies as part of their validation procedures.

For each CCP you will also need to validate that, under normal operating conditions, the process can be realistically and consistently maintained within the defined critical limits. One way of assessing whether a process is capable is to use statistical analysis. Such statistical techniques have been developed and used for many years, predominantly for process monitoring and control in the engineering industry. The techniques are not really difficult to apply, but for those with no prior knowledge the use of a good reference book or, better still, an expert in the field will be invaluable.

In addition, it is useful to further challenge the HACCP plan in terms of the control systems that will be applied should normal control be lost at each CCP. This can be achieved by studying the potential failure modes and considering additional levels of control that may be built in to strengthen the system overall.

These three sets of activities are likely to happen synchronously as they are interlinked and it is only when all three have been completed that the HACCP plan can be said to be fully valid. It is also helpful in practice to do this before you establish the monitoring and corrective action requirements as it helps to more fully understand your process. If you are working in a food business with existing HACCP plans, you will obviously have CCPs already working; however, you will find that following these activities as part of revalidation of HACCP will strengthen the overall HACCP system.

6.7.3 Confirming Process Capability

As part of the HACCP plan the critical limit for each CCP has been established for the control of the significant hazards. These limits will usually only be a minimum value, such as the time and temperature requirements for a heat treatment process, or the limits may be solely a maximum value, such as cold storage temperature. Other CCPs may require a process to be contained between a minimum and a maximum limit, e.g., nitrite in bacon, where the minimum level controls microbiological safety but the maximum level is necessary to ensure chemical

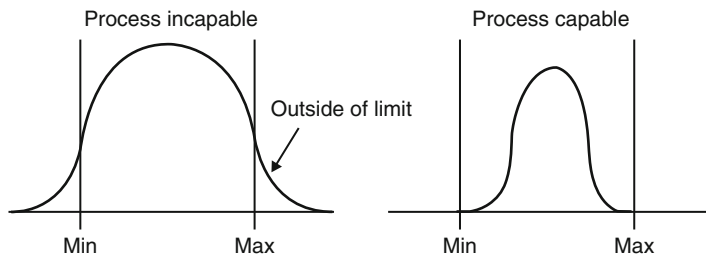


Fig. 6.13 Process capability

safety. Alternatively, it may also be necessary to have a minimum limit in terms of food safety, but also to have a maximum limit in terms of product quality. Process capability studies can show that these critical limits will be achieved within the normal operational variability of the process.

The statistical verification of a process in order to establish the probability (confidence) of its ability stay within specified limits is known as establishing the **process capability** (Fig. 6.13).

A stable process is one that is statistically in a state of control. In assessing the process capability we are doing two things:

1. Determining whether the process is capable of achieving the control criteria (the critical limits) that have been established.
2. Determining whether the process is capable of being controlled.

All processes are subject to natural and inherent variability. This type of variation is known as “common cause” variation and is usually the result of a combination of many small sources of variation within the process. If the common cause variation is known, then we know over what range the process is capable of being controlled. Some processes are subject to “special cause” variation, where the source can be attributed to an unexpected change. These special causes can usually be investigated and corrective action taken to prevent a recurrence.

In establishing the process capability we want to be sure that the process is only subject to common cause variation, i.e., in statistical process control, and that common causes are minimized (Fig. 6.14).

There are a few basic requirements for the application of process capability:

1. A series of random samples/readings are taken from the process in consecutive groups of 5–10 (with 50–100 samples taken in total). These measurements of the process must be obtained at a time when all process controls were left untouched throughout the duration of the run.
2. These readings must be shown to be normally distributed. A normal distribution must meet mathematically defined requirements and has a characteristic bell-shaped appearance (Fig. 6.15). If this type of distribution can be verified as being contained within the defined limits throughout the process, then the process can be said to be running in “statistical process control.”

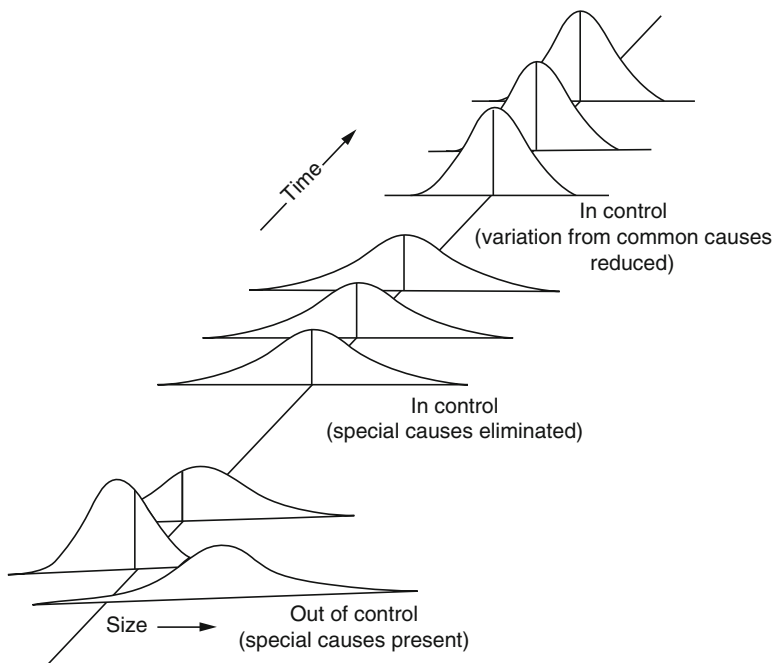


Fig. 6.14 Stages of process improvement

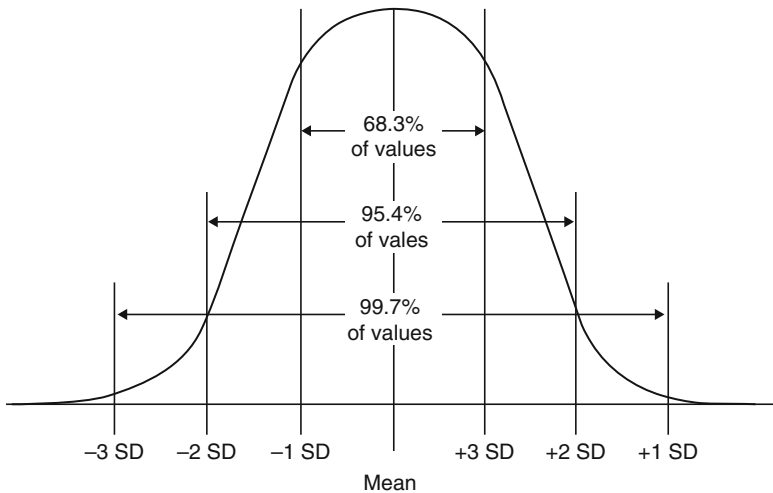


Fig. 6.15 The normal distribution

3. The degree of natural variation (spread) of results within the normal distribution can be quantified numerically by statistical analysis. This measurement is known as the **standard deviation (SD)**. From the standard deviation it can be determined by calculation whether the process is capable, or not capable, of running within defined limits.

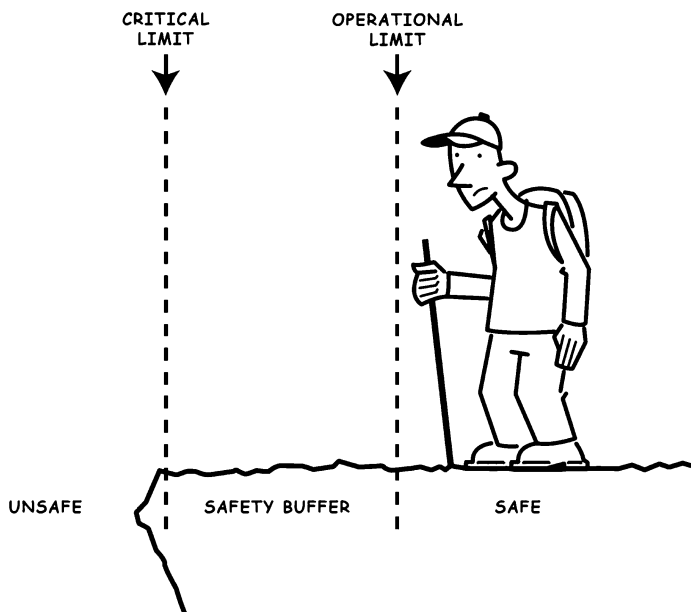


Fig. 6.16 We do not want to run our process on the edge of the food safety cliff

Standard deviation $\times 2 = \pm$ variation from the mean value within which 95.4 % of the process readings/samples would be expected to be found.

Standard deviation $\times 3 = \pm$ variation from the mean value within which 99.7 % of the process readings/samples would be expected to be found.

Process capability must be established for all process-based CCPs **before** the HACCP plan is implemented.

In addition to your critical limits you will find it necessary to have another layer of control to help you manage the process. This can be done by setting up **operational** limits within your critical limits. The operational levels can be used as an additional measure to indicate drift in the process, and you can then adjust the process to maintain control before the CCP actually deviates from its critical limits. In other words a buffer zone for safety is provided (Fig. 6.16). An example of operational limits can be found at the pasteurization step during ice cream production. The critical limits for the destruction of vegetative pathogens through the heat process are 79.4 °C for 15 seconds. In order to make sure that deviation does not occur, the process parameters might be set at 82 °C for 15 seconds, i.e., the operational limit.

OPERATIONAL LIMITS (also sometimes known as action or target levels):

Control criteria that are more stringent than critical limits, and that can be used to take action and reduce the risk of a deviation (Mortimore and Wallace, 1994)

Managing your system to operational limits should ensure that a deviation from the critical limits never occurs. They are set for day-to-day management of the process. Operational limits may be added to the HACCP control chart, e.g., in the

control measures column, or you may choose to document them elsewhere. You will, however, need to ensure that they are documented and that they tie in with your monitoring procedures. The best way of doing this is to document operational limits on your monitoring log sheets, and you must ensure that all monitoring personnel understand how they work.

6.7.4 Finding the Right Monitoring Procedure

Monitoring is the measurement or observation at a CCP that the process is operating within the critical limits. This is HACCP principle 4. It is one of the most important parts of the HACCP system once it is implemented, ensuring that the product is manufactured safely from day to day.

MONITORING:

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

The specific monitoring procedure for each individual CCP will depend on the critical limits, and also on the capabilities of the monitoring device or method. It is essential that the chosen monitoring procedure must be able to detect loss of control at the CCP (i.e., where the CCP has deviated from its critical limits), as it is on the basis of monitoring results that decisions are made and action is taken.

Monitoring procedures may involve:

- In-line systems, where the critical factors are measured during the process. These may be **continuous** systems where critical data are continuously recorded, or **discontinuous** systems where observations are made at specified time intervals during the process. In-line systems are the best type of monitoring as it is real time.
- Off-line systems, where samples are taken for measurement of the critical factors elsewhere. Off-line monitoring is normally discontinuous (unless a continuous sampling device has been used) and this has the disadvantage that the sample taken may not be fully representative of the whole batch.

Most monitoring systems are based on some form of inspection and testing. We pointed out the limitations of inspection and testing as control measures in Chap. 1 and, although these procedures do have serious limitations as control measures, they can be useful indicators that control has been maintained (by the control measures at the CCPs). As monitoring procedures, inspection and testing activities are properly targeted on critical factors throughout the process, and set up through a planned way in order to demonstrate ongoing control. Increasingly, automated online sensors are being used for monitoring to increase confidence that control is being achieved.

The frequency of monitoring will depend on the nature of the CCP and the type of monitoring procedure and the process throughput. It is imperative that an appropriate frequency is determined for each monitoring procedure. For example, in the case of

a calibrated metal detector, the frequency of checks is likely to be every hour, while with a seasonal vegetable crop, the CCP for pesticides may be monitored per application and verified through pesticide testing once per crop season.

It is vital that inspection and testing programs being used to monitor CCPs are valid and appropriate.

The most important issue with allocating responsibility for monitoring is that you ensure that it is properly defined. All personnel involved, need to clearly understand what they are required to do, and also how to do it and what to record. These details should be decided by the HACCP team in conjunction with other management staff and must be fully documented on the HACCP control chart.

As we have seen, monitoring is a key part of the HACCP system operation and it is therefore vital that the persons involved in it understand and are fully accountable for their monitoring actions. Monitoring procedures are closely related to the production process, so it is usually most appropriate that the responsibility for monitoring lies with the Production Department.

We can now fill in the monitoring procedures and frequencies, along with responsibility for each activity, in our HACCP control chart example, shown in Table 6.12.

6.7.5 *Corrective Action Requirements*

HACCP principle 5 requires that corrective action be taken when the monitoring results show a deviation from the Critical Limit(s) at a CCP. However, since the main reason for implementing HACCP is to prevent problems from happening in the first place, you should also endeavor to build in corrective actions that will prevent deviation from happening at the CCP. Your HACCP plan is therefore likely to have two levels of corrective action, i.e., actions to **prevent** deviation from occurring, which will be associated with operational limits, and actions to **correct** the situation and deal with any potentially unsafe product produced following deviation. In this latter case there will need to be further investigation so that actions can be implemented to **prevent** deviation from occurring again. This is root cause analysis.

Corrective action procedures should be developed by the team and should be specified on the HACCP control chart. This will minimize any confusion or disagreements that might otherwise occur when the action needs to be taken. It is also important to assign responsibility for corrective action both to prevent and correct deviations. This will be discussed in more detail at the end of this section.

CORRECTIVE ACTION:

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

Action to be taken when the results of monitoring at the CCP indicate a trend towards or actual loss of control (Mortimore and Wallace, 1998)

As we have seen, there are two main types of corrective action.

Table 6.12 Ice cream manufacture—HACCP control chart

HACCP Plan No. HP001				Ice Delights HACCP control chart				Date: March 28, 2012	Supersedes: April 01, 2009
HACCP Plan No. HP001				Ice Delights HACCP control chart				Approved by: Marge Inovera (HACCP team leader)	
CCP no.	Process step	Hazard	Control measure	Monitoring				Corrective action	
				Critical limits	Procedure	Frequency	Responsibility	Procedure	Responsibility
	HACCP Module Ingredients:								
1.1	Chocolate Chips	Salmonella	Effective supplier control. Agreed specification (maximum acceptable levels).	Continued approved status (Audit passed). Absent/50 g	Audit by trained SQA auditor Check supplier certificate of analysis for compliance	Annual Every lot	SQA Auditor Goods Inwards Operator		
1.2	Cookie Dough	Salmonella, <i>E. coli</i>	Effective supplier control. Agreed specification (Heat-treated flour). Agreed specification (maximum	Continued approved status (Audit passed). Absent/50 g	Audit by trained SQA auditor Check supplier certificate of analysis for compliance	Annual Every lot	SQA Auditor Goods Inwards Operator		

(continued)

Table 6.12 (continued)

HACCP Plan No. HP001				Ice Delights HACCP control chart				Date: March 28, 2012	Supersedes: April 01, 2009
								Approved by: Marge Inovera (HACCP team leader)	
CCP no.	Process step	Hazard	Control measure (acceptable levels).	Critical limits	Monitoring			Corrective action	
					Procedure	Frequency	Responsibility	Procedure	Responsibility
	HACCP Module 11: Ice Cream Base Manufacture								
11.1a	Pasteurizing	Survival of vegetative pathogens	Correct heat process, Operational Limit 82 °C/ 15 seconds	79.4 °C/ 15 seconds	End of holding tube temperature measurement via chart recorder. Visual inspection and sign off	Continuous	Production Operator		
			Automatic divert	Divert working	Check automatic divert operation	Twice daily (start and end of production)	Production Operator		
					Check temperature sensor against traceable calibrated thermometer	Daily	Production Operator		
11.1b	Cooling	Cross- contamination with pathogens due to leaks in plate pack	Correct pressure differential	Constant pressure	Check pressure gauge	Daily start-up	Production Operator		

	HACCP Module 12: Filling Room								
12.2	Metal detecting	Metal not detected	Effective metal detection	All product passes through a working metal detector	Check metal detector is working at start-up and throughout the run— with specified test pieces	Start-up and hourly. Include end of run	Production Operator		
12.7	Labeling	Allergens not identified	Bar code scanner.	All product passes through a working bar code scanner	Check bar code scanner is working at start-up and throughout the run	Start-up and hourly. Include end of run	Maintenance Operator		

1. Actions that adjust the process to maintain control and prevent a deviation at the CCP

This first type of corrective action normally involves the use of operational limits within the critical limits. When the process drifts towards or exceeds the operational limits it is adjusted, bringing it back within the normal operating bands.

This is typified by in-line continuous monitoring systems that automatically adjust the process, e.g., automatic divert valves in milk pasteurization that open when the temperature falls below the operational limit, sending milk back to the unpasteurized side. However, preventative (corrective) actions can also be associated with manual monitoring systems where the CCP monitor takes action when the operational limits are approached or exceeded, and thus **prevents** a CCP deviation.

The factors that are often adjusted to maintain control include temperature and/or time, pH/acidity, ingredient concentrations, and flow rates. Some examples are as follows:

- Continue to cook for longer to achieve the correct center temperature.
- Add more acid to achieve the correct pH.
- Chill rapidly to correct storage temperature.
- Add more salt to the recipe.

When adjusting the process to maintain control, you must ensure that you can do so without causing or increasing the hazard. For example, if the product temperature had risen above 5 °C and you implement rapid chilling to bring it back down, then you must know that the temperature has not risen high enough for long enough to allow the growth of any microbiological hazards that might be present.

2. Actions to be taken following a deviation at a CCP

Following a deviation it is important to act quickly. You will need to take two types of action and it is vital that detailed records are kept.

- Adjust the process to bring it back under control.

This may involve stopping and restarting the line if it is not possible to return the process to its normal operating level during production. Possibly a corrective action will involve the provision of a short-term repair so that production can restart quickly with no more deviations, while the permanent corrective action takes a longer period of time, e.g., the provision of temporary off-line metal detection until the in-line metal detector is repaired.

- Deal with the material that was produced during the deviation period.

In order to handle non-complying materials effectively you will need to implement a series of further actions:

1. Place all suspect product on hold.
2. Assess the situation, seeking advice from the team, facility management, and other relevant experts. Here it is important to consider the likelihood of the hazard being present in the product.
3. Conduct further tests, where appropriate.

When you have obtained sufficient information, the decision about what should happen to the product can be taken. This would probably be to:

1. Destroy the nonconforming product.
2. Rework into new products.
3. Direct nonconforming product into less sensitive products such as animal feed (with appropriate hazard analysis to determine fitness for purpose).
4. Release product following statistically based sampling and testing.

Destruction of the non-complying product is the most obvious action, and the main one to be taken when the likelihood of the hazard occurring, in products, which cannot be reworked, is high. However, this has the disadvantage of being costly and is therefore normally the action of last resort.

Reworking the product can be carried out where the hazard would be controlled through the reworking process. It is important to ensure that any reworking does not cause new hazards in a secondary product, e.g., when allergenic ingredients such as nuts are reworked into a product where they will not appear on the pack ingredients listing. The key here is to rework like with like and to include this activity within the HACCP system.

If the product can be diverted into another safe use then this is another option. This might involve diverting into another product where the hazard will be controlled, for example, where it is treated as a potentially contaminated raw material and will receive a subsequent kill step. Note in these situations the possibility of cross-contamination in the plant must also be evaluated. Here the presence of heat-stable toxins must be carefully considered.

You may decide to sample and test the product to help establish how widespread the contamination is. Great care must be taken when implementing sampling regimes due to the low statistical probability of detecting the hazard.

It is imperative that you do not release the product if the CCP fails. Product safety is not negotiable and product manufactured during a deviation cannot simply be released. In addition to the serious impact on human (or animal) health, the company's legal position would be untenable if hazardous products were knowingly sold.

It is important that detailed records are kept of all stages. It is essential that you investigate the cause of the deviation and take appropriate steps to ensure that it does not happen again. The defined corrective action procedures are added to the HACCP control chart that should detail:

- What is to happen to the suspect product
- How the process/equipment is to be adjusted
- Who is to do what
- Who is to be informed

The brainstorming technique can be utilized during this discussion. What are all the likely failure modes and how would the team respond in terms of corrective action? What you don't want to see in the Corrective Action column of the chart is

“Contact QA Manager”—something well thought through and specific will be of more value to the company.

It is a very important that the team carries out a detailed investigation to determine the actual root cause of the failure so that preventive actions can be taken. This is essential to ensure that a recurrence does not happen a second time. Various problem-solving techniques can be employed including brainstorming, use of Pareto charts and “why why” analysis. It is likely that the team will need to collect and review data to confirm their hypothesis before implementing the required preventive actions.

Responsibility for taking corrective action will depend on the monitoring activities but day to day this will often lie with the Production Department who are implementing the HACCP plan. You should consider assigning particular responsibilities at different levels in the management structure and across functions.

On-line responsibilities of the CCP monitor or line operator will often involve the notification of a supervisor who will then coordinate further actions. However, responsibility may also be given at this level for stopping the line or adjusting the process in order to prevent large quantities of product being made while the CCP is out of control.

Off-line, more senior responsibility will be appropriate where the corrective actions involve shutting down the plant for periods of time or where disposition actions and root cause analysis are required. These decisions need to be taken by personnel who have the knowledge to recommend the appropriate corrective action for product manufactured during a deviation, as outlined in the previous section. This may involve the team Leader in discussion with facility management. However, if the team Leader is an expert in HACCP techniques rather than in hazards and their associated risks, it is important that other experts should be involved in the decision-making process, e.g., toxicologists, microbiologists, process specialists who could be external to your company.

It is also important to ensure that the individuals who are responsible for documenting and signing off the corrective action procedures are defined. This information will be crucial in proving that the required action has been taken, particularly important for legal protection.

At this stage the HACCP control chart should almost be complete as in our example in Table 6.13. The remaining verification columns will be discussed and completed in Chap. 7.

The locations of CCPs should then be added on the final Process Flow Diagram for retention in the HACCP plan, as in Fig. 6.17.

6.8 Validation of the HACCP Plan

When you have completed your HACCP control chart and highlighted all CCPs and OPRPs on your Process Flow Diagram then the HACCP plan is complete. You have already validated the critical limits but, before going on to implement the plan it is important to know that it is correct and valid—a final check that you have got it

Table 6.13 Ice cream manufacture—completed HACCP control chart

HACCP Plan No. HP001				Iced Delights HACCP control chart				Date: March 28, 2012		Supersedes: April 01, 2009
								Approved by: Marge Inovera (HACCP team leader)		
CCP no.	Process step	Hazard	Control measure	Critical limits	Monitoring Procedure	Frequency	Responsibility	Corrective action		
								Procedure		Responsibility
1.1	HACCP Module Ingredients: Chocolate Chips	Salmonella	Effective supplier control. Agreed specification (maximum acceptable levels).	Continued approved status (Audit passed). Absent/50 g.	Audit by trained SQA auditor. Check supplier certificate of analysis for compliance	Annual Every lot	SQA Auditor Goods Inwards Operator	Change supplier. Reject and report to QA Manager.		Purchasing manager Goods Inwards operator
1.2	Cookie Dough	Salmonella, <i>E. coli</i>	Effective supplier control. Agreed specification (Heat-treated flour). Agreed specification (maximum acceptable levels).	Continued approved status (Audit passed). Absent/50 g.	Audit by trained SQA auditor. Check supplier certificate of analysis for compliance	Annual Every lot	SQA Auditor Goods Inwards Operator	Change supplier. Reject and report to QA Manager.		Purchasing manager Goods Inwards Operator
	HACCP Module 11: Ice Cream Base Manufacture									
1.1.1a	Pasteurizing	Survival of vegetative pathogens	Correct heat process. Operational Limit 82 °C/15 seconds.	79.4 °C/15 seconds.	End of holding tube temperature measurement via chart recorder. Visual inspection and sign off	Continuous	Production Operator	Report to Manager. Contact QA and discuss. Ensure divert working correctly. Repair thermograph. Hold product until correct heat		QA and Production Managers, Engineers

(continued)

Table 6.13 (continued)

HACCP Plan No. HP001				Iced Delights HACCP control chart				Date: March 28, 2012	Supersedes: April 01, 2009
HACCP Plan No. HP001				Iced Delights HACCP control chart				Approved by: Marge Inovera (HACCP team leader)	
CCP no.	Process step	Hazard	Control measure	Critical limits	Monitoring			Corrective action	
					Procedure	Frequency	Responsibility	Procedure	Responsibility
								process verified; dump if not.	
			Automatic divert	Divert working.	Check automatic divert operation	Twice daily (start and end of production)	Production Operator	Start: Production does not start until corrected. End: Quarantine product; call engineer; notify QA and discuss as above.	QA and Production Managers, Engineers
					Check temperature sensor against traceable calibrated thermometer	Daily	Production Operator	Quarantine product (rework or disposal decision). Call engineer. Recalibrate sensor.	Operations Manager QA Manager Production Operator, Engineer
11.1b	Cooling	Cross-contamination with pathogens due to leaks in plate pack	Correct pressure differential.	Constant pressure.	Check pressure gauge	Daily start-up	Production Operator	Notify QA. Production does not start until corrected.	Production Operator, Engineers
	HACCP Module 12: Filling Room								
12.2	Metal detecting	Metal not detected.	Effective metal detection.	All product passes through a working metal detector.	Check metal detector is working at start-up and throughout the run—with specified test pieces	Start-up and hourly. Include end of run	Production Operator	Repair/recalibrate metal detector. Quarantine and recheck product back to previous good check.	Production Operator QA Supervisor, Engineers
12.7	Labeling	Allergens not identified.	Bar code scanner.	All product passes through a working bar code scanner.	Check bar code scanner is working at start-up and throughout the run	Start-up and hourly. Include end of run	Maintenance Operator	Quarantine and recheck product back to previous good check.	Production Operator QA Supervisor, Engineers

HM11: Ice-cream Base Manufacture

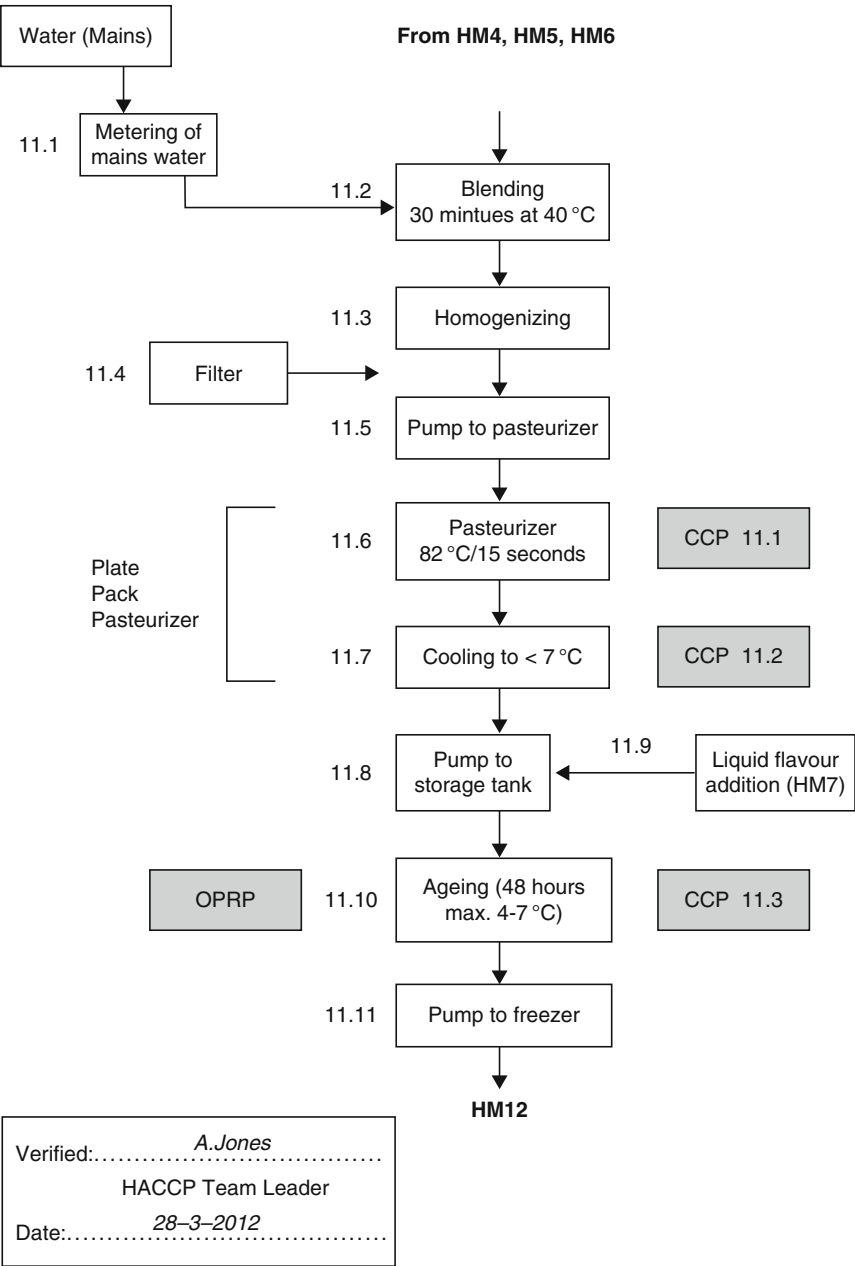


Fig. 6.17 Process flow diagram, example—showing CCP positioning

Table 6.14 Defining validation and verification (adapted from Wallace et al., 2011)

Term	Codex definition (Codex, 2009b)	Clarification
Validation	Obtaining evidence that the elements of the HACCP plan are effective.	<ul style="list-style-type: none"> • Is the HACCP plan capable of controlling all relevant hazards if correctly implemented? <p>OR</p> <ul style="list-style-type: none"> • Will it work?
Verification	The application of methods, procedures, tests, and other evaluations, in addition to monitoring, to determine compliance with the HACCP plan.	<ul style="list-style-type: none"> • Is there compliance with food safety requirements defined in the HACCP plan <p>OR</p> <ul style="list-style-type: none"> • Is it working in practice?

right. This should be carried out soon after the plan is completed so that implementation can follow without delay.

Validation and verification are important elements of HACCP implementation and maintenance so it is useful to remind ourselves of the definitions of these key terms here (Table 6.14).

We will close this chapter by looking at overall validation as this is what happens before the plan is implemented. In Chap. 7 we will look at verification which occurs on a daily basis once the plan is in place.

As discussed earlier, what you need to do for validation is to provide sufficient evidence to justify both the selection of the significant hazards and the effectiveness of the proposed control measures. According to ILSI (1999), to meet the objectives of validation it is necessary to critique, firstly, the supporting evidence used in the HACCP study and, secondly, the control measures, including monitoring and corrective actions.

So basically there are two main elements to validation:

1. *Validation of the supporting evidence used in the HACCP study.* In other words you need to prove that the control measure will control the hazard of concern and that the hazard is real.

Evidence must be gathered to support why the team included or excluded all relevant hazards considered during the hazard analysis. This could come from the scientific literature, trade associations, regulatory and legislative departments, historical data, professional bodies, or company knowledge.

You should also have the supporting evidence to show that the established operational and critical limits will adequately control the identified hazards to a level which meet your product safety requirements. This may be achieved using the same sources that were used for the selection of the hazards and by testing. Testing is the process by which proposed control measures are positively tested for their effectiveness. Examples of testing include deliberate contamination, heat distribution and penetration tests, 100 % incubation or inspection of production lots, and mathematical modeling of microbial growth.

2. *Validation of the control measures.* This is really a final reconciliation (cross-check) of the HACCP control chart and process flow diagram to make sure that all the CCPs (and, where relevant, OPRPs) have been correctly identified and that the management of them (operational and critical limits, monitoring and corrective action procedures) are adequate. You should systematically work through all the information in the Process Flow Diagram and HACCP control chart to make sure that all the details are accurate, relevant to the hazards, and that the control criteria, i.e., the Critical Limits, have been set at tight-enough levels to ensure control of product safety. It is equally important that you ensure that no hazards have been missed during the study.

As you progress towards implementation, it is also essential to inspect the processing area in order to make sure that all required control measures (particularly new measures) are in place. Critical process and monitoring equipment should also be examined to ensure that it is capable of achieving the desired control criteria and is appropriately calibrated.

Although members of the HACCP team can carry out some or all of the HACCP plan validation, it may be appropriate to use other experts to cross-check the study and ensure that no issues have been missed. It is really important to know that you have got it right, so if it is your first HACCP plan then you should involve other relevant experts in the validation. This could be done by other experts within your company, e.g., at corporate level, or by external independent subject matter experts and HACCP specialists.

6.9 Key Point Summary

Application of the HACCP principles is a logical and systematic process as outlined in this chapter. It requires:

- A thorough understanding of your product (what is making it safe and what could, or would, make it unsafe)
- A thorough understanding of your process (think about the operating environment)
- A thorough understanding of likely hazards
- Determination of appropriate control measures
- Identification of those controls that are critical—the CCPs
- Identification of critical limits and confirmation that they will control the identified hazards of concern and that they can be achieved in your facility
- A thorough understanding of the PRPs that are essential for avoidance of significant hazard cross-contamination—the OPRPs
- Establishing corrective action requirements—well thought through in advance of you needing to utilize them
- Validation that the HACCP plan will be effective for food safety assurance

It also requires a cross functional, knowledgeable team in order to ensure the appropriate knowledge and experience; otherwise the HACCP system may not be effective. All decisions need to be thoroughly discussed and the HACCP plan needs to be validated as being capable of controlling the hazards of concern once it is implemented in the workplace.

Chapter 7

Implementation, Verification, and Maintenance for Ongoing Risk Management

Now that we have seen how to apply HACCP principles to develop a HACCP plan, the next step is to implement it in your operation so that you have everyday control of food safety hazards in practice. You have made a commitment to use the HACCP system in order to effectively control all safety issues, and unless the HACCP plan is properly implemented, its real benefits will not be realized. This is a vital stage and yet the relief at having completed the HACCP studies can sometimes mean that businesses see the documentation as the end in itself. Now is **not** the time to breathe a sigh of relief and assume that you are using HACCP to manage food safety—the HACCP Study was completed at a point in time and if it is to remain as effective as it was on the day it was written it **must be implemented in practice and following that, it must be routinely verified and maintained**. Even more important is to utilize (24/7) the mindset of hazard identification and analysis as you go about your day-to-day activities, and to ensure to ensure that **all** employees are thinking in this way, i.e., seeing their operation through a “HACCP lens.”

Implementation, verification, and maintenance of the HACCP system are, therefore, key to the overall success for ongoing food safety management, and ongoing maintenance of HACCP is where many of the benefits really lie. The initial study will result in a system that will act as a benchmark for future improvements—driven through identification of weaknesses and by taking corrective action. HACCP should be seen as a way of life throughout the entire company from the moment that the initial studies are completed and the implementation is under way. In this chapter we will consider some of the activities that can drive the system forward, making it live instead of remaining as a set of documents on the QA Manager’s office shelf.

In order to implement the system properly, you must ensure that sufficient resources are available, so that the identified Critical Control Points (CCPs) can be monitored, and that sufficient records will be kept. It is also crucial that the workforce is able to take over the day-to-day running of the system and they may need education, training, and support in order to fully take ownership of HACCP.

If you are using OPRPs this will also need to be considered as many of the requirements for implementation will be the same as for HACCP. All of this needs careful planning. The HACCP system must also include verification procedures to provide assurance that the HACCP plan has been implemented effectively and that it is being complied with on a day-to-day basis. Moving forward to the verification and maintenance phases, activities will include HACCP audit, microbiological and chemical testing, analysis of data, consumer complaint monitoring, continued awareness of new emerging hazards, ongoing training requirements, and procedures to keep the HACCP plan up to date.

In the previous edition of this book (Mortimore and Wallace, 1998), implementation and maintenance activities were covered in separate chapters. In rewriting the book we have chosen to put these key stages of HACCP together in one chapter because, in practice, there should be a seamless progression of the completed HACCP plan through implementation and into the verification and maintenance cycle. In this chapter we will be considering all of the necessary activities that make up implementation, verification, and maintenance and in this way will discuss how to meet the requirements of HACCP principles 6 and 7. This will allow us to complete the third and fourth Key Stages of HACCP (Fig. 7.1).

Whilst focussing here on implementation and ongoing verification and maintenance of the HACCP system, it is crucial that similar procedures are developed for prerequisite programs (PRPs) and, where relevant, OPRPs.

7.1 Implementation of the HACCP plan

There are likely to be several different approaches to implementation and, similarly, alternative approaches to verification and maintenance that can be chosen to make up an appropriate “toolkit” in each business. There is no one right or wrong way and the methods chosen should reflect the maturity of the existing business and the resources available to it.

All production operations are operating under certain constraints and these are most likely to be associated with time and money. When implementing the HACCP plan it is important to ensure that all the critical issues can be addressed while working within your constraints. Similarly, when verifying and maintaining HACCP, it is crucial to ensure that resources are available to achieve the necessary activities. You have already put a large amount of resource into drawing up the HACCP plan, through the HACCP team training, making personnel time available for the study, and developing appropriate controls. Now it is important to ensure that this resource has not been wasted through improper implementation, verification, and maintenance of the HACCP plan. By following the steps and activities outlined in Fig. 7.2, HACCP will become a cornerstone of the effective food safety management system, achieving ongoing risk management in practice.

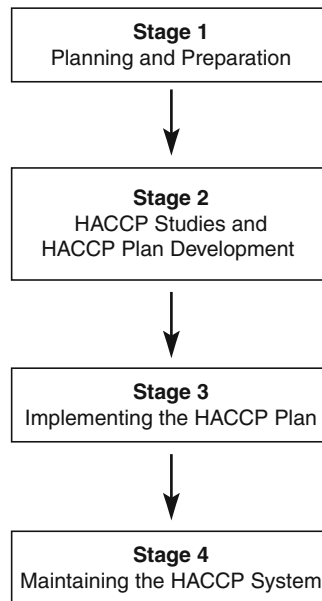


Fig. 7.1 The key stages of HACCP

7.1.1 Preliminary Steps: Challenging Your Controls and Corrective Action Systems

The value of HACCP as a tool for reducing food safety risk comes from the structured approach to evaluation of hazards and likelihood of their occurrence. Therefore, before implementing the HACCP plan, it is worthwhile utilizing this concept further by systematically considering whether you really do have sufficient control for all possibilities. What happens, for example, when a CCP fails? Do you have the appropriate contingency plans in place?

It is important to challenge your controls and to understand what would happen in the event of a failure. This can be done using a structured approach considering the consequences of CCP failure.

In order to challenge your CCPs, you will need to investigate all the possible failure modes, the contributory cause(s) of the failure, and what the outcome would be. Then consider your current controls and corrective action systems, and any additional activities required to give more confidence and increase the effectiveness of the HACCP system.

This approach also depends on teamwork and brainstorming to identify all the possible failure modes and their associated causes. It requires the team to think the unthinkable and challenge commonly held beliefs such that all potential outcomes are considered. When this has been done it is relatively straightforward to identify

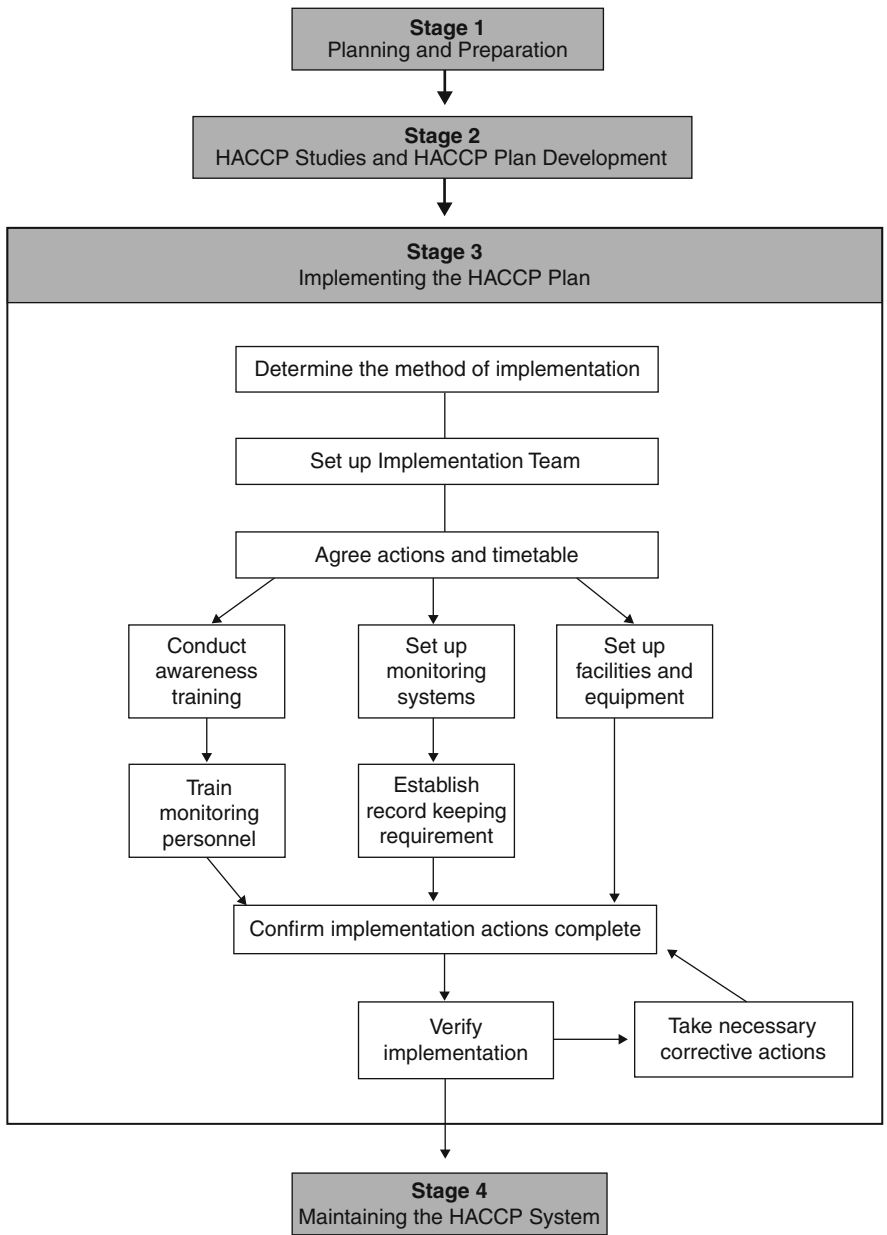


Fig. 7.2 Key stage 3—implementing the HACCP plan

and implement an extra “safety net” of controls so that deviations at CCPs are minimized, that corrective action systems will always be effective, and that there is no chance that deviations will be missed through failure in monitoring.

Table 7.1 Example: Challenging metal detection control

Failure	Outcome of failure	Cause of failure	Current control system	Recommended controls
Failure to detect metal	Metal in product	Metal detector breakdown	Run all product through the metal detector and verify the metal detector is working on an hourly basis. Document the result	Metal detector function verified at start-up
	– Injury			
	– Complaints of metal in product from customers			Maintenance schedule
	– Lost credibility			
	– Prosecution			
	– Bad publicity	Metal detector not properly calibrated		Set up calibration schedule for correct sensitivity
	– Lost customers			Confirm sensitivity appropriate for all products
	– Product disposition and high-cost penalties	Incorrect metal detector		
		Metal detector in wrong place in line		Move to just before packing
		Rejects not controlled		Locked cage for rejects or other fail-safe system
		No early warning magnets (or earlier in-line metal detectors)		Install magnets earlier on the line

It may be appropriate to use other personnel (e.g., a different HACCP or Management Team) to carry out this process, as the original HACCP team may be too close to the CCPs they have identified.

An example of this approach is shown in Table 7.1. The team should use brainstorming to fill in the first three columns, and then discuss whether the CCPs, Critical Limits, and monitoring procedures (i.e., the “current controls”) identified during the HACCP Study are sufficient and effective. Following this exercise the final column can be completed as the team considers any extra control criteria required for a more fail-safe system. The example given shows the considerations for metal hazards being found in the product.

When you are confident that all your proposed controls are sufficient for all possible outcomes then your HACCP plan is valid and you can move on to implementation.

7.1.2 Implementation Requirements and Action Planning

As shown in Fig. 7.2 several sets of activities will be involved in implementing the HACCP plan and there are also likely to be several different approaches to implementation. There is no single right or wrong way and the method chosen should reflect the maturity of the existing business, its size, and the resources available to it.

All production operations are operating under certain constraints and these are often associated with time and money. When implementing the HACCP plan it is important to ensure that all the critical issues can be addressed while working within your constraints. You have already put a large amount of resource into drawing up the HACCP plan, through the HACCP team training and making personnel time available for the study. Now it is important to ensure that this resource has not been wasted through improper implementation of the HACCP plan, which is often linked to insufficient commitment to the HACCP system, one of the key reasons for HACCP failure. If your personnel have limited time available, it is important to ensure that their time is well spent and this means providing adequate management support and resources in addition to being well organized.

There are several ways in which a tight budget can be maintained whilst implementing the HACCP system. What most companies find is that the major portion of the cost of food safety improvement comes from the major PRP investments that need to be made. It is crucial that you do not try to save money by only implementing selected parts of the overall food safety program. Instead, concentrate on how HACCP can be used to help prioritize the required investments.

In terms of implementing the documented HACCP plan itself, you can often incorporate that into many of the already existing activities. For example, you may not need to create new log sheets for monitoring all the CCPs. It is likely that many of your existing monitoring sheets can either be used directly or amended to take on additional data and/or signature columns (e.g., dating and signing of thermograph charts).

Training is essential for the successful implementation of HACCP, but this does not necessarily have to be done through the use of external courses. Some of your HACCP team members could be trained to train other company personnel and conduct briefing sessions. You may also be able to save some time and money by combining training sessions, e.g., food hygiene and HACCP, where the same personnel require different types of training.

If HACCP implementation is carried out to a carefully thought-out plan, it does not need to be a drain on your resources, and instead can really help to target resources effectively at those areas which are **critical** to the safety of your business. The flow diagram shown in Fig. 7.2 is provided as a guide to implementation, and the same project planning techniques as shown in Chap. 2 can be used here. We will follow the main steps in the process through the remainder of the implementation part of this chapter.

Table 7.2 Implementation methods—advantages and disadvantages

Method	Advantages	Disadvantages
Implementation methods 1: The “Big Bang” Implementing everything all at once	<ul style="list-style-type: none"> – Rapid implementation potential – Works well in companies with well-established Quality Management Systems – Whole workforce involved (more effective than trying to change behavior of a small group within an existing culture) – Ease of workforce briefing – Suitable for larger plants with sufficient resource 	<ul style="list-style-type: none"> – May take longer period overall than anticipated – All HACCP monitoring and control procedures must be developed before implementation starts – May prove difficult for smaller businesses – No trials of individual system elements – Loss of credibility: <ul style="list-style-type: none"> – If employees see that it’s poorly managed – If a CCP fails through lack of support network – Large immediate training requirement – Resource thinly spread, e.g., HACCP team
Implementation methods 2: Phased Implement a bit at a time	<ul style="list-style-type: none"> – Quality Management System support elements can be developed as required and alongside – Staged training allows more individual attention – System can be trialed and refined as implementation progresses – More manageable approach → system less likely to fail – HACCP team resource focused at each stage 	<ul style="list-style-type: none"> – Longer overall implementation timetable – Working with small groups of people in isolation → difficult to change culture – Implementation may lose momentum

(a) Implementation approaches

The overall approach to implementation may vary but basically there are two main methods—doing it all at once (the “Big Bang” method), or phased evolution. The former involves waiting until all studies are complete and implementing them in one go, whilst the latter requires that each section of the overall system is implemented as it is completed.

There are advantages and disadvantages of each method (Table 7.2) but the phased method is likely to be the most practical option for most businesses.

(b) Implementation Team

It is helpful to set up an Implementation Team, the membership of which might include some personnel from the original HACCP Study Team plus additional

personnel who are able to help transfer the HACCP plan to the operations. The Human Resources or Personnel Manager may be very helpful given the training implications and potential changes in working practices. Representation from Production, Engineering, and Quality Assurance will also be appropriate and, in a larger organization, you may be able to choose different people from those involved in the initial HACCP studies.

The responsibilities of the Implementation Team will begin with the agreement of the method of implementation and drawing up of an implementation Project Plan (see Chap. 2). The team may also require a budget, so finance representation may also be helpful. The team should also be responsible for reporting regularly on progress to Senior Management within the company.

Questions to ask when drawing up the implementation Project Plan will include whether you have enough personnel to adequately monitor the CCPs and whether they are the right people for that task. Do your chosen monitors have enough time to fit the monitoring procedures in with their other responsibilities? Have you considered the required level of supervision of CCP monitors, and is this in place? Training will be a key stage in the implementation phase.

The Implementation Team should consider all these issues together with the rest of the management team, in order to identify all the resources required to put together an implementation Action Plan.

(c) Implementation Action Planning

Members of the Implementation Team need to develop a detailed Action Plan (or Project Plan) identifying all the different activities that need to be completed. These are likely to fall into three main areas:

- Setting up CCP management systems as required (monitoring, corrective actions, and record keeping requirements)
- Additional HACCP implementation activities such as equipment and facility review
- Education and training

Essentially this step is about creating a detailed list of all that needs to be achieved, establishing who will be responsible for what, and assigning a practical and realistic timetable for completion. The action plan is a living document that will be continually updated as the implementation phase progresses. It will be constantly reviewed and is the key tool to ensure that all necessary activities are completed. In each area of the action plan it will be necessary to go through a cycle of actions and reviewing completeness so that items can be checked off the list. For these reasons it is important to list adequate detail at the planning stage.

We will now consider the main groups of actions within the Implementation Action Plan.

7.2 Set Up CCP Management Systems: Monitoring, Corrective Action and Record Keeping Requirements

Monitoring involves conducting tests or observations to confirm that the process remains in control via the CCPs. The monitoring requirements have already been defined within the HACCP control chart; here you need to think about the practicalities of implementation within the workplace.

7.2.1 Developing Monitoring Records

The monitoring record should have details of the critical limits and corrective action procedures. Target levels or operational limits within the critical limits can be included if the CCP monitor is to adjust the process in order to maintain control. It is also useful to include details of the monitoring method, but this may not be necessary in all cases, particularly when operating within a Quality Management System or where separate work instructions are made available. In drawing up the work instructions it is a good idea if the monitors themselves are asked either to prepare these or to contribute to them. It is better if they are clear, simple documents and the main purpose is usually for ensuring a consistent training approach and for easy reference. The monitoring log sheets themselves should have sufficient space available to record the necessary data and columns should be included for the monitor to sign off and date each monitoring event. In addition, each monitoring sheet should have a cross reference to the HACCP plan and CCP number. It should be remembered that special CCP log sheets are not a HACCP requirement and existing workplace monitoring sheets are often acceptable, perhaps with some modification to ensure that all the necessary data are collected. Computer-based records are being used increasingly and can have significant advantages when analyzing trends. Again it is important to ensure that the computer entry screens allow all the required information to be recorded and there will need to be a password system to ensure that the name of the operator is known (the sign off) and also security in place to prevent records being changed or tampered with after the event.

An example of a CCP monitoring sheet for one of the CCPs for our ice-cream product is shown in Table 7.3. The “Reviewed by” section is usually completed by a supervisor or a manager, whose role is to double-check that critical limits have been met and that any necessary corrective action has been taken.

Table 7.3 Ice cream—CCP monitoring sheet

Log Sheet CCP No. 11.1		Pasteurizer Automatic Divert Check		HACCP Plan Ref. No. HP001	
Monitoring procedure : See Work Instruction ID240 – check flow divert operation during cleaning cycle – confirm actions on chart recorder – check sensor against calibrated thermometer			Frequency: daily – at start-up and at shutdown		
Corrective action: Start-up checks: – postpone start up – call maintenance engineer and QA Manager Shutdown checks: – contact QA Manager regarding quarantine of product					
Date	Time	Result	Action Taken	Signature	
Reviewed by: Title: ----- Signature: ----- Date:-----					

7.2.2 Monitoring Methods: Use of Statistical Techniques

A method which may be useful to some organizations when setting up monitoring and verification systems is Statistical Process Control (SPC).

Once a statistical analysis has been carried out for a particular process and has demonstrated that it is capable of achieving an acceptable level of performance (as we saw in Chap. 6), then the statistical profile which has been built up from the

capability study can be used to produce a Process Control Chart for the control of a process and its parameters. Such a chart takes the form of data capture with graphical plotting of the variations on a time or a batch basis. By using the information of the process profile, the process controller (with the aid of a control chart) will be able to tell whether variations in measurements taken of a process parameter are inherent and to be expected as a result of natural random fluctuations of the process (i.e., due to common causes), or whether the variations are of such a magnitude as to be statistically significant and indicate that this shift in the process must be due to some assignable reason (i.e., due to special causes). When a significant variation occurs it indicates that there has been a shift in the overall equilibrium of the process and that an adjustment must be made to restore the process; the shift may also indicate the failure of some plant component. The Process Control Chart is an effective online CCP log sheet which is filled in by the operator. The chart gives the operator very rapid notification that the process is going out of control.

Process Control Charts can be used to analyze the process parameters in two respects—mean and range (or standard deviation)—which measure the accuracy and the precision of the process, respectively. The control chart may have upper and lower action limits marked onto them (where appropriate) and can sometimes include intermediate upper and lower warning bands. By taking the mean of the process measurements (say 4 or 5 readings) the operator will get a “consensus” reading of any overall shift in the process. American Process Control Charts are usually only marked with upper and lower action limits, with no intermediate warning bands. The action and warning limits for the charts are derived from values generated from the process capability analysis and constants extracted from SPC tables.

By looking at the range of the individual results used to produce the mean, the operator gets an indication of the stability (“wobble”) of the process. Excessive range variation may well indicate the start of plant failure (e.g., a sluggish control valve)—analogous to a spinning top just before falling over. Although the mean reading of all the wobbles may still indicate that it is stationary on its spot, the excessive wobbling (range) would indicate the inherent instability and that the spinning top is just about to fail (i.e., in this case fall over).

The information for a Process Control Chart could be captured on a table as set out in Table 7.4 and a Mean Range Chart would look as set out in Fig. 7.3.

The basic interpretation of the chart would be that:

- Any result above the upper action level (UAL) or below the lower action level (LAL) should be considered significant and process adjustment should be considered.
- Any result between the warning levels (upper and lower) and the corresponding upper and lower action levels should be considered to be suspect; two results in a row in the same band would be considered significant and process adjustment should again be considered.
- Any series of results that show a consistent upward or downward trend should also be considered to be significant.

Table 7.4 Information gathering for process control charts

Time/batch no.	08:30	09:00	09:30
Measured values			
1	6.5	7.6	8.3
2	7.6	7.4	7.8
3	7.5	8.2	7.5
4	8.1	6.8	7.2
Sum	29.7	30.0	30.8
Average	7.4	7.5	7.7
Range	1.6	1.4	1.1

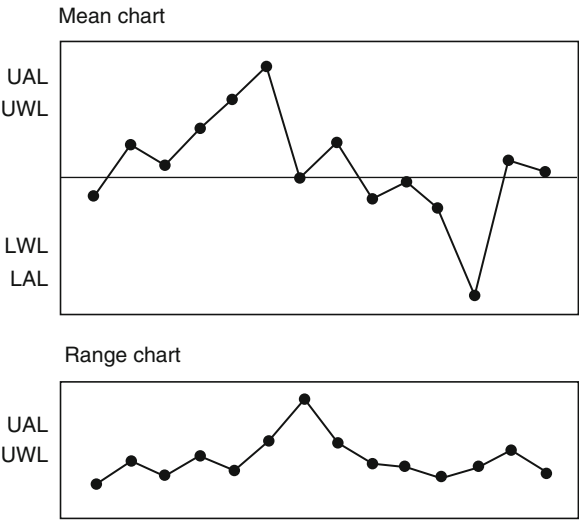


Fig. 7.3 A mean range chart. *UWL* upper warning level, *LWL* lower warning level, *UAL* upper action level, *LAL* lower action level

The use of Process Control Charts is of most benefit when an immediate reading or measurement can be made for assessment in order to achieve instant process control and adjustment.

This section has been dealing predominantly with the interpretation of variable data, such as that obtained by measuring time, temperature, flow rate, etc. However, the application of control charts can be used equally effectively with attribute data, such as the YES/NO result obtained when checking that a metal detector is working.

7.2.3 Corrective Action: Requirements for Reporting and Acting on Deviations

A deviation occurs when the critical limits are not met and the CCP goes out of control. The CCP monitors must understand exactly what constitutes a deviation with reference to the critical limits. It is essential that procedures are established at

line level to ensure that they know what action to take and when to report a problem and who to report to, so the corrective action details and reporting structure must be specified in sufficient detail. This could be done on the monitoring log sheet or in work instructions.

A deviation also occurs if a monitoring requirement is missed. It can be helpful to measure how well you are doing, in terms of not only operating within either the critical limits or target levels but also whether all CCP checks are actually being carried out. Some companies choose to report this as two different results and on a daily, weekly, or monthly basis. The method is straightforward and can be a simple percentage figure. For example:

1. Number of CCP checks out of control \div number of CCP checks possible $\times 100 = \%$ out of compliance (use either the target level or critical limits values)
2. Number of CCP checks missed \div number of CCP checks possible $\times 100 = \%$ checks missed

7.2.4 Feedback on Results

The workforce needs to see the whole picture and understand how well the HACCP system is working. This is important from the point of motivation and helps in getting CCP monitors to take responsibility for their part in the proceedings.

You need to establish a communication plan to enable feedback to be given both individually and in groups, and it is always important to stress positive aspects, e.g., telling the monitor that his/her fast action saved the company from financial loss by preventing reject product being produced. This may be done through departmental briefings and performance charts or through written reports being circulated to appropriate personnel. It is also helpful from the motivation point of view if all other staff in the processing area know the importance of the CCP monitor's actions. If the percentage compliance figures are known, this can be presented as a performance chart on a regular basis. This will enable the HACCP team to better identify trends in the results.

If routine feedback briefings are not already established then you'll need to work with the Plant Manager and HR team to work out an appropriate time and place in which to do this. It could be a weekly staff meeting, newsletter, or daily informal departmental briefings.

7.3 Additional Facilities and Equipment for HACCP Implementation

In addition to the training requirements and the necessary management systems for CCP management, there are likely to be a number of other changes necessary in order to support HACCP plan implementation. These will include activities to

strengthen PRPs and, where appropriate, OPRPs, as well as any other modifications that have been identified as necessary for food safety during the HACCP study, e.g., removal of redundant plant and equipment, etc. Whilst there may be some overlap here with the requirements for training and CCP management systems, it is worth considering some of the general facilities and equipment requirements as a reminder of what needs to be achieved.

7.3.1 Facilities

Different facilities are needed for the process itself and for the additional implementation requirements. You should consider the main processing area along with specific facilities required during the process. For example, do you have sufficient handwash basins and are they correctly sited? Will the existing disposal system cope with additional waste from this process? Is there sufficient space for handling the packed product? This will also require a review of PRPs and their suitability to support the HACCP plan.

You will also need a training facility so that you can brief staff and carry out any specific training required. This may need to be capable of holding large numbers of employees during awareness training sessions, and smaller numbers, for example, during the training of CCP monitors. You may be able to use external training facilities for this purpose.

Additional facilities should be considered, such as a separate test area where log sheets can also be stored, additional computer workstations if electronic data gathering is required, storage for records retention, and perhaps a defined location may be needed for work instructions and procedures, e.g., work tables, manual holders on the walls, etc.

7.3.2 Equipment

It is important to establish that you have the correct equipment for each situation. Can it, for example, carry out the process specified and achieve the desired control criteria? Has it been properly calibrated and maintained, and will it be reliable when the HACCP system is implemented? Some important questions to consider at this stage are as follows:

- Do you have the right equipment in place or will you have to buy any new equipment?
- Is it appropriate to the task?
- Is it sensitive enough?
- Can it be calibrated?

- Does it require ancillary equipment, e.g., locked boxes for dud detectors on a can line?
- Is it difficult to operate, e.g., a gas chromatograph?
- Can the CCP monitor interpret the results?
- Will it work on the line or does it require special facilities, i.e., will it withstand the rigors of the production environment?
- Is it cleanable?
- Are there any health and safety constraints?

7.3.3 CCP Identification on Facilities and Equipment

Although not a requirement of HACCP, it may be helpful to identify clearly where the CCPs are physically located within the process. This can be done very simply by the hanging of additional signs within the plant stating “CCP.” While a very basic element of implementation, seeing signs go up can have a great impact on the workforce and also serves as a constant reminder of which points are CCPs. It is also a visible change which occurs during implementation.

7.3.4 Modifications: Are They Complete?

Modifications to plant and equipment that have been identified during the HACCP study as essential to food safety **MUST** be completed before HACCP plan implementation. This is likely to involve members of the HACCP team working closely with engineers and contractors to ensure that the specified modifications are made and that these have no detrimental effect on food safety management.

All modifications should be checked and signed off as complete by appropriate personnel.

7.4 Education and Training

It is often more successful if the main education and training of the workforce in HACCP requirements are left until right before the implementation phase. Completion of HACCP studies can take time and, if the workforce is made aware of the HACCP Project at the start, there may be a need for retraining by the time the system is ready for implementation. However, it is useful to brief the workforce regularly about the project progress and status from the start.

Training is core to food safety culture and is fundamentally important if the food safety management system is to control product safety effectively. *All* personnel within a food business should be trained commensurate with their work activities. CCP monitors, their supervisors, and managers will need specific training in their

role within the HACCP system. Other personnel, including operators, will need HACCP awareness training as a minimum.

7.4.1 Foundation Training

As indicated in Chap. 2, all personnel will need a basic understanding of the HACCP concept, how it will apply to their working environment, and why following CCP monitoring and corrective action requirements is vital. It is also important that all personnel understand the relationship between HACCP and the prerequisite programs (and OPRPs where applicable), where their compliance and support of such routine activities is essential to overall food safety management. This is part of the educational requirements for implementation and ties in with development of the food safety culture. As part of this activity, many companies include stories of failure in other companies including what happened, how the events could have been prevented, and the consequences of failure. If training in hygiene has already taken place, review whether employees need a refresher training, and could this now be linked directly to a hazard analysis approach? With specific regard to HACCP, you can probably obtain basic-level visual aids, such as an introductory video or PowerPoint slides, which would facilitate training. There are a lot of fun video clips and more sobering ones too on YouTube that can be used to ensure that you have the attention of all attendees. A practical exercise is also helpful and this can often be delivered by a member of the HACCP team. As a start, here is an idea that has worked well elsewhere:

1. Using a flip chart, and with the help of the trainees, draw a Process Flow Diagram which represents a simple process. Making a cup of coffee and/or a sandwich, going shopping, or boiling an egg are all easy options.
2. Again, using a flip chart, transfer the process steps to a Hazard Analysis Chart. Get the trainees to brainstorm possible hazards at each step. Depending on their level of prior knowledge, you may need to give a brief reminder of the basic physical, chemical, and biological hazards that may occur.
3. For each hazard identified, ask the group for possible control measures.
4. Use the Process Step CCP Decision Tree to show them how to identify which of the control measures are CCPs.

You don't need to do a hazard analysis and identify CCPs through the entire process flow diagram for them to understand the concept, and at this stage you can show them one of the completed HACCP Plans for your business.

Note: We do not suggest attempting to assess hazard significance with this level of personnel training; however it would be useful to point out that significant hazards have been identified and to link these with the actual CCPs, plus OPRPs and PRPs, as appropriate.

7.4.2 CCP Monitors

For CCP monitors, their supervisors, and managerial staff, you will need to provide additional training.

Monitoring, along with its associate record keeping and corrective action, is one of the most important aspects of any HACCP system. This is how we measure that the CCPs are working. CCP monitors therefore play a key role in the production of safe products and they will be able to perform effectively if they understand not only what they are expected to do and why they are doing it, but also how their role fits in with the rest of the HACCP system. An understanding of how essential their role is for the safety of the product is also a key factor in maintaining motivation.

It is vital that all your CCP monitors are instructed in basic HACCP philosophy as previously shown and, in particular, the importance of accurate monitoring. They must understand what the specific hazards are for the CCP in question and how to take corrective action when a deviation occurs. Where appropriate, they will also need to understand the differences between a target level and a critical limit, and what these values are for each CCP that they are monitoring. In some cases you will need the CCP monitors to adjust the process in order to maintain control and prevent a deviation from occurring. Here it is important to know that your monitor is capable of the required actions. The detail and accuracy requirements for CCP records must also be agreed. In order to achieve this you will have to ensure that training is available for all CCP monitors and this may be carried out by your HACCP or Implementation Team members. Because of the importance of this role, it is recommended that you not only provide training but also check understanding and competency in the specific task.

New skills may be involved in monitoring, such as taking samples and filling out documentation or keying data into a computer. The involvement of the Human Resources Manager and in some instances the Trade Unions and Works Councils may be necessary where working practices will change as a result of HACCP implementation. CCP monitor understanding and competency may not be gained solely by using a classroom-type training session; it is more likely to be developed through a learning by experience approach, i.e., being shown how to do it and then “having a go” under supervision.

Both the trainer and supervisory/managerial staff will be more effective at this stage if they have some knowledge of learning styles. This will allow best practice training in line with the learners’ needs and reinforcement of the training after the main intervention has occurred. Their role in this should also be emphasized and made a specific responsibility within their job function. Overall, the training process should be regarded as a motivating experience and shouldn’t be conducted in a negative environment. Positive involvement of the CCP monitors is important and this will not usually be gained by dictating rules to them and warning what will happen to them personally if they get it wrong. Obviously any legal obligations are important, but they need to be made aware of their vital role within the food safety management program as a whole and made to feel part of a team. An additional point to consider is not to forget to train deputy CCP monitors as well, in order to plan for sickness and holiday cover.

7.5 Confirm Implementation Actions Are Complete: Verification of Implementation

Having decided on the implementation method (“Big Bang” or phased) at the planning stage, then established that the monitoring and corrective action activities are set up, the required facilities and equipment are available, and the workforce is adequately trained, the actual implementation of the HACCP plan simply requires the following actions:

- Monitoring CCPs
- Taking any corrective action as required
- Recording results

This is where HACCP goes “live” and managing the CCPs day by day becomes the responsibility of personnel within the operation. This is also where we go further into Verification (Principle 6) mode—i.e., confirming that all activities as specified in the HACCP plan are being carried out correctly.

A verification audit of implementation can and should occur for the first time immediately once the HACCP plan has been implemented, in order to identify any corrective action requirements as soon as possible.

7.6 Verification as a Way of Life

At the start of this chapter, we looked at the setting up of an Implementation Team. One of the final and important stages in the Implementation Project is to confirm that all actions in the Project Plan have been completed satisfactorily prior to handing the system over to the operations staff. At this stage the responsibility for managing HACCP passes to operations; however it is likely that HACCP team members will remain involved alongside their operations colleagues. In practice, the HACCP team often becomes a HACCP maintenance team and includes strong representation from production personnel.

Following handover to operations, HACCP moves into Key Stage 4, its maintenance phase (Fig. 7.4). We will now move on to look at application of routine verification and potential maintenance activities.

VERIFICATION:

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

Verification activities will vary according to the control measures in place; however they will always include some form of audit and records review, and may include additional testing procedures. Verification is really done to ensure that CCPs are being monitored correctly and activities can be broken into three main areas:

- (a) Those that are concerned with records review
- (b) Those that are concerned with the reliability of the monitoring equipment—calibration

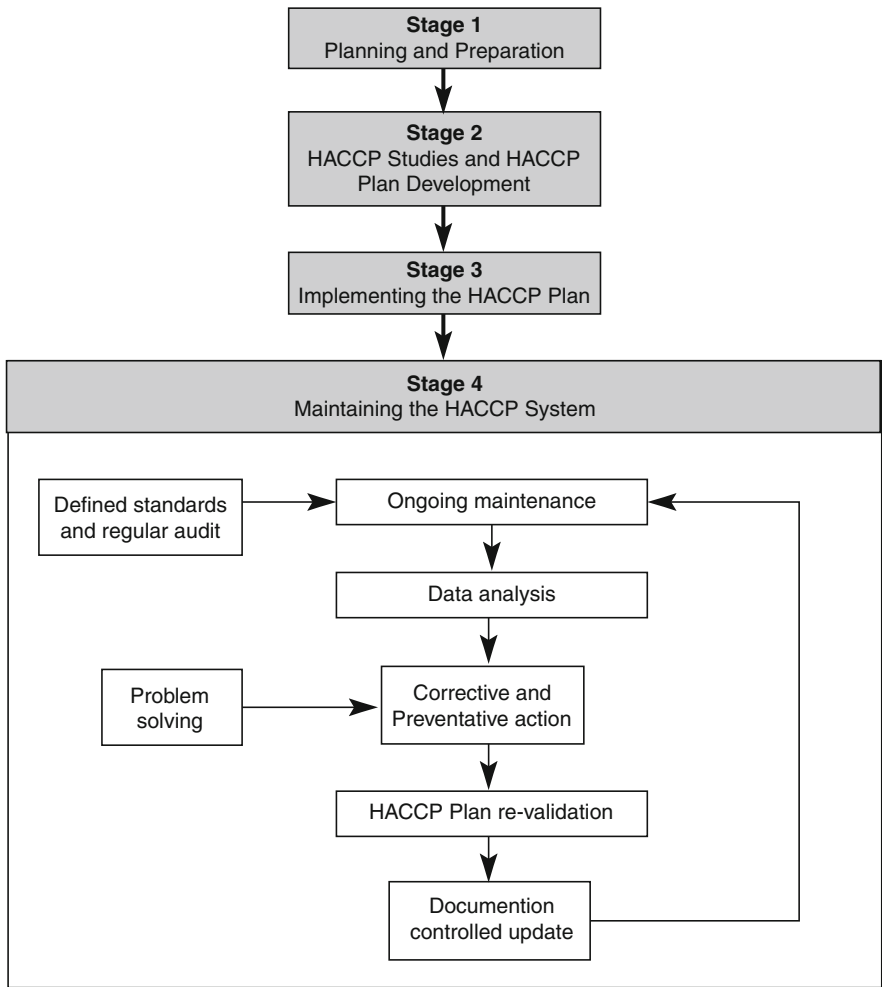


Fig. 7.4 Key stage 4—HACCP system maintenance

- (c) Those that are concerned with the competency of the CCP monitor—observational review and audit

7.6.1 Records Review: Analysis of Data

The HACCP procedures will generate a number of records which should be reviewed on a regular basis as part of verification. There is nothing worse than seeing useful measurements information, i.e., data, pile up in the QA Manager’s office, not being used to make process improvements and with no analysis carried out. Some suggested answers to common questions on this data analysis are as follows.

Why Analyze Data?

It is important to analyze available data as part of the verification procedures that will demonstrate that the HACCP plan continues to be effective. Data analysis will enable trends to be recognized and corrective action teams to be set up to deal with the cause, e.g., customer complaints and recurring CCP deviations. This is also an extremely useful activity to launch investigatory audits of problem areas and to ensure that timely corrective actions are being taken through trace audits of meeting minutes. An effective data analysis program can demonstrate that HACCP and the supporting PRP and, where appropriate, OPRPs are in control.

What Data Should Be Available?

A wide range of data is available onsite, some information being the direct outputs of HACCP and others from the wider food safety and quality management systems. Specific examples include:

- CCP log sheets
- Finished product test results, e.g.,
 - Microbiological
 - Chemical
 - Physical
- Process Control Charts
- Audit reports
 - Noncompliance notes
 - Corrective action reports
- Minutes of food safety-related meetings
 - HACCP teams
 - Hygiene
 - Quality review
- Pest control records
- Consumer and customer complaint data

In considering how often the various data should be reviewed, the following table is intended to provide some guideline suggestions (Table 7.5); however specific data analysis plans may vary.

How Should the Data Be Analyzed?

It is important that the information available is used to provide verification that the HACCP system and its supporting network of PRPs are working effectively. The actual analysis of the information will be made much easier if handled

Table 7.5 Example data analysis plan for HACCP verification

Type of data	Frequency of review	Reviewed by
– CCP log sheets – Process Control Charts	Daily ^a	• Operations Manager • Operations Supervisor
– Finished-product test results – Environmental microbiological test results	Weekly	• Quality Manager • HACCP team • Operations Manager
– Customer complaints reports – Hygiene meeting minutes/inspection reports	Monthly	• HACCP team • Quality Manager • Operations Manager
– CCP deviation summaries – Corrective action reports – Audit reports – HACCP and quality meetings – Pest control records	Three-monthly	• HACCP team • Quality Manager • Operations Manager
– Audit reports – Minutes of food safety meetings – Customer complaints trend analysis	Annually	• HACCP team • Quality Manager • Operations Manager • Operations Supervisor

^aCCP monitoring records should be signed off both by the CCP monitor and by a responsible reviewing official. This is a requirement of Codex (2009b)

electronically, though all businesses may not be able to do this. Whichever method you choose, the analysis should clearly indicate trends. Use of graphs and charts can provide an easily interpreted visual record that can be shared with the workforce. Where performance indicators are used, these can be plotted on a graph to indicate performance, likewise with complaints data.

For the identification of microbiological trends, on a more retrospective basis and as part of the verification procedures, the use of a rolling (moving) average of percentage of samples that were either present/absent per unit weight, or the percentage of samples with counts that were either less than or greater than a specification per gram, can be particularly effective at picking up trends and eliminating fluctuations (Fig. 7.5). It is however also important to respond to and investigate each individual incidence of unacceptably high microbiological results. These rolling averages can be calculated on a weekly, monthly, or quarterly basis (as found to be most appropriate) and associated with each rolling average can be an assigned warning level. This may be particularly useful for monitoring the effectiveness of a cleaning schedule.

The use of the principles of SPC can be a very powerful tool in the implementation of HACCP, for ensuring that the CCPs are being effectively monitored and controlled on an ongoing basis, and for the evaluation of critical hygiene data (Hayes et al., 1997).

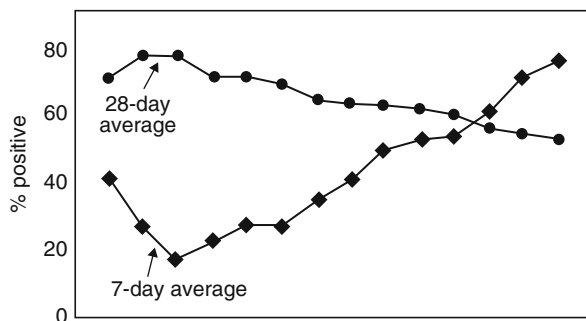


Fig. 7.5 Moving average control chart

7.6.2 Calibration

You have already considered process capability to meet the critical limits at CCPs and how this will be monitored to give confidence that they are being achieved. Another essential facet of CCP management is the calibration of all necessary process and monitoring equipment. This will include items such as cookers, pasteurizers, temperature holding devices (e.g., on liquid pasteurizers where product residency times need to be proven under normal/maximal flow conditions), temperature probes and indicators, etc. Calibration of equipment may be done onsite or, in some cases, equipment may need to be sent to reference laboratories, e.g., for calibration against national standard reference equipment.

Calibration is likely to involve engineering specialists within the company and may also need input from external specialists, e.g., engineers from equipment manufacturers. Full records of calibration should be kept, along with details of limitations, such as any necessary environmental conditions that must be maintained, and information on when the equipment needs to be calibrated next. This information will be important evidence of the validation that the process can meet the critical limits. Frequency of calibration will relate to the specific piece of equipment and advice on frequency necessary in particular situations may be sought from equipment suppliers and engineering experts.

7.6.3 Verification Through Observation and Scheduled Audit

One of the main methods of verification is through observation and audit. An audit can be regarded as an independent and systematic examination which is carried out in order to determine whether what is actually happening complies with the documented procedures, and also whether the procedures have been implemented such that the stated objectives (safe food) have been achieved. The benefits of auditing a HACCP system will include:

1. Maintaining confidence in the HACCP system through verifying the effectiveness of the controls
2. Having an independent and objective review of the effectiveness of the HACCP system
3. Identifying areas for improving and strengthening the system
4. Providing documented evidence of Due Diligence in managing food safety
5. Continually reinforcing awareness of food safety management
6. Removing obsolete control mechanisms

AUDIT:

A systematic and independent examination to determine whether activities and results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve the objectives (European Commission, 2006)

In HACCP terms, achieving the objectives means managing the manufacture and distribution of safe food products through the use of HACCP.

The audit can be considered as a “health” check of the HACCP system. It is a means of determining its strengths and weaknesses and, by taking appropriate corrective actions, a route to continuous improvement.

(i) Types of audit used in HACCP

There are three main approaches to auditing a HACCP system.

The Systems Audit

If you have chosen to manage HACCP using a Quality Management Systems approach, that is, against each of the HACCP principles, defined procedures are in place which state precisely how HACCP will be implemented and maintained, the systems audit may be used. The purpose of the audit is to find any weakness in the system and to ensure that corrective action is taken. This will entail taking a thorough, systematic, and independent review of all or part of the HACCP system. Priorities for corrective actions can be assigned against food safety risk. For example, if you have a clearly defined requirement for a HACCP team approach, the auditor may want to look at the team structure, team member qualifications and training records, and details of who had carried out the HACCP Studies—one team member or with full team input. Both current and historical documentation will be reviewed. This type of audit is most commonly used for ISO 9000 series (Quality Management System) audits.

The Compliance Audit

This is the most common type of audit used in HACCP verification, from checking CCP compliance to ensuring that the HACCP team had originally identified the hazards correctly along with the appropriate controls in the process. Again, the audit will be independent, but usually involves a more focused, in-depth inspection of the operation against the standards defined in the HACCP plan. The compliance audit will normally be done either by internal or external HACCP audit experts.

In summary, the HACCP Compliance Audit could be assessing two areas:

- Compliance with the requirements of the HACCP principles.
- Compliance with the documented HACCP plan—Has it been implemented properly and is it still correct?

The Investigative Audit

This is an investigation into a specific problem area. This type of audit may be used when a CCP regularly goes out of control—investigating the real cause in order to take corrective action, or where a previously unknown problem has arisen.

In implementing and maintaining HACCP, all three types of audit may be used, either on their own or in combination. Whatever type of audit is used, the essential elements will remain the same.

(ii). Identification and training of auditors

HACCP auditors must be skilled in the techniques of auditing, knowledgeable in HACCP itself, and technically qualified in the area under study. For this reason it is often advisable to use members of the HACCP team as auditors, as many of the required competencies will be the same. However, it is also important to have a degree of independence and therefore it can be an advantage to use someone who wasn't on the original HACCP team and/or a representative from another discipline. They may be more inclined to challenge existing practices and beliefs than HACCP team members who are closely involved with the system.

For “in-house” audits, care must also be taken to ensure that the auditors do not audit their own departments. You could use external specialists such as HACCP experts or, alternatively, could work together with your customer technologists or regulatory authorities, if this is appropriate. In larger manufacturing sites with several HACCP teams it can be helpful to have them audit each other's HACCP plans.

It is important to establish the competence of HACCP auditors before assigning the task of auditing the HACCP system. This is true both for internal and external auditors.

Audit techniques can be learnt through attending a practical auditor training course and by shadowing experienced auditors. If the auditor is inexperienced in hazard analysis and HACCP techniques, then the training period will take considerably longer. Where an audit is to be conducted by more than one person, the responsibility for leading the audit should be defined.

(iii). Scheduling and conducting audits

It is essential that an audit schedule is established. You will want to ensure that the scope of each audit is clearly defined in order that the entire HACCP system is reviewed and no element missed out. It is recommended that, following an initial verification that the HACCP plan has been implemented, a 3-monthly audit of the CCPs would be reasonable. It would be possible to perhaps schedule audits of part of the system on a weekly or a monthly basis. The frequency will depend on the

nature of the business, for example a seasonal vegetable packer may only audit once a year whereas a ready-meal factory with frequent menu changes may audit monthly. The schedule needs to be established so that auditors can be assigned to it well in advance.

Let's now consider the steps that will be required in a HACCP Compliance Audit (Fig. 7.6). This audit guidance is based on doing a first-time, third-party audit, e.g., of a key (CCP Sensitive Ingredient) supplier, or a HACCP plan verification audit for a different department within a larger company, but it will also be useful for those who wish to conduct internal audits as verification of their own systems. You should adapt this for your own use depending on circumstances.

We will now take each of these stages and look in detail at what happens.

A. Audit program

It is useful to prepare an agenda for the audit program. This will serve to notify personnel who may be required during the audit of your intended timetable and for them to ensure that they are available. Include the start and finish times.

You will need also to make sure that you have all documentation required for the pre-audit review. In alerting the auditees to the agenda for the audit, you will be able to request all relevant documentation, as indicated.

B. Pre-audit Document Review

Before the audit, all documentation relating to the scope of the audit can be reviewed by the auditors. This will be a very important part of the audit as an initial audit checklist can be drawn up during this process. However, in some instances, e.g., auditing another company, it may not be possible to have sight of the necessary documents in advance, and so time may need to be set aside on the day of the audit.

What documentation should be reviewed? In answering that question, let us consider what would be available. Firstly, the site layout plan, which is useful for understanding both the flow of product through the site and also the scale of the operation, including other products produced. Secondly, the HACCP plan. Start with the process flow diagram and product specifications relating to it. Compare one against the other, noting whether all elements of the corresponding specifications are included in the Process Flow Diagram and vice versa. Consider whether all time/temperature information is adequately covered by the Process Flow Diagram.

The pre-audit Document Review can be done as an initial scan—to get a feel for who carried out the HACCP Study, the style, completeness, and also familiarization with the site being audited, and the product and process itself. It will also give you an opportunity to carry out some research before the audit.

If you are auditing a HACCP plan for the first time (perhaps as part of a verification exercise), an important part of your audit will be to assess the competency of the people responsible for the study. One way of doing this is to take sections of the Process Flow

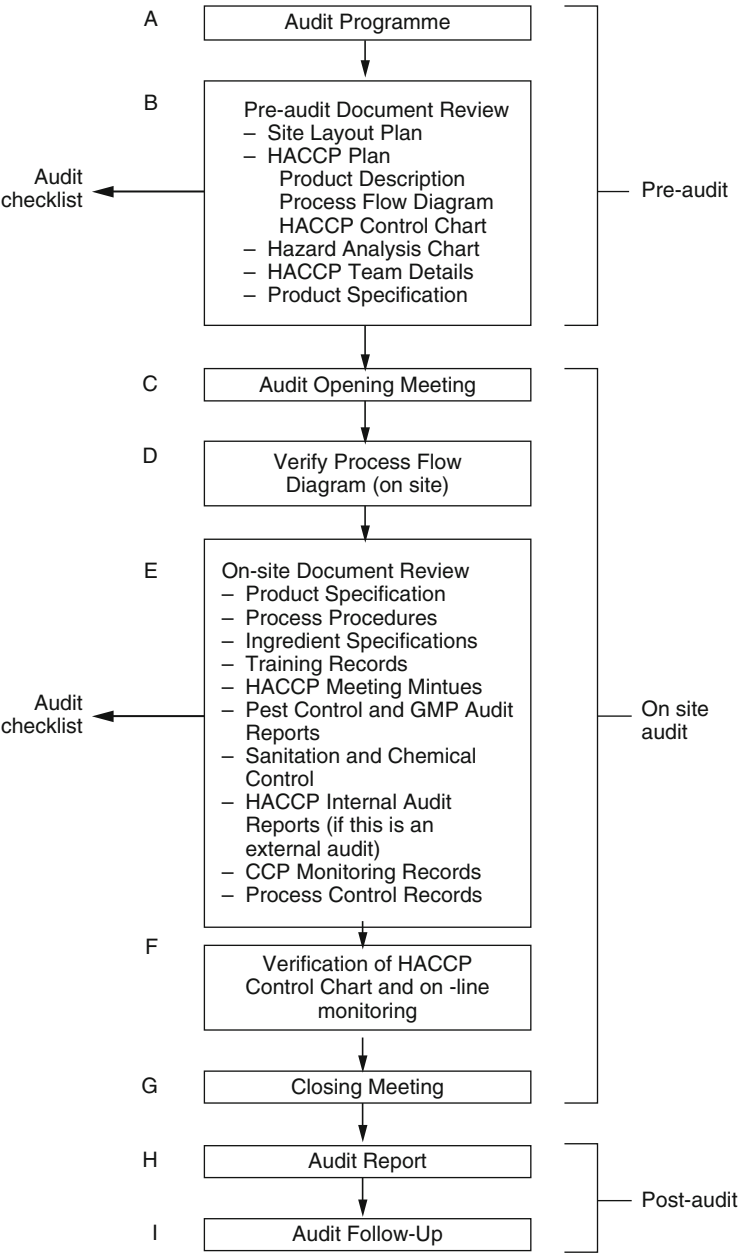


Fig. 7.6 Example of typical steps in a HACCP Audit

Diagram, preferably a high-risk section, and without reference to the HACCP control chart carry out your own hazard analysis based on your expert knowledge and use of reference material, legislation, etc. Having done that, compare your result with the original Hazard Analysis Chart. At this stage, too, you will be able to consider whether food safety hazards only have been included or whether quality and legal hazards have been identified, and also whether the hazards and control measures are defined precisely or are rather vague and general—Is there a control measure for each specific significant hazard? Has the hazard analysis been carried out in an organized manner or is it a jumble of hazards and control measures? Following on from this, you will begin to be able to judge how the CCPs have been established. Make a note to check whether records were kept of the decision-making process.

You may decide to assess the competency of the HACCP team by then taking the CCP decision trees and using your own expert knowledge, determining where you think the CCPs are, and why.

In looking at the HACCP control chart, make sure that food safety hazards are clearly and separately identified. Considering each of the columns on the chart, is the corrective action identified going to be effective and is it realistic? What about the people responsible for monitoring and taking corrective action? Make notes of who they are so that you can talk to them during the audit. For example, if the “Goods-Inwards” clerk is defined as being responsible for checking Certificates of Conformance for certain high-risk raw materials, you will be able to question him or her to assess whether he/she has been trained, what his/her terms of reference are, where his/her CCP log sheets are kept, who reviews them, and so on. The same approach can be taken for each CCP. Consider the monitoring procedures and frequency—perhaps a Certificate of Analysis of a Salmonella test of an ingredient is specified and the procedure for checking this is cross-referenced by a reference number. You will be able, during the audit, to check that the procedure exists, and that the issuing laboratory has been validated.

You should by now have a great many questions that you will want to ask during the audit. You may also want to discover what steps were taken to capture any information relating to process control points. This is a useful indicator of the approach of the HACCP team—Are they using HACCP to effect business improvement in addition to product safety?

If you feel that the Document Review has indicated obvious inadequacies, it may be advisable to stop the audit at this point. The deficiencies should be discussed with the HACCP team, who can then review their HACCP system and implement any further training requirements.

– Audit checklists

One of the most important aspects of an audit is the required organized approach to its execution. Many people find that using a checklist is helpful during an audit and the Process Flow Diagram itself might be useful in drawing this up. One possible audit checklist format is shown in Table 7.6. The “Considerations” column can be completed during the Document Review for each step of the process, and the “Auditors’ findings” column during the audit itself.

Table 7.6 Example of audit checklist

Process step	Considerations, questions and points to raise on site	Auditor's findings
Raw materials (including goods inward and storage) (List raw materials here) ↓		
Process and CCPs (List process steps here, indicating where the CCPs are in the process flow) ↓		
Packaging and despatch (List packaging steps here)		
PRPs/OPRPs (List the different PRPs/OPRPs here) ↓		

As an example of the type of operations the auditor might add to the checklist, the following (non-exhaustive) list is provided:

Raw materials and Supplier Quality Assurance

- Are the “critical” ingredients identified?
- Are they being handled according to specification?
- Storage conditions—Are they as stated?
- Are all raw materials and process/storage activities included in the flow diagram? (Rework can be included as an ingredient.)
- Are positive release or quarantine requirements being adhered to?
- Are agreed specifications in place?
- Are the packaging materials as specified?
- Have auditors been trained, and how?
- Have all suppliers been audited?
- Have suppliers changed since HACCP plan development?
- Check visit reports—Has all corrective actions been followed up as required?
- *Certificates of Analysis and Conformance*
 - Are these being used?
 - Do goods-receiving operators know what to do with them?
 - Have they been checked as accurate?

Process and CCPs

- Have all activities been included?
- Is the Process Flow Diagram correct?
- Have process capability studies been carried out?
- Have any changes been made since the Process Flow Diagram was drawn up? If so, how does the HACCP team get notified and how were the changes recorded and approved?
- Were any changes discussed with the HACCP team before implementation?
- Are there rework opportunities and have they been included?
- What methods were used to ensure the accuracy of the Hazard Analysis?
- How were Critical Limits established?
- Are the HACCP records clearly identified by unique reference numbers?
- Are all documents accurate and current?
- Is monitoring equipment calibrated?
- Have CCP monitors been trained?
- Are CCP records being reviewed? By whom?
- Is the information on the HACCP control chart accurate?
- Are time/temperature parameters being achieved?
- Are CCP log sheets being filled out correctly?
- Is frequency of monitoring adequate?
- Has corrective action been recorded and has the effectiveness been verified?
- Have statistically valid sampling plans been drawn up?
- Are the packaging materials as specified?
- Are SPC records being used to demonstrate that the process is in control on a day-to-day basis?
- Do records agree with stated activities?

PRPs and OPRPs (where applicable)

- What is the general standard of GMP and other PRPs such as Pest Control, Chemical Control, and Allergen Control?
- Is there a hygiene schedule?
- Are production codes legible on the packaging?
- Are customer usage instructions clear and accurate?
- How was shelf-life determined?
- Are there any cross-contamination opportunities?

Packaging and dispatch

- Are storage conditions as stated?
- Are distribution procedures in-house or third party?
- Are good distribution practices being maintained? Check hygiene, handling, and temperature if chilled or frozen.

This list is not exhaustive but, as with hazard analysis, there are many areas to be covered.

The above activities can happen in advance of the audit itself. Let's now consider what happens on the audit day(s).

C. Opening meeting

It is good audit practice to begin with a brief opening meeting. Use it to confirm with the key people being audited (auditees) the audit scope, timetable, and personnel required. Confirm too the time and location of the closing meeting and who will be needed. Request any additional documentation required for the on-site Document Review.

D. Verify Process Flow Diagram

It is essential to verify the Process Flow Diagram at an early stage, unlike other Quality System audits, where other aspects of the documentation may be considered before going into the factory or process operation. This is simply a matter of walking through the process from start to finish. However, it may take some time and should not be hurried. Stand and observe what is happening in each area.

The auditor's tools of eyes, ears, and mouth are essential to:

- **Watch** what is going on.
- **Listen** actively to what people are saying.
- **Ask** questions, and talk to operatives; for example, ask them what they are doing. Do they always do it that way? When might they do it differently?

Check for evidence of any time/temperature stages. Look for opportunities for cross-contamination. What about holding periods? Could there be time enough for toxin formation or spore germination? This may be particularly relevant to high-risk raw materials or part-made product where there is a high degree of handling. Make a note of people with whom you have spoken, and check their training records during the Document Review.

You may want to pick up a few finished product codes out in the stores during your Process Flow Diagram verification and use this to trace test results and records, and to test traceability procedures during the on-site Document Review and factory audit.

E. /F. On-site Document review and verification of the HACCP control chart

Having established the Process Flow Diagram status, you will be able to carry out a thorough on-site Document Review from a more informed base. As with the Process Flow Diagram verification, use eyes, ears, and mouth to search for evidence of compliance with the HACCP plan. This time you should include a full review of operational procedures for CCP monitoring, CCP monitoring records, training records, etc. Check the prerequisite GMP and hygiene maintenance records, pest control, and also the HACCP team meeting minutes. In the latter case, it may be helpful to get an idea of the decision-making process, who attended the meetings on each occasion, how often they occurred, and whether difficulties were encountered.

The review will also include previous internal audit records where noncompliances may have been found. The assurance of the effectiveness of any corrective actions taken must be sought. Other quality- and safety-related data for review will include a review of customer complaints, customer audit reports, and any minutes of HACCP or Quality Improvement Project meetings relating to the audit. The on-site Document Review is aimed specifically at verifying that the HACCP system is working effectively in the workplace. At this point, the audit process is in the conclusion stage. A few key points to note are the following:

- Final investigation of any anomalies found during the audit process.
- Note any points of concern that cannot be resolved.
- Ensure that identified deficiencies are clearly understood and supported by evidence (specific examples of corrective action not being followed up, for example).
- Communicate any deficiencies at the time of discovery and obtain agreement.

G. Closing meeting

This is the first opportunity to present the audit findings and give an overall view of the proceedings. Noncompliances should be discussed together with supporting evidence and a schedule for major corrective actions agreed. The recommended corrective actions should be generated by the auditee and agreed by the Departmental Manager. It is important that recommendations are feasible. An example of a noncompliance note is shown in Table 7.7. This type of record can be used to document the outcome of the audit.

H. Audit reporting

Audit reports should provide evidence of the findings of the audit—primarily what deficiencies have been found in the HACCP system.

While noncompliance notes should be issued ideally on the day of the audit, it may be appropriate for the auditor(s) to issue an audit summary report. This may be useful to company management and also to the HACCP team and subsequent auditors.

Again, a pro forma might be a useful means of summarizing. An example is given in Table 7.8. The “Additional comments” section can be used to note any observations that may not have resulted in a noncompliance note but where minor corrective actions are perhaps needed.

I. Audit follow-up

Outstanding noncompliance notes may be discussed at HACCP team meetings and, if seriously impacting on food safety management, by senior management or board meetings in order to ensure that timely corrective action is taken. Noncompliance notes should be closed and signed off as soon as the corrective action has been taken. Even so, they will need to be reviewed during any subsequent audit to ensure that the corrective actions taken have been effective on an ongoing basis.

Table 7.7 Example of noncompliance note

HACCP Audit Non-compliance Note		No:
Location:	Date:	
Area under review:	HACCP Plan Ref. No.	
Non-compliance:		
Action required by (date):		
Auditors:		
1.	2.	3.
Accepted by Auditee:		
Corrective action:		
Verified (Auditor)		Date:

(iv). Use of Third-Party audit in HACCP Verification

Increasingly, third-party audit programs are playing a role in the verification of HACCP systems. These may be third-party or external auditors who are auditing against Codex requirements (Codex, 2009b) or it could be a third-party standard covering food safety and HACCP requirements such as those meeting the requirements of the Global Food Safety Initiative (GFSI, 2011). As with all audits of HACCP systems, a key factor is the competence of the auditor(s) and so it is as important to understand the qualifications, experience, and training of third-party auditors as it is for internal HACCP audit.

7.7 HACCP system Maintenance

Maintenance requirements (including verification) will normally be discussed during HACCP plan development (Chap. 6) and they may be recorded within the HACCP plan documentation. Some companies find it easier to decide how

Table 7.8 Example of a HACCP audit summary pro forma

HACCP Audit Summary	
Location:	Date of Audit:
Audit Ref. No:	Area under review:
Auditors:	
NCN Ref. No.	Summary of Non-compliances
Additional comments:	
Signed Auditor(s)	Date:
Circulated to:	

maintenance will be done during the implementation phase. There are a number of activities which can be considered as part of HACCP maintenance (Fig. 6.4).

HACCP maintenance is an area of weakness within HACCP systems (Chap. 1) and so it is essential that maintenance requirements are considered and systems developed where necessary. We explore both these important aspects in some depth over the remainder of this chapter, using the HACCP system Maintenance wheel (Fig. 7.7) as a guide. Whilst focussing here on ongoing verification and maintenance of the HACCP system, it is crucial that similar verification and maintenance procedures are developed for PRPs and, where relevant, OPRPs.

Verification activities will vary according to the control measures in place; however they will always include some form of audit and records review, and may include additional testing procedures. Maintenance actions will include keeping the system up to date and ensuring continuing suitability to control relevant significant hazards. This involves both keeping the documents up to date and continually horizon scanning and updating on potential new threats which might affect the company and its products. As part of an effective food safety culture, these activities will be wide-ranging and will involve personnel at all levels of the business.

It can be helpful to construct a summary of HACCP and PRP/OPRP maintenance requirements and to formalize this as a document within the HACCP plan

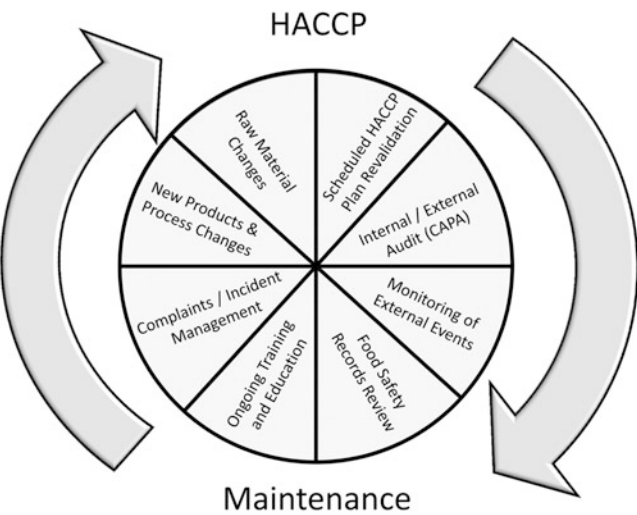


Fig. 7.7 HACCP maintenance wheel

Table 7.9 Ice cream—HACCP system maintenance requirements

Maintenance requirements	Approved by:	A. Jones
		HACCP Team Leader
	Date:	18.6.12
<div>1. Quarterly audit of HACCP plan</div> <div>2. Review of regulatory visit and customer audit together with corrective action progress</div> <div>3. HACCP plan to be revisited for all process ingredient changes</div> <div>4. Quarterly CCP log sheet review for deviation trend analysis</div> <div>5. Monthly review of customer complaint data for trends</div> <div>6. 6-monthly simulation of trace/recall procedures</div> <div>7. Monthly discussion of technical information update obtained via symposia and technical journals</div> <div>8. Quarterly analysis of training needs and conduct refresher training of operators as required</div> <div>9. Monthly HACCP team food safety updates to the company</div> <div>10. Annual plan revalidation</div>		

file. Whilst such a summary is not a requirement of HACCP Principle application, it is of practical use for everyone involved to know the approach being taken. In addition to the HACCP system itself, the verification requirements summary can also be audited for compliance.

As an example, the HACCP team at the Iced Delights ice-cream factory came up with the verification and maintenance elements shown in Table 7.9.

7.7.1 *Safety Review for Product and Process Changes*

One of the reasons HACCP fails to deliver is that it is not reviewed in a timely manner when changes occur. All food operations have changes occurring on a regular or a periodic basis. The frequency of changes will depend on the type of operation—in some cases changes may be very frequent, e.g., in a business manufacturing a continuously changing range of products for a private label customer, whilst in other cases they may be rarer, e.g., in a commodity processing or handling business. Changes might include a wide range of aspects to do with products, processes, and the processing environment, for example:

- New ingredients and raw materials
- Changes to existing ingredients/raw materials made by the supplier
- Change of supplier for ingredients/raw materials
- Process amendments
- New processing equipment
- Changes to process layout
- Improvements to the processing environment
- Changes to handling practices
- Changes to packaging, pack size, etc.

For effective food safety management all proposed changes need to be assessed for food safety implications **before** they are implemented in the operation. This enables appropriate controls to be built into the operation to address any new hazards that might be presented. What is needed is a formal change review process so that all proposed changes are identified to the appropriate people who can then review safety implications and develop the necessary additional controls. This is best achieved using an adapted version of the product safety assessment (Chap. 5), so the safety review can be formally recorded.

Where any proposed changes might result in new significant hazards then it is important to review the suitability of the existing HACCP plan to control these hazards and any new/amended CCPs will require update of the HACCP plan documentation.

One of the reasons for failure of HACCP to control safe food production is because the HACCP team may not be receiving timely notification of changes to the product formulation or process, which in turn will not result in an update of the HACCP system. How can this situation be avoided? Product formulation and ingredient changes can be controlled through the design function, and use of a more structured approach such as the product safety assessment discussed in Chap. 5 can ensure that the changes are captured and analyzed for possible hazards, or to see whether they eliminate any existing ones. Process changes such as equipment modification can be more difficult to capture, and this really requires the complete support of engineering, production, and other key functions within the business. Use of a “HACCP Change Request” pro forma can sometimes be helpful. An example is given in Table 7.10.

Table 7.10 HACCP Team Assessment

HACCP Change Request Form		HACCP Plan Ref. No.	
Details of change:			
Submitted by:		Date:	
HACCP Team Assessment:			
Action required:			
Authorised by:		Date:	
HACCP Team Leader			
Copied to:	HACCP Team Leader Originator		

The HACCP team Leader on receiving the HACCP Change Request form can discuss the likely issues with the team. Again, they will conduct a hazard analysis to determine whether any new hazards arise or whether any existing hazards can be eliminated.

Using the Iced Delights example, we will now look at the activities that occurred when the company decided to introduce a new flavor variant—chocolate peanut ice cream. Their review process can be divided into three categories: product safety assessment, HACCP plan amendment, and prerequisite review.

(a) Product safety assessment

Here the Iced Delights HACCP team identified additional hazards for the new product itself (Salmonella from the peanuts, aflatoxin, and nutshell, allergic reaction if wrongly packaged/labeled) and all other existing products in the range (allergic reaction through cross-contamination). Table 7.11 shows how this information was captured. Bold type indicates the additions made to the table since the previous assessment.

(b) HACCP plan amendment

The Iced Delights HACCP team used the information on the product safety assessment to go on to complete the amendment of the modular HACCP plan.

Table 7.11 Product safety assessment—chocolate peanut ice cream

PRODUCT Chocolate peanut ice cream				FORMULA CPI		DATE 5-5-2012	Page 1 of 4
Stage	Considerations	Criteria	Likely hazard	Control measures	Is control possible?	Validation of control	Recommendations to HACCP team
Concept	Targeted at general population including high-risk groups	Frozen product to be eaten without any further process	Vegetative pathogens with low infective dose	Pasteurization, filtration, supplier assurance	Yes		Whilst it is pasteurized at the facility, there will be many ingredients added post pasteurization that must be made safe by the supplier
			Allergic reaction from vulnerable groups	Labeling	Yes		Check labeling for presence of the nut ingredient
Ingredients	Sensitive ingredients and supplier control						Careful control at supplier → effective supplier management (including audit of processing site for hygiene assessment and microbiological test facilities)
	SMP	Dried	Vegetative pathogens (Salmonella) Allergen (Dairy)	SQA	Yes	Supplier's antibiotic monitoring procedures	Verify that antibiotic monitoring procedures satisfactorily covered during SQA audits
	Cream	Pasteurized, chilled	Antibiotic residues	SQA	Yes		
	Chocolate chips	Ready to use	Salmonella Allergen (Dairy)	SQA	Yes	Certificates of Analysis received with each batch	A above. careful control at supplier → effective supplier management (including audit of processing site and microbiological test facilities). This is a CCP

(continued)

Table 7.11 (continued)

PRODUCT Chocolate peanut ice cream				FORMULA CPI				DATE 5-5-2012	Page 2 of 4
Stage	Considerations	Criteria	Likely hazard	Control measures	Is control possible?		Validation of control	Recommendations to HACCP team	
	Water	Mains	Chemicals, heavy metals, etc.	Supplier control	Unknown		Legal obligation	Ensure proactive relationship with water authority	
	Stabilizer	White powder	No hazard identified	Labeling in plant	–	–	–	Controlled labelling of white powder ingredients must be in place in the factory	
	Packaging	Plastic tubs and film	Plasticizers and additives	SQA	Yes		Supplier testing results	Ensure product suitability testing has occurred and is documented as complying with legal requirements	
	Roasted Peanuts	Chopped and shelled	Salmonella Aflatoxins Nutshells	Supplier control Supplier control	Yes Yes		Testing and Certificates of Analysis with every batch	An audit of the supplier will be necessary. This is likely to be a CCP in the supplier system but will need to be assessed. There is no kill step at Iced—Delights following ingredient addition	
Legal	Ingredients/product	Thermal process control recipe	Food safety		Yes		Regulations as per manufacturing country	Check compliance	

PRODUCT Chocolate peanut ice cream			FORMULA CPI			DATE 5-5-2012		Page 3 of 4
Stage	Considerations	Criteria	Likely hazard	Control measures	Is control possible?	Validation of control	Recommendations to HACCP team	
Recipe/ intrinsic factors	a_w , pH, chemical preservatives, organic acids—none will control product safety	Insufficient sugar to prevent micro growth totally	No—product is frozen	–	–	–	–	
Process	Process conditions	Pasteurization failure	Survival of vegetative pathogens	Correct heat process	Yes	Required	Ensure that the effectiveness of the heat process is validated for this formulation. Critical limits will need to be established	
		Temperature control	Spore outgrowth	Effective temperature control and stock rotation	Yes	Audited on a monthly schedule. Calibrated temperature recording already in place	None	
	Contamination	Air filtration failure	Introduction of pathogens	Effective filtration	Yes	Required	Check filter size and performance criteria. Microbiologically filtered air necessary	

(continued)

Table 7.11 (continued)

PRODUCT Chocolate peanut ice cream				FORMULA CPI		DATE 5-5-2012		Page 4 of 4
Stage	Considerations	Criteria	Likely hazard	Control measures	Is control possible?	Validation of control	Recommendations to HACCP team	
	Contamination	Nut contamination of processing equipment. Incorrect label	Allergen contamination of other products where labeling would not provide controls. Nuts not properly identified	Additional cleaning and dedicated equipment where possible Check label	Unknown Yes	Residue testing of rinse waters and of first product through the line Audit labels	No production trials can take place until this has been validated as other products could become contaminated. Dedicated nut filler hopper could be a CCP as well as label control	
Post factory	Shelf-life	Product consumed beyond shelf-life	No hazard identified	–	–	–	–	
	Customer abuse	Temperature abuse	Unlikely—sufficient abuse for growth will render product inedible	–	–	–	–	
		Contamination with serving spoon	Unlikely—only low numbers; will not grow in freezer	–	–	–	–	
			Slight risk perhaps from leaving serving spoons in water between servings	None possible	No	–	The product is targeted at the domestic market rather than catering, therefore hazards associated with mass servings are unlikely to be realized. Revisit if a “catering” version is launched	
Signed: <i>J. Smith</i>			(Position) Development Manager			Date: 5-08-12		

First, they reviewed the Process Flow Diagrams and then a Hazard Analysis was undertaken starting with Module HM8, Dry Particulate Preparation. They saw that the subsequent module (which Module HM8 linked into) would need review also, namely, the Filling Room HM12. The HACCP team needed to assess physically, through online audit, where cross-contamination was likely to occur and whether additional control measures were needed in order to support the existing cleaning schedule, which was also reviewed for effectiveness. During this stage, validation trials were conducted and cleaning rinse waters sent away for external analysis. Additional filling heads were found to be necessary due to the difficulties in cleaning them, which eventually meant that an additional CCP had been identified. Production scheduling was also felt to be necessary such that the peanut product was always scheduled last, before a major clean down, and the product following down the line from the peanut variety would be tested for peanut residue. The section of the amended HACCP control chart is shown in Table 7.12.

(c) Prerequisite program review

We have already seen that the cleaning schedule was reviewed by the HACCP team. This would have been strengthened to include additional verification controls on the general cleaning. Also, observations of physical cross-contamination (i.e., nut spillage) would need procedures and training on how to clean these up. These additional controls will be fully assessed in order to see whether any are regarded as critical, i.e., CCPs. Other prerequisite reviews will include occupational health procedures where existing and future employees will need to be screened for their own susceptibility to peanut allergic reaction.

7.7.2 *Information Searching: Keeping Up to Date with Emerging Issues/Hazards*

Having established your HACCP system, you will need to ensure that you are kept up to date on new emerging hazards which could have an impact on your product and require modification of the HACCP plan. Why will new hazards arise? Let us consider just a few of the possible answers to this question.

1. **New technologies.** This could cover a wide range of activities, but a few recent (within the past 20 years) areas to consider are irradiation, electric field processing, microwaving, macrowaving, Ultra Violet, and advances in aseptic packaging, modified atmosphere packaging (MAP), and extrusion technology. Each brings its own hazards and risks.
2. **More natural foods.** Consider the ongoing trend for fewer preservatives and more natural, organic, and locally produced foods—Does this increase the food safety risk?
3. **New combinations of foods.** For example, chilled ready-to-eat sandwiches and salads containing unusual combinations of fish, fruit, meat, nuts, eggs, vegetables, mayonnaise and conserves, products in oil, etc., where the interface

Table 7.12 Amended HACCP control chart for ice cream with addition of peanut hazard controls

HACCP Plan Ref. HP001/2				Lead Delights HACCP CONTROL CHART						Date:28-5 -2012	Supersedes: 28.3.1012
				Monitoring						Approved by	A. Jones HACCP Team Leader
CCP No.	Process step	Hazard	Control measure	Critical limits	Procedure	Frequency	Responsibility	Corrective action	Responsibility	Action	Responsibility
	HACCP Module 12: Filling room										
12.1	Date coding	Inability to trace and recall product resulting in unfit product in marketplace	Effective date and batch coding	Correct code applied	Visual inspection	Start-up and half-hourly	Production Operator	Quarantine product and recode Input correct code or repair as appropriate	Production Supervisor/Operator	End of day review of records	Line Manager
12.2	Metal detecting	Metal in packed product	Effective metal detection	2.0 mm ferrous, 3.0 mm nonferrous, 4.0 mm stainless steel	Check metal detector with test pieces	Start-up and half-hourly to include end of run	Production Operator	Repair/recalibrate metal detector—Quarantine and recheck product back to previous good check	Production QA Supervisor Engineer	4-hourly audit of records	Quality Assurance technician
12.3	Filling	Allergen cross-contamination	Change to unique filling head (Peanut 1)	Must be in place for the peanut variety only	Confirm presence	At start-up of peanut variety	Maintenance Supervisor	Stop line and change to correct filling head	Engineer	Rinse-water testing of the filling operation for peanut residues at changeover CIP	Quality Assurance Manager
					Confirm removal	At change-over to other varieties	Maintenance Supervisor	Stop line, put any production on hold	Production Operator		
										Residue testing of next product through the line	
12.4	Labeling	Absence of nut identification	Confirm correct labeling	Present	Visual inspection	Start-up and half-hourly to include end of run	Production operator	Await correct labels	Production operator	End of day review of records	Line Manager
		nb ^a						Hold product to last good check	QA supervisor	End of day review of records	Line Manager

^anb: To ensure that labels are consistently correct throughout the run, bar code scanners may be introduced as an additional control measure

between foods may present an opportunity for microbiological growth that was not there in the individual components.

4. **Changing legislation.** The banning of additives or approval of new chemicals may introduce new issues, as could the change in approved levels of contaminants. This will also be of particular interest where product is being shipped across national boundaries.
5. **New information on existing issues.** Keep updated on information regarding, for example, causes of microbiological food safety incidents, increased understanding of microorganisms and methods for their detection, and increasing importance of emerging pathogens, bovine spongiform encephalopathy (BSE), and other transmissible encephalopathies. Also, look out for, trends in chemical hazards and increased awareness of issues such as those related to packaging or economic fraud such as melamine. Keep abreast of the results of any government surveys and research programs that may be relevant.
6. **New ways of presenting food to the consumer.** Many examples could be considered here, as companies are always looking for ideas that will increase market share through changes in product usage or to meet a new demand which has arisen through our changing lifestyles or health concerns such as reducing salt and sugar. Consider the enormous growth of chilled ready meals, new sales outlets such as garage forecourts complete with microwaves, restaurant trend for warm meat or fish salads, and trend for shopping on a weekly basis instead of daily.

Information on such matters can be obtained through Universities, Laboratories, Government agencies, and Food Research Associations, many of whom regularly circulate abstracts of newly published information. Access to a good reference library may also be helpful. Otherwise use your customers and suppliers as a source of information which is likely to be highly relevant to your products and market. Industry symposia can also be a useful way to meet people with a similar interest. In addition, experienced consultants and data published by the government and media can be used. Increasingly, the Internet is also proving to be a good source of up-to-date information; however the quality of Web site sources should always be established prior to information use.

7.7.3 Formal Periodic System Review

Formal HACCP system review is a periodic element of the HACCP verification and maintenance cycle that is necessary to challenge the system for suitability to control all relevant food safety hazards. This should take into account any new information gained as part of the information searching activities plus any changes to the product, ingredients, processes, processing environment, etc. Formal system review in this way is intended to assure the continued “validity” of the HACCP plan, i.e., will the HACCP plan continue to control all significant hazards that are likely to be

present in the operation (including products, processes, and materials). This covers the ongoing requirements for validation included in HACCP principle 6 and, as such, should include not only a consideration of potential significant hazards but also a review of the continued suitability of control measures, CCPs, critical limits, and monitoring and corrective action.

It is recommended that formal periodic review of the HACCP system should be performed at least annually. Whilst this is a separate activity, it can be successfully combined with scheduled HACCP audit where the review element looks at validity of the HACCP plans and the audit verifies that they are working in practice.

HACCP system review is often done by the HACCP team, although the need for independence from the system should be considered and the presence of “an external pair of eyes” on the review team can be invaluable. An in-depth review is carried out of all HACCP control limits and documentation. This is an excellent opportunity for the HACCP team to consider the effectiveness of the HACCP system, and to determine what new approaches may be needed in the year ahead.

7.7.4 Documentation Update: Amending Your HACCP plan

The HACCP plan will need to be updated and amended periodically to ensure that it remains current. This is only really common sense—a HACCP plan which was drawn up a year ago is unlikely to reflect current activities accurately unless it is updated. In the real world, manufacturing operations change and do so for various reasons. We have already discussed some of the reasons for update, including changes to materials, products, processes, and the processing environment plus changes that might become necessary as the result of new information, for example new information might require a review of the critical limits, e.g., new data on toxicity of chemical hazards or the infectious dose of microbiological hazards. The HACCP audit may also provide reasons for updates to documentation but remember that the audit is only a sampling exercise, an indicator of whether the HACCP plan is being complied with and is correct.

Any changes made to the HACCP plan will need to be recorded and approved. The revalidation exercise should also be recorded even if no changes to the plan were needed. This may provide useful due diligence evidence in the event of a prosecution or a customer audit.

Once the HACCP team has completed its assessment and the HACCP control chart updated, all related procedures, such as those used for monitoring and verification, will need also to be updated to include the change. This is where use of a broader Quality Management System can be really helpful in providing the framework for control of documentation.

A useful method of recording these activities is to draw up a History of Amendments sheet. This may be the reverse or a second page to the HACCP plan approval sheet, if this is a separate document. The main elements to include are

Table 7.13 History of amendments sheet

HACCP Plan Reference:.....			
Page:.....			
Date	Amendment	Reason	Approval signature

shown in Table 7.13, demonstrating how amendments to the HACCP plan can easily be captured and recorded.

7.7.5 Ongoing Training Requirements

We have already considered initial training needs, and the implementation training needs, but what about ongoing training requirements? Training is a key element of the ongoing maintenance of HACCP and food safety management systems, which makes an essential contribution to the development of an effective food safety culture. Whilst a full discussion of food safety culture is beyond the scope of this book, we will outline some of the important training considerations for continued successful application of HACCP.

(a) Refresher training

It is important that the company updates and refreshes its approach to HACCP on an ongoing basis. A year or two on from implementing HACCP, and if the program is really a part of the company culture, you will almost certainly have begun to develop your own interpretation of the HACCP Principles. It will be useful to keep up to date with current international thinking through attendance at industry seminars and literature surveys. This obviously does not need to be done by everyone in the company; most likely it will be a HACCP team member who, on returning, should use the new information to brief other company employees.

CCP monitors will also need refresher training in order to maintain their understanding of the HACCP system and to keep them engaged. This too can be done through internal briefings or by posting information on notice boards.

(b) Training new HACCP team members and CCP monitors

Clearly, when all HACCP plans have been implemented the HACCP team will still require to meet in order to discuss maintenance, but this will be on a less frequent basis. It is important that HACCP team members do find the time to participate in maintenance activities and training will be important, both refresher training for existing team members and training of new team members.

Personnel changes will make it necessary for new people to come into the HACCP teams or new CCP monitors to be appointed. These new people will not have the advantage of being involved from the beginning, so care must be taken to ensure that they have the same level of understanding as their colleagues. HACCP is a team activity and it may be useful when appointing new HACCP team members to go back through a team-building exercise and revisit some of the rationale and discussions from when the system was first implemented. This will help to establish the new team relationship—trust and interdependence will not automatically appear with the new member.

(c) Training new staff

In addition to new HACCP team members and CCP monitors, the company staff turnover must be considered. At all levels and disciplines of staff, HACCP training will need to be carried out appropriately, from spending a whole day briefing a new board director to an hour of awareness training with administrative personnel. This can be a problem if not done well, slowly eroding the developing food safety culture as people who were not part of the initial implementation come on board.

(d) HACCP plan Amendments training

CCP monitors, and their supervisors, may need to be trained following a change to the HACCP plan. It is important that they are aware of what the change is, why it occurred, and what it means to their activities.

This will also help to encourage them to give feedback regarding any areas that are not quite correct as they will see that the HACCP system is a “live” system which relies on input from all personnel in order to make it work effectively.

(e) Ongoing awareness training

In order to keep the HACCP system alive, it will be necessary for the company to promote HACCP on an ongoing basis. This can be done by building HACCP into the annual training program, linking it with new training initiatives in hygiene or SPC for example. Notice boards and suggestion boxes can also be used to good effect, as can quizzes within company in-house newsletters. Another way of ensuring that the workforce remains aware of the system is to regularly report successes, failures, audit performance, and changes down through the line management.

It is essential that the HACCP team continually keep their awareness of new emerging hazards up to date. Again, this could be achieved by attending external seminars and reviewing literature. Membership of industrial food research associations and professional bodies can be particularly useful.

(f) Design of new training material

Whether initially you did much of the HACCP training “in-house” or not, you may wish to design internal training materials for future needs. This can be cost effective providing you have people who are suitable to act as trainers for the company. It is a complete waste of time and money to allow ineffective trainers to try to train people. A good investment in using your own training materials will be to train competent trainers. Don’t make the mistake of using someone who happens to be either available or superenthusiastic—consider the competencies needed for the role. These include being able to motivate others, communication and interpersonal skills, leadership skills, being able to manage diversity by recognizing and valuing differences in people, and finally having a sound, in-depth knowledge of the subject matter in which they are going to train others.

External “Train the Trainer” courses are readily available and usually last a minimum of 2 days. It will be useful if the designated company trainer(s) has an input into the design of in-house materials. Use of an external consultant may also prove beneficial if resources are not sufficient within the company. Alternatively, you may be able to purchase off-the-shelf training packages which you can then adapt. Computer-based packages and eLearning have evolved considerably and are often considered nowadays.

Ongoing training activities should be seen as a way of continually raising company standards and as a way of ensuring that the HACCP system continues to grow.

7.7.6 Incident Management

Food safety management systems based on HACCP principles are designed to prevent food safety problems and a strong HACCP maintenance program will be an important element in making sure that all significant hazards are controlled on an ongoing basis. However, it must be recognized that things do go wrong in food operations from time to time and, therefore, it is essential to have an effective

incident management program within all food businesses. Whilst this will likely operate as a separate system, it is mentioned as part of the HACCP verification and maintenance cycle because it is necessary to test incident management procedures for consumer health protection as part of HACCP system maintenance. The incident management system will need to include procedures for tracing, quarantining, and recalling suspect product that might be the result of CCP/critical limit failure. In addition, communication channels to provide information to customers and consumers will be important and all of these aspects will need to be tested as part of HACCP maintenance to assure the business that an incident could be handled swiftly and professionally such that public health would continue to be protected if an element of HACCP should fail.

7.7.7 Ongoing Documentation and Record Keeping

HACCP principle 7 requires that effective record-keeping procedures are established to document the HACCP system. Records will be kept of all areas which are critical to product safety, as written evidence that the HACCP plan is in compliance, i.e., verification that the system has been working correctly. This will also support a defense under litigation proceedings. Records will also be useful in providing a basis for analysis of trends (which in turn may contribute towards improvements in the system) as well as for internal investigation of any food safety incident that may occur. As time goes on, having the right system for records management will prove invaluable. With paper-based systems it is extremely useful to allocate a unique reference number to each HACCP plan. This number may then be used on all pieces of documentation relating to the HACCP plan and cross-referencing of CCP log sheets, monitor training records, etc. will be made easier. It is also increasingly likely that you will have records in electronic format, in which case they may be more easily archived, but it may be more difficult to prove that they haven't been tampered with in the event of litigation.

The length of time for which records should be kept will vary, depending on several factors. First, there is likely to be a minimum time for which records must be kept for legal reasons, and this will be determined partly by the country where your operation is located and/or the countries to which the product will be shipped. The record retention time will also depend on the nature of the product itself, e.g., there is little point in keeping records for production of a sandwich with 2 days' shelf-life for as long as the records for production of a canned product which has 4 years' shelf-life. As a general rule, it is wise to keep significant records for at least 1 year following the end of the product shelf-life, although if you have a certified quality or food safety management system you may need to keep them for a specified period, e.g., 3 years. It will therefore be necessary to develop effective archiving systems so that monitoring records can be identified and located when necessary (Fig. 7.8).

Records of CCP management systems which need to be kept to demonstrate effective HACCP plan implementation include the following:



Fig. 7.8 “Retaining records”

- CCP monitoring records: The amount of paper involved in retaining all log sheets may be prohibitive, in which case a monthly/3-monthly summary is recommended. This should clearly detail the CCP number and Critical Limits and indicate any deviations and corrective actions taken, and persons involved. Again, the trend analysis and compliance summaries could prove useful.
- Corrective action records, including Hold/Trace/Recall records where appropriate: In the event of a deviation at a CCP, it may be necessary to hold the product in quarantine pending a decision as to the means of disposition. If the product has been dispatched, it will need to be traced and recalled. Records of these activities will need to be retained. It may prove useful in the event of a serious incident if evidence in the form of documented challenge tests on the trace and recall system is available.

7.8 Key Points Summary

- Implementation, verification, and maintenance of HACCP plans and supporting PRPs are essential aspects of HACCP system effectiveness, which contribute enormously to consumer health protection.
- Lack of implementation and/or maintenance are key reasons why HACCP fails.
- Implementation of new HACCP plans or HACCP plan amendments requires careful planning and attention to detail. This included the need for validation of HACCP plan elements prior to implementation.

- HACCP plan implementation needs to be built on strong prerequisite foundations; therefore verification that necessary prerequisites are in place and working plays an important role.
- Systems and procedures to manage CCPs need to be developed and applied and all actions identified by the HACCP team as necessary for food safety need to be completed before the HACCP plan is implemented.
- Training of operations personnel and building confidence in their ability to manage CCPs is an essential part of the handover from the HACCP team's development stage to the day-to-day operation of HACCP in practice.
- Verification and review are essential steps in implementation to check status of implementation actions prior to the final handover of HACCP to operations personnel.
- Following implementation and handover, ongoing control of food safety is achieved by the PRPs and HACCP systems working together as a cohesive system. The keys points to achieve this are the following:
- Verification of food safety system elements effectiveness, using tools such as audit and records review. This might involve the use of external certification systems in addition to internal audit/review.
- Change control procedures that require formal safety assessment and approval for all proposed changes to ingredients, process activities, and products.
- Information searching and horizon scanning to identify new information and potential new threats to food safety which need to be controlled.
- Formal periodic review of system elements and their suitability for food safety, with particular reference to changes in knowledge about food safety hazards and their control and changes to ingredients, products, processes, and operating practices at the manufacturing site.
- Ongoing document management and update of system elements/documents.
- Training and retraining of staff, including new recruits and temporary personnel.
- Incident Management programs, including testing of their ability to protect the consumer.

Chapter 8

Considerations for HACCP Application in Different Supply Chain Sectors

8.1 Introduction

In the previous chapters we have looked at the theory and practicalities of applying HACCP principles as a cornerstone of food safety management systems within food businesses. This chapter aims to develop this further using input from companies operating in different parts of the food supply chain to illustrate real examples and experiences of HACCP application in practice.

In Chap. 1 we looked at a simplified supply chain model (Fig. 1.5). In reality, the food supply chain is much more complicated and is more a lattice of linked units rather than a straightforward chain. A number of supply chain models have been published and the following model (Fig. 8.1) starts to illustrate the greater complexity involved, although even this could be broken down into further groups of stakeholders.

The sections of this chapter are designed to provide case study material covering the major supply chain stakeholders, with the exception of the processors (food manufacturers) whose food safety control arrangements are covered in more detail in the example HACCP plan provided in Chap. 6. Contributors were asked to address, for their sector, the following points:

- What are the key hazard types and typical control measures
- What approach(es) are generally taken to HACCP application
- What difficulties and issues are experienced in their sector

The following text can, therefore, be used as a guide¹ to the key considerations when applying HACCP in these segments of the food supply chain.

¹ However, please note that, although the contributors are highly experienced in the sectors concerned, the findings may not be exhaustive and so should not be taken as an exact “recipe” for HACCP application in the field. Rather they are a demonstration of some of the key points that may need to be considered. The case studies do not necessarily reflect the views or approaches taken by the contributor’s companies nor those of the book authors.

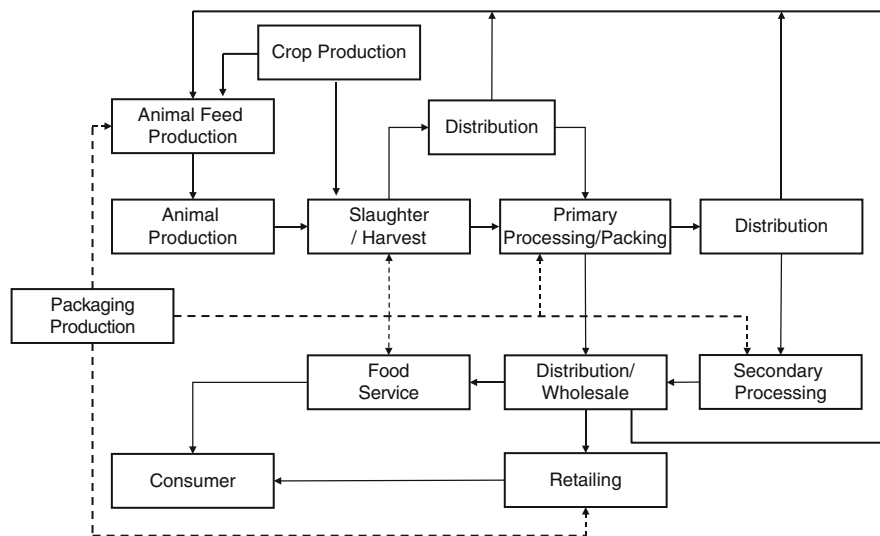


Fig. 8.1 Food supply chain model (adapted from Wallace et al., 2011; after Sperber (2005))

The authors would like to thank all contributors for their participation in this chapter².

8.2 HACCP Application in Packaging Production

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When HACCP is applied to packaging material supply, it can be a powerful tool, but because of application nuances, it has been more difficult to adopt. Packaging and HACCP go back years as individual Consumer Packaged Goods (CPG)³ companies sought to make their processes safer for food applications and/or packaging suppliers took on the challenge by themselves. Combining HACCP and Packaging has been met with some hurdles and is only now being properly addressed through conversations between food manufacturers and the packaging material industry.

² Note: Sections where no specific contributors are noted were prepared by the book authors.

³ CPG companies are businesses that produce and package food products that are used by the consumer nearly every day; therefore, this will include companies operating in a variety of locations within the food supply chain, e.g., food manufacturers and processors, retailers, and packers.

An important feature about the packaging industry, often not appreciated by food companies, is that, even though they participate in the food supply chain, they also supply other industries. The packaging industry has one foot out of and one foot in the food business. This disparity creates challenges in focus and understanding of the issues. This, coupled with the fact that CPGs have focused initially on their own process and upstream ingredient suppliers, there has been, up until now, a lack of attention in the packaging supply area.

When the CPGs began asking the packaging material industry to incorporate HACCP-based programs, the packaging industry response was often, “Why another level of quality? We have foreign material abatement programs in place, and they would not be a CCP anyways.” Adding to the challenge was an overall CPG lack of understanding of the packaging material manufacturing process, so they could not directly speak to the issues at hand. Of the three hazard risk areas, Microbiological, Chemical, and Physical hazards, the majority of training that the CPGs could offer to their packaging suppliers was on microorganism controls—which, in turn the packaging industry thought they had very little impact on.

The packaging industry sometimes sees themselves at odds with the food industry’s requests. Asking a glass jar supplier “What is your glass policy?” or a metal can supplier “How often do you calibrate your metal detectors?” illustrates a misunderstanding of the supplier’s industry and can undermine an otherwise important area of discussion. These examples highlight the areas that food manufacturers and packaging suppliers were not always well aligned.

Training materials have been recently developed to specifically address the area of food packaging and food safety. The Packaging Association, or PAC (see <http://www.pac.ca/index.php/pac/about>), has training and certification programs for packaging suppliers wanting a certified HACCP packaging program. The Global Food Safety Initiative (GFSI) is also a resource for companies wanting to become HACCP certified. Another resource, which is free, is the Institute of Packaging Professionals’ (IoPP) Food Safety Alliance for Packaging (FSAP) models—see <http://www.iopp.org/i4a/pages/index.cfm?pageID=2264> for more details. FSAP was jointly founded by CPGs and the packaging industry to discuss the issues and to create HACCP plans and prerequisite programs (PRPs) for all to use.

Whichever path the packaging supplier takes to receive training, there are some key points which must be kept in mind. These “rule breakers” of HACCP speak to the uniqueness that the packaging industry must keep in mind when applying HACCP principles to itself.

- **Rule Breaker #1:** There will be more than 1 Critical Control Point (CCP) for a particular hazard in a packaging plant. This goes against all training that exists which shows that there is normally only 1 CCP for any given hazard in the food industry. This is illustrated in the example of mixing labels and mislabelling at the packaging supplier (Fig. 8.2). Mixing/mislabelling (and therefore the potential presence of undeclared allergen/chemical) is the resultant hazard, but it does not just have 1 CCP.
- **Rule Breaker #2:** Glass is allowed. It must be carefully controlled. For most food plants, it is easiest controlled by eliminating it. For the food glass manufacturer,

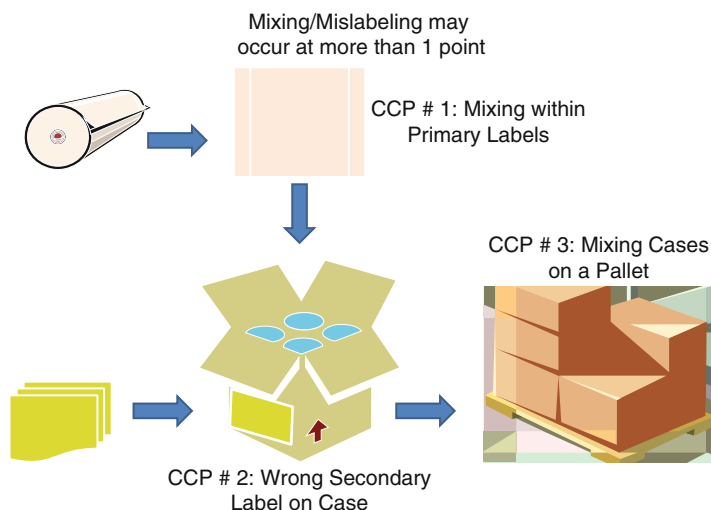


Fig. 8.2 Control of mixing/mislabelling hazards

it means understanding contamination zones upon breakage, 100 % inspection, proper temperature, coating, and handling controls.

- Rule Breaker #3: Allergens do not only pertain to food materials, but they also require strict label control. While CPGs do not **want** peanuts (for example) or other allergens in the packaging supplier's facility, on the production environment the CPG companies **need** the packaging supplier to have programs in place that prevent mixing of printed packaging materials. This can occur on lines that run side by side, or on an individual line that runs a variety of print copies.
- Rule Breaker #4: Pest control is about harborage. The food industry has an obligation to protect the food supply from insects and pests. While packaging suppliers do not have a natural food supply, their materials can provide harborage. To this point packaging suppliers must also have programs in place to prevent insects and rodents from coming into contact with packaging. For example corrugated board can provide a place for insects to hide if not properly stored in an area with proper GMPs in place. The other area where we see some of the most frequent violations of basic GMPs is pallets being stored outside. There is no adequate pest control. Once in a pallet, there is no good "kill step" to ensure that the pallets are fit for food manufacturing distribution.

By applying these "rule breakers" into the HACCP process, we can start to eliminate confusion, usually one of the barriers to adopting HACCP into a packaging facility.

A good way of looking at the packaging industry and its effect on the food manufacturers' supply chain is through the simple equation:

$$\text{Risk} = \text{Hazard} \times \text{Exposure.}$$

This is a great tool to use when evaluating all types of packaging industries. In the example of corrugated fiberboard (cardboard), this packaging medium is usually a secondary or a tertiary unit to the food item. If the hazard is a transient or a resident infestation at the packaging supplier's plant, the recipient food plant is at greater risk. Why do we consider exposure? Due to the nature of exposure through volume, one food plant may receive multiple truckloads everyday from the corrugated supplier. This constant resupply links the corrugated supplier much more closely with the CPG supply chain and increases the risk of cross contamination.

If we look at the flipside, one hazard could be a trial of a new glass item; while the hazard is great (foreign material, glass), the one-time run on a trial might have one think about the overall risk differently than setting up the item for long-standing production.

Some packaging material suppliers have adopted HACCP and are much more aware of the food supply chain risks which they could impact. This new awareness has brought on the next level of learnings. Improved understanding between CPGs and packaging material suppliers has resulted in shared "realizations" around methodology.

- **Realization #1: If You Test, Do Not Ship.** If the packaging supplier has (as a part of its control process) a Gas Chromatograph (GC) test for release, do not ship the packaging material to the CPG company while waiting for the results. On occasion, a breakdown in communication has resulted in the food manufacturer consuming the packaging material before a "bad" test result is communicated—adding to the significant cost of food manufacturing. The effect on the supply chain can be anywhere from expensive to devastating, depending on the size and the nature of the failure. Bringing material back, or worse yet, pulling product from the marketplace costs way too much compared to holding the packaging material at the supplier's location until the proper clearances have been given.
- **Realization #2: Test for One Customer, Impact Another.** An extension of the last scenario, an additional issue arises when a test is implemented at a request of one CPG (Company A), and the testing result affects another CPG company's (Company B) products. If there is a "bad" test result then both companies could be implicated by the results. However, since the company B did not request the "testing for release" program, they may not be notified that testing is going on at all, or that there is potential "bad" material in their possession.
- **Realization #3: Communicate Results, Not actions.** Packaging material suppliers have in certain circumstances reached out to CPGs and asked to recall their packaging material. Packaging material suppliers must understand that recalls of food products have specific legal implications in many countries. The packaging material company's obligation is to carefully and comprehensively communicate the hazard (actual or potential) and the quantity impacted. It should not state that material needs to be recalled. Recalls should be issued by the CPG company through the appropriate internal and governmental channels.

- **Realization #4: When Quantifying Impact, Go Big.** This may be the biggest mistake that the packaging industry makes. When a defect is found, the common approach is to go back to the last good check and hold material in question. That practice does not always protect the food manufacturer. Just because a defect was not found in the last round of inspection does not mean that it was not happening for a long time. Here is a time-based series of events:

10:00 Maintenance over-greases a gearbox above a production line.

10:05 Grease sporadically drips into empty cups (packaging material) on the line below.

10:30 As part of a QC check ten cups were pulled for measurements and visual inspections. No issues reported.

11:00 QC Check again on ten new cups. No issues reported.

11:20 A packing operator notices a foreign material substance on the inside of the cup.

11:28 QC evaluates and issues a hold for material produced back to 11:00.

You can see that material from 10:05 on is suspect and the supplier only captured material back through 11:00. Until the assessment can positively be made as to where the contamination came from and its root cause, a hold should be issued for the entire production time (and perhaps even further back) and then released for use after a positive root cause and time can be established. Going through records, hopefully there should be a time stamp and specific activity noted in the maintenance log stating the intervention, and the hold should be made for 10:00 as it would be difficult to pinpoint when the dripping actually occurred.

HACCP is an excellent tool for understanding and identifying risks from the packaging material supplier to the food industry. With careful consideration of unique packaging processes, associated controls, and an understanding of the rule breakers and realizations listed above, a packaging manufacturer can protect itself, CPG companies, and ultimately the consumer of the packaged food products.

8.3 HACCP Application in Animal Feed

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8.3.1 Introduction

In its purest form, HACCP is concerned solely with food safety and only with food intended for human consumption. The methodology behind HACCP is, however,

suitable for much wider application and is already used by the feed industries of several countries in considering potential hazards to both human and animal health.

8.3.2 *What Are the Hazards?*

By definition, HACCP is intended to control hazards, typically divided into physical, chemical, and biological hazards.

In the context of the feed-food supply chain, the hazards to be considered fall into two main groups:

- (a) Hazards that have the potential to cause direct harm to animals eating feed products.

These may be physical (e.g., stones are a choking hazard, wire may pierce the gut wall, glass may cut the gut, etc.), chemical (e.g., mycotoxins produced from fungal activity, fertilizers or pesticides used in the growing of crops, etc.), or biological (e.g., various diseases, salmonellae, or other pathogens).

- (b) Hazards in feed products that have potential to cause actual (or perceived) harm to humans subsequently consuming animal products.

The hazards most likely to affect humans through this route are of chemical or biological origin. For example, chemicals hazardous to humans include Aflatoxin B1 that may be present in certain feed materials, synthesized in the gut of dairy cows, and excreted into milk as Aflatoxin M1. The most notorious biological hazards are probably the various types of salmonellae that can be present in feed materials and feed products, ingested by livestock, and subsequently can contaminate eggs or carcasses. Formerly the agent causing the UK BSE outbreak entered the food chain via feed; however strict controls mean this has now been designed out of the feed system.

A hazard which may fall into either of the above categories would be the unintended or unlabelled presence of veterinary medicines, which in many countries are commonly delivered to farmed livestock through feed.

It is important to remember that potential hazards may be:

- Inherent to the feed ingredients themselves (e.g., mycotoxins in crops or heavy metals in minerals)
- Inherent to the processes that produce feed ingredients (e.g., by addition to growing crops as fertilizers or pesticides, through contact with combustion gases from direct flame driers, or solvent residues left in oilseed meals from vegetable oil extraction)
- Introduced to feed products subsequently during transport, storage, or handling (e.g., through contamination, weather damage, pest damage, or chemicals used in pest control)

8.3.3 *Typical Control Measures*

Control measures employed are broadly similar to those used in the wider food industry, with selection and approval of suppliers and appropriate pest control programs often being implemented as PRPs. Some other examples of typical PRPs include:

- Smoking, eating, and drinking policy
- Cleaning schedules and hygiene audits
- Plant operating procedures and instructions (including product scheduling)
- Job descriptions and responsibilities
- Staff training

Once these prerequisites are appropriately implemented, control measures will center on ensuring correct ingredient inclusion, correct processing, and where applicable minimizing carryover between product batches. Avoidance of recontamination of feeds treated to control microbiological hazards and correct labelling indicating intended use can also be important control measures in some circumstances.

8.3.4 *Approach(es) Taken*

The techniques associated with HACCP can also be used to consider additional issues that may not strictly be hazardous, but are of critical interest to the feed industry. For example, it may be that regulations, the media, or consumers regard an aspect of the feed product or feed material as “hazardous” although there is no factual basis for concern. An example is the European Union ban of meat fit for human consumption from any livestock feeds, where the legal framework assumes that the feeding of meat is potentially hazardous and therefore the feed business operator must do the same. Control of these kinds of issues may need to be included in the HACCP plan.

8.3.5 *Difficulties and Issues*

The nature of the animal feed industry is extremely varied, covering raw materials ranging from quarried minerals, fine chemicals, and plant and animal products/coproducts to surplus food products no longer intended for human consumption. The assessment of hazards is also complicated by the variety of species to be fed. The sensitivity and tolerance of different livestock species to nutrients or anti-nutrients are extremely variable. Any consideration of hazards therefore has to include the particular needs and sensitivities of all the species for which the feedstuff is intended.

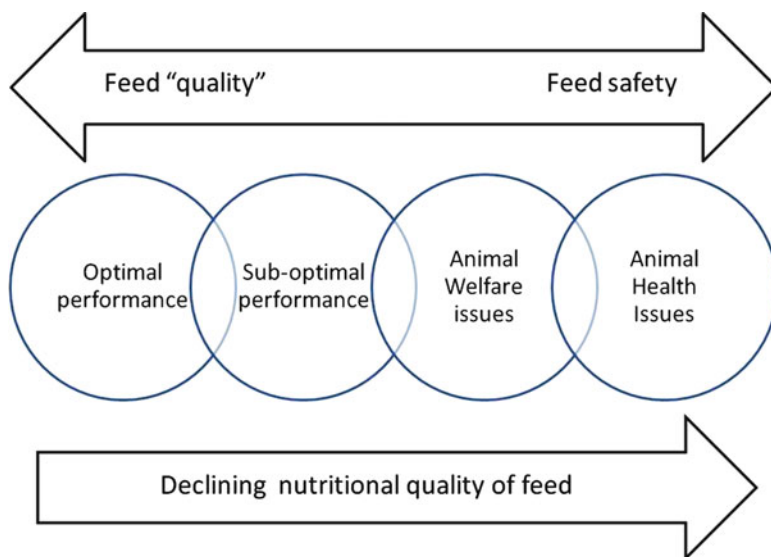


Fig. 8.3 Quality and safety of animal feed

The distinction between “quality” and “food safety” is less clear in feed than it is with food (Fig. 8.3), as a quality failure may quickly affect the health or performance of the animals being fed and consequently make the feed unsafe, particularly for livestock where only one source of feed is available. Some examples may illustrate this point:

Insufficient sodium will cause tail biting in pigs, navel sucking in cattle, and reduced egg production in laying hens. Excessive sodium in feed will in contrast make all classes of livestock drink substantial quantities of water and cause diarrhea, and actual mortality in chickens.

A significant and uncontrolled drop in the fiber levels of a feedstuff can cause constipation in livestock and in worst-case scenarios will result in collapsed guts or prolapse.

For humans, if we do not find food attractive we can usually replace it with something we do like. For intensive livestock species in particular, feed that is unpalatable or does not flow out of the feeders correctly may fairly quickly result in a loss of growth performance, a drop in milk yield, or a reduction in the number of eggs produced, simply because the livestock have no other source of nutrition available and have starved.

Although the control of sodium, fiber, palatability, and flow characteristics in feedstuffs is a matter of “quality,” the effects of getting it wrong can be hazardous to the well-being of the animals concerned. Whereas relatively minor adjustments

in the nutrient levels of any given foodstuff will rarely have a severe effect on most humans (because human diets often offer a wide selection of items that balance each other), the same relatively small adjustments in the nutrient levels of animal feedstuffs may have severe effects on the animal. The relationship between quality and food safety in animal feed is therefore far less distinct than it is for human food and critical quality parameters are worthy of consideration when undertaking a HACCP study.

8.4 HACCP Application in Primary Production

Application of HACCP in Primary Production, i.e., the growing of crops and food animals, has been done successfully by many food businesses. Whilst there has been some controversy about HACCP application at this and other primary stages in the food chain, usually because of the lack of a kill step for microbiological hazards, the use of HACCP principles alongside strong PRPs will, at least, reduce the likelihood of occurrence of hazards such that the security of the food product through the entire food chain is enhanced.

Typical hazards and control measures will depend on the type of food material being grown. For example animal production is likely to be subject to risks posed by microbiological hazards, which may be controlled by specific control measures at the growing stage, e.g., vaccination of laying flocks for *Salmonella* spp., or may need specific PRPs. An example of the latter is the requirement for animals to be presented for slaughter in a hygienic manner to prevent cross-contamination of microbial hazards from fecal contamination of the hide during the slaughter process.

The growth of plant food crops may similarly be at risk from a range of microbiological hazards due to exposure during the growing period and steps may need to be taken at this stage in the chain to minimize the risk, e.g., where possible, preventing access to animals that could bring in contamination. Plant crops will also be at risk from pesticide contamination and/or other environmental contaminants, and control and monitoring procedures for these issues, where relevant, are likely to be through primary production HACCP plans.

Physical hazards such as stones and other environmental contaminants may also enter the food chain at this stage but will often be controlled by measures applied at processing steps later in the food supply chain, e.g., flotation/washing steps.

A good example of HACCP application in this sector is provided by Chipollini (2011) who constructed a HACCP plan for egg production, including the growth of the laying hens. From the process flow diagram (Fig. 8.4) the complexity of this operation can be seen; however, following detailed analysis and CCP identification

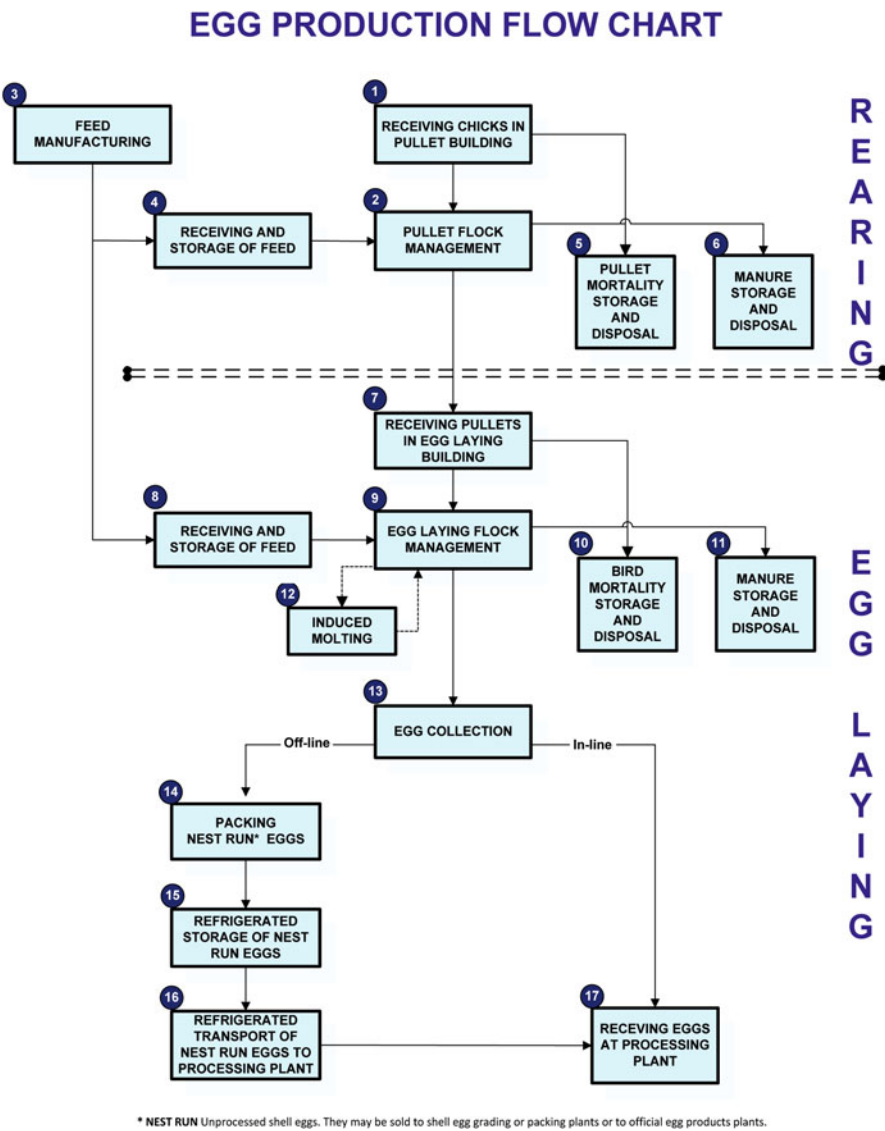


Fig. 8.4 Egg production process flowchart (Source: Chipollini, 2011)

via the Codex (2009b) decision tree, only one CCP was identified at this stage in the supply chain (Table 8.1). The importance of this point in the process is that *Salmonella* Enteritidis-infected chicks at day old are likely to produce *Salmonella* Enteritidis-positive eggs.

Table 8.1 Egg production HACCP control chart (Source: Chipollini, 2011)

Process step	CCP no.	Hazard to be controlled	Control measure	Critical limits	Monitoring			Corrective action		Responsibility
					Procedure	Frequency	Responsibility or	Procedure	Responsibility or	
Receiving chicks in pullet building	1	<i>Salmonella Enteritidis</i> (<i>Se</i>)	Approved Suppliers Agreed specifications Certificate of analysis Surveillance	No <i>Se</i> (+) chick box paper tests	Check NPIP form or letter documenting NPIP source Check COA for evidence of compliance Sample ^a one in ten chick box papers and submit to laboratory for <i>Se</i> Testing. 9 CFR 147.12 (a)(4)	Every delivery	Ownership or Farm Manager	Reject delivery if chicks are from an unknown source If test result is <i>Se</i> (+): Depopulate flock immediately Clean and disinfect building and equipment Test the environment prior to restocking	Ownership or Farm Manager	

^aSee eCFR Bacteriological Examination Procedure

8.5 HACCP Application at Slaughter/Harvest

Depending on the types of operation and businesses concerned, slaughter and harvesting operations may be done at the end of the primary processing link in the food supply chain or may be a separate link in their own right. It is perhaps more likely that the harvesting of growing plant crops will be seen as part of the primary production link, whereas harvesting of marine products through fishing, etc., and the slaughter of food animals and birds, will most likely be a completely separate operation, with its own application of HACCP.

The Second Edition of HACCP: a Practical Approach included a Case Study on beef slaughter and dressing (Sloan, 1998) which showed typical hazards and control measures in use for the beef supply chain in the UK at the time, with particular reference to control of “specified risk material” regarding the hazards associated with Bovine Spongiform Encephalopathy. This highlights the need for specific controls appropriate to the relevant specific significant hazards in each food operation and for the need for HACCP to be kept up to date. (Before the 1990s HACCP in this sector would not have included consideration of BSE and since the 1990s further development has occurred in controls and regulation due to the progression of this specific outbreak.)

Hazards during slaughter/harvest will again depend on the materials being “processed” and the environment where the operation occurs. Likely issues will be to do with cross-contamination with microbiological hazards during the slaughter process; however damage of materials at this stage, e.g., grain crops, may lead to the proliferation of hazards later in the chain, e.g., mold growth and toxin formation during storage.

8.6 HACCP in Manufacturing

Manufacturing or food processing is the traditional “home” of HACCP, in that the system was originally developed to assure food safety at this stage in the food chain. Much has been written about application of HACCP in this sector and the traditional approach to the application of HACCP principles (Codex, 2009) using the Codex Logic Sequence (Chap. 6) works very effectively in this sector. Since this approach is discussed in detail in the preceding chapters of this book, it will not be repeated here; however it is worth just taking some time to consider the breadth of food manufacturing operations and, therefore, the wide scope of likely hazards in different types of manufacturing operations.

Food manufacturing can be split down into a wide range of product sectors and includes manufacturers of finished products for retail, foodservice, and the consumer, as well as production of simple and complex ingredients and product components that will be converted into finished products by other manufacturers. Whilst Fig. 8.1 identifies primary processing and secondary processing at this part of the supply chain, in actuality there may be a number of different levels/processors

involved in the manufacture of the materials that make up each finished consumer food product. This added complexity underlines the need for consistent application of HACCP-based food safety management systems, including the need for full traceability through the food supply chain.

Hazards and potential control measures likely in a range of manufacturing situations are described in Chap. 3, with further resource material on the design of appropriate control systems in Chaps. 4 and 5. The manufacturing HACCP plan example in Chap. 6 further illustrates the application of HACCP in this part of the food supply chain, in this case relating to a “secondary processor” who buys ingredients and components from other food manufacturers.

Because of the wide variation in processing operations and ingredients handled in manufacturing, the likely hazards and control measure options are similarly diverse. It is crucial that each food business involved in food manufacturing has the skills and expertise necessary to identify likely significant hazards and to develop and implement appropriate control systems via its HACCP plans.

8.7 HACCP Application in Retail: The Supermarket

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8.7.1 Introduction: HACCP in the Supermarket

With the right approach and appreciation of the time and commitment required, it is possible to successfully implement and manage HACCP in a supermarket setting. These days there is a whole array of food products available at store level. From baked goods to cut produce, deli meats to prepared foods, the selection is vast and the safety of these items prepared in store is just as important as that of the packaged goods sold to the customers. However, the supermarket itself is changing, with the degree of food preparation approaching what one might see in a restaurant. The opportunity for food-related illness is increased as a result. By controlling risks to a safe level, you can prevent foodborne illness outbreaks and do your utmost to ensure that the food your company sells is safe for the consumers. So, where do you start? First of all, your company must identify who is responsible for store food safety and then select a team to work with that food safety leader. Then you must make sure that they are adequately trained and given the tools and support to succeed.

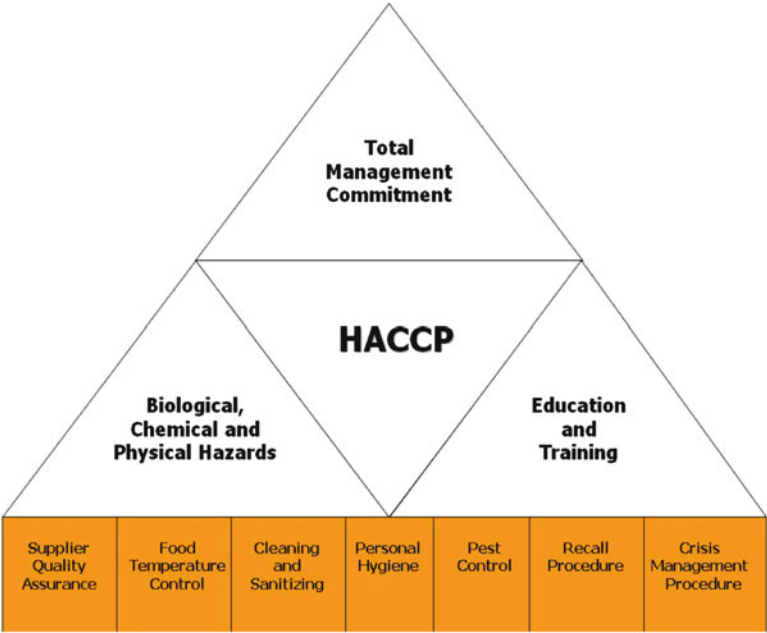


Fig. 8.5 Wegman’s Store Level Food Safety System (reproduced with the kind permission of Professor Robert Gravani, Dept of Food Science, Cornell University, USA)

(a) Management Commitment

Obviously, you must have the commitment of the company’s senior management to undertake this initiative. Embarking on such an initiative requires time and investment though not as much as you might think. Food safety matters and so the company needs to demonstrate its commitment by supporting this project and devoting the necessary resources to do the job. The company may need to seek out an external expert if it does not have the technical resources in-house to help with the risk assessment of the operations at each step. A local university or college with a strong food safety program would be a good place to start.

(b) Prerequisite Programs (Back to Basics . . .)

Before a company can even embark on creating a HACCP system at retail it must make certain that the food safety foundations are in place. Fig. 8.5 is a visual representation of how Wegmans represents its food safety system at store level.

To assure successful implementation of any HACCP system at retail, PRPs, also referred to as Good Retailing Practices or GRPs must be strengthened. You should walk a store and visit the back rooms and production areas to understand the layout and risks associated with your department operations. Any improvements and enhancements which make the job of adhering to basic food handling practices easier should then be made. Examples might include replacing permanent racking

in coolers with moveable racks for ease of cleaning; and introducing Master Sanitation Schedules so that regular cleaning of equipment can be addressed. Another example might be to reconfigure your process to minimize risks associated with cross-contamination. For example, take production of raw chicken out of an area that primarily handles ready to eat foods, moving it to the meat department where raw meats are handled. Good Retailing Practices that need to be in place before beginning to create your HACCP program should include: Supplier Quality Assurance, Food Temperature Control, Cleaning and Sanitizing, Personal Hygiene, Pest Control, Recall Procedure, and Crisis Management Procedure. A Supplier Quality Assurance program helps assure the safety and quality of ingredients and products coming from your suppliers. Recall and Crisis Management procedures are necessary to enable timely and effective handling of recalls and crisis situations.

(c) Employee Education and Training

Employee practices are critical to ensure safe food: proper hand washing, comportsment, and respect for the GRPs are essential to making the food safety system work. A sound understanding of basic food safety concepts is vital for adherence to prerequisite programs (GRPs) and the success of a store-based HACCP program. The training material can be delivered in various formats. The best format is whatever works for your employees and your company. Training can be delivered in a classroom with an instructor, or through a computer, or through use of message posters that convey a simple food safety message. The advantage to Computer-Based Training (CBT) is that it is self-paced and it can be modular, affording you the ability to add new topics, e.g., allergen control, as the need arises. Also, you can add an exam at the end or even during the course to test understanding and grasp of the concepts.

Basic training is required for all food handlers and should include the following: personal hygiene, calibrating thermometers, maintaining safe product temperature, wash, rinse and sanitize, making and testing sanitizer, following the master sanitation schedule (MSS), storing food, packaging and cleaning supplies, process, and package and display products. For entry-level employees, particularly those with little food experience, it is important to keep the training simple. Use of storytelling and hands-on exercises, such as Glo-germ™, will make the concepts memorable. Posters with brief food safety messages strategically placed in the work area serve to remind employees of the importance of following certain practices.

For more advanced training for supervisors and managers, there are other options such as the *SafeMark for Supermarkets*® program (from the Food Marketing Institute, USA). This program has various levels and was tailor-made for the supermarket industry. The program includes a nationally accredited exam which complies with the regulatory requirement for many jurisdictions. Upon successful completion of the exam, candidates receive certification which is valid for 5 years and may be required in some of the areas in which your company operates. Some states require employee recertification more frequently. Additional training and education programs may be necessary for those individuals who need to understand HACCP in more depth (store managers, perishable department managers, chefs, department managers, and corporate personnel such as category buyers, store design personnel, and store maintenance personnel). These programs focus specifically on HACCP concepts and enable

participants to recognize the hazards, know how to build a plan, and have a better understanding of the importance of following the GRPs. This training can be done through partnering with a food safety expert at a local university or college.

Once the employees have been trained, reference materials reinforce what they have learned. These can take the form of employee work instructions, job aids, reminder cards, and textbooks, such as those provided with *SafeMark for Supermarkets*[®]. Additionally, food safety information placed on your company's internal internet site will help ensure that all the food safety requirements are accessible when employees feel they need them. You can also use links to external websites that can provide more in-depth information (i.e., FDA, local health departments, etc.).

8.7.2 Approach Taken

At Wegmans, we followed the seven Principles of HACCP (Codex Committee on Food Hygiene (1994, 1997, 2003, 2009) and the National Advisory Committee on Microbiological Criteria for Foods (NACMCF, 1992, 1997), in order to implement our system at store level. In the United States, regulatory authorities and agencies can conduct HACCP-based inspections at store level. The inspectors take a risk based approach and are trained to look for issues that are critical to the safety of the food focusing less attention on floors, walls, and ceilings where food safety risks are minimal. A few states, such as Maryland, require HACCP at retail. Maryland requires that the company provides HACCP plans that cover the menu items produced in the establishment and that store personnel are trained and understand how to write a HACCP plan. A HACCP inspection is performed annually to assure that the establishment is following the plan and has the CCPs under control.

(a) Implementation

To implement HACCP at retail requires bringing different people within the organization together to offer different perspectives to the process. There should be a combination of people, the team leader, those who are working in the store, store maintenance and design people, buyers for the food, and equipment used in the various departments and those with the scientific background to assess the risk involved. A suggested team would include: the perishable department manager (for the relevant department), food safety person (leader) for that store, food buyer, equipment buyer, and HACCP expert (internal or external).

(b) Seven Principles of HACCP

- Conduct a Hazard Analysis (using process flowcharts)
- Identify the CCPs
- Identify the Critical Limits for the CCP
- Establish monitoring procedures at CCPs
- Establish Corrective Action where there is a deviation at CCPs
- Verify that the system is working
- Establish effective record keeping systems that document the HACCP system

8.7.3 *What Are the Hazards?*

Typical hazards in retail operations include the following:

Microbiological hazards: Pathogens (bacteria, viruses, parasites).

Controls: Practice good personal hygiene (i.e., hand washing), Employee Health Policy that excludes or restricts employees who are ill with symptoms associated with foodborne illness; avoid cross-contamination, particularly between raw and ready to eat; maintain proper temperature controls to prevent pathogen growth; adhere to cleaning and sanitizing practices.

Chemical hazards: Man-made chemicals such as cleaners and sanitizers, or naturally occurring chemical hazards such as seafood toxins and food allergens.

Controls: The Sanitation Standard Operating Procedures (SSOPs) call for all chemicals to be stored away from food in order to prevent contamination. Knowing who your seafood suppliers are and working only with approved suppliers to minimize seafood toxin concerns, and full disclosure of ingredients to allow consumers with allergen concerns to make proper purchasing choices.

Physical hazards: Foreign objects such as metal fragments, wood, broken glass, and pests.

Controls: The Standard Operating Procedures (SOPs) call for visual inspection of product, minimal use of glass, and restricted jewelry as per the employee food safety policy.

8.7.4 *Benefits*

The following are some of the benefits that can be attributed to having effective HACCP in place in a retail setting: heightened employee knowledge and awareness of food safety, more attention being paid to the critical issues, better performance on regulatory inspections, support from merchandizing and other corporate groups, store equipment upgraded and food safety considerations being included in future store design and remodels, and, ultimately, safer food for your customers.

8.7.5 *Challenges and Issues*

The food retail world is constantly changing. Changes to equipment, store layout, and store programs can have an impact on food safety risks as can changes in product offerings and ingredients. Such changes can alter the process flows and necessitate a review of your store operations to ensure that food safety is not compromised. Once the HACCP system is in place and operating within a culture of food safety then it becomes a way of life. Ideally, employees working with these foods can easily identify potential hazards and are empowered to take appropriate action to keep the product and consumer safe.

To gain consumer confidence food handling areas are designed to be open allowing customers to see how foods are produced. These open production areas are not the controlled production areas one might see in a food manufacturing plant. Supermarkets tend to have a very young workforce with high employee turnover requiring a sizable investment in employee training. With fewer and fewer foods being prepared in the home, some of these young employees start work with very little understanding of proper food preparation basics. Continuous education is needed.

Additionally, cold chain maintenance can be a challenge between receiving and storage in back rooms and display, particularly in the summer months in some regions. Refrigeration monitoring and performance are crucial. The importance of product protection and proper handling of ingredients, product packaging and utensils, etc. cannot be stressed enough. Ultimately, design of the production areas, logical flow of the food preparation, and cooking processes are essential to doing this right.

Discipline at store level can be a challenge with so much going on. Manual temperature taking and record keeping for CCPs are time consuming but are crucial to the success of the HACCP program. Follow and adhere to the system you build takes time and money. Ideally, automate your record keeping process, e.g., taking cook temperatures, wherever possible. Periodic auditing is also an important component to any HACCP or food safety program. The audit not only should be used as a tool to point out concerns but also should, more importantly, be used to provide employees with an opportunity to get answers to questions they may have regarding food safety and HACCP. Being able to answer the “why” goes a long way to gaining compliance and changing the culture from performing a food production task to understanding that there may be a hazard associated with the way in which that task is currently being performed and feeling empowered to change it to avoid the hazard. This is the cultural change.

The company must be willing to devote the resources to upgrade the back rooms, food preparation areas, and equipment where necessary, to enable easy cleaning and logical flow of processes. Master Sanitation Schedules (MSS) become very important particularly when scheduling deep cleaning of overhead refrigeration units, hoods, ovens, etc. A significant time commitment needs to be made to train employees, create the process flows, conduct the Hazard Analysis, create the HACCP plans, and implement, assess, and review that the system is working and up to date.

In order for HACCP to be effective, it must be simple, manageable, and specific to each establishment. There is not one size that fits all. The degree of hazard risks that may accompany each step will be different depending on preventive measures (i.e., GRPs) that an establishment may already have in place to mitigate the risk of particular hazards. So, going through the seven principles is very important, although wherever possible steps should be taken to simplify the process, and keep it “doable.”

Historically, food safety and merchandizing functions at store level have not always been in agreement. Therefore once the HACCP system has been implemented, consistent food safety messages are needed across all stores in the company with no mixed messages. Ongoing assessment of retail food handling operations along with an annual documented formal review of the HACCP system will assure that the system remains meaningful.

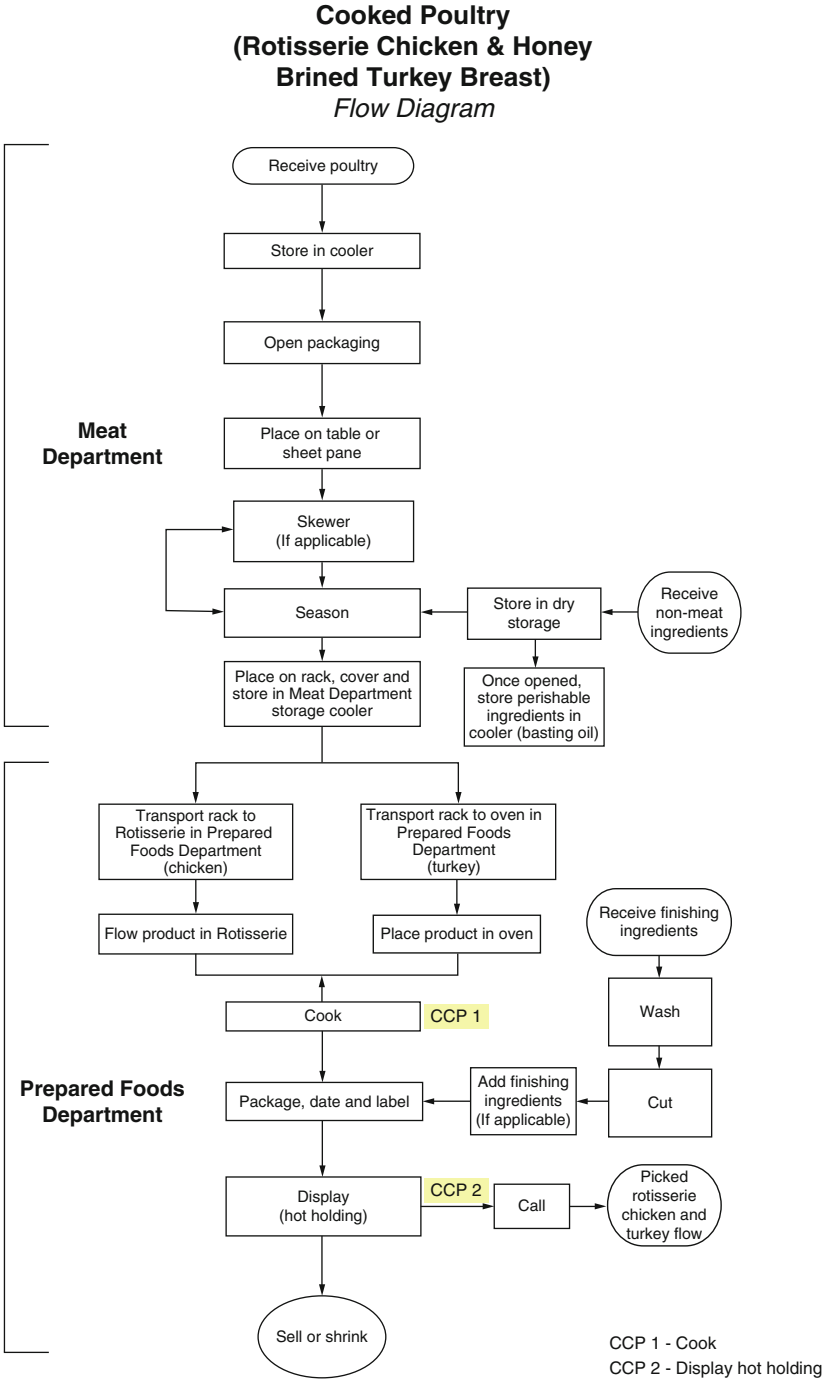


Fig. 8.6 Rotisserie chicken process flow diagram example (Wegmans Markets)

Table 8.2 Rotisserie chicken HACCP plan example (Wegmans Supermarkets)

HACCP PLAN										
Product:		Cooked Poultry (Whole Rotisserie Chicken and Honey Brined Turkey Breast)								
Product Description:		Raw chicken or turkey breast cooked in store								
Method of Storage:		Refrigerated								
Method of Distribution:		Retail food grade containers								
Intended Use and Consumer:		Consumed by general public on or off premises								
CCP	Hazards Addressed	Preventative Measures	Critical Limits	What	How	Frequency	Who	Corrective Action	Verification	Record Keeping
Cook Ccp 1	B-Pathogen survival	B-Cooking sufficiently to kill pathogens.	≥165 degree Fahrenheit for at least 15 seconds	Internal product temperature	Calibrated and sanitized thermometer placed into appropriate area of poultry	Every batch	Trained employee	1. Retrain. 2. Notify the department manager. 3. Check additional product within the unit. 4. Continue cooking until the critical limit is met. 5. DISCARD product, if necessary. 6. Evaluate the unit and call store maintenance, if necessary. 7. Document corrective action on the Corrective Action Log.	1. Periodic observation of monitoring. 2. Daily calibration of thermometer. 3. Daily review of documentation to assure that critical limits have not been exceeded.	Cook Temperature Log
Display in warmer CCP 2	B-Pathogen growth (sporeformers)	B-Warmer maintains product temperature above 135 Degree Fahrenheit	≥135 degree Fahrenheit	Internal product temperature	Calibrated and sanitized thermometer placed into appropriate area of poultry	Every two hours	Trained employee	1. Retrain. 2. Notify the department manager. 3. Check additional product within the unit. 4. Remove and reheat the product if less than two hours. 5. DISCARD if temps are between 41°F and 135°F for more than two hours. 6. Evaluate the unit and Contact maintenance, if necessary. 7. Document corrective action on the Corrective Action Log.	1. Periodic observation of monitoring. 2. Daily calibration of thermometer. 3. Daily review of documentation to assure that critical limits have not been exceeded.	Holding Temperature Log

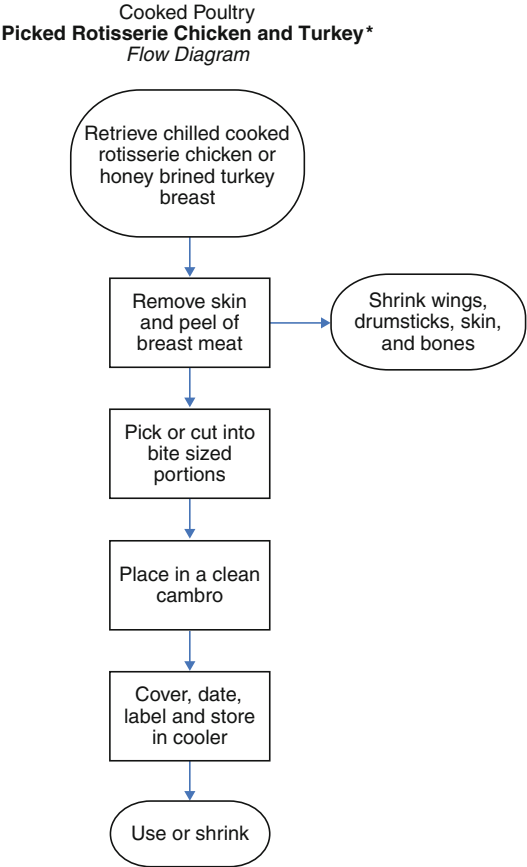


Fig. 8.7 Picking of rotisserie chicken

The following examples show the application of HACCP within a supermarket operation for in-store processes. These include rotisserie chicken preparation at store level and HACCP plan detail for the same product (Fig. 8.6, Table 8.2); the picking and handling of cooked rotisserie chicken (Fig. 8.7, Table 8.3); and the preparation of soup, which may include picked chicken from the rotisserie operation (Fig. 8.8, Table 8.4). These examples illustrate the level of complexity found in supermarket store operations and highlight the essential use of HACCP to manage food safety requirements.

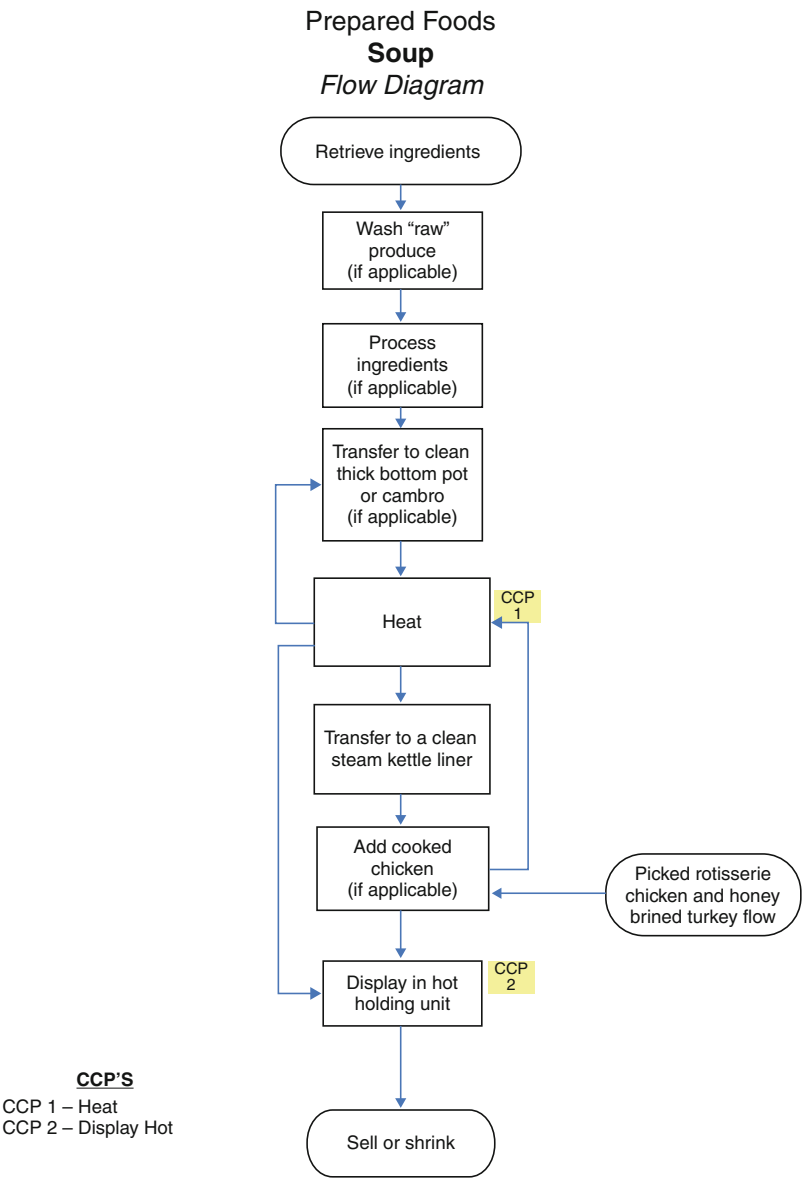


Fig. 8.8 Soup preparation

Table 8.4 Soup preparation HACCP plan

HACCP PLAN									
		Product: Soup							
		Product Description: Store prepared soup made from scratch, reheated soups or vendor prepared (C/C) soup where additional							
		Method of Storage: Refrigerated, then displayed hot in a steam kettle							
		Method of Distribution: Retail, food grade containers							
		Intended Use and Consumer: Consumed by general public on or off premises							
(CCP)	Hazards Addressed	Preventative Measures	Critical Limits	Monitoring			Corrective Action	Verification	Record Keeping
				What	How	Frequency			
Heat CCP 1	B-pathogen survival	B-Heating sufficiently to kill pathogens.	≥165 °F for 15 seconds	Internal product temperature	Calibrated and sanitized stem thermometer	Every batch	1. Retrain. 2. Notify the department manager. 3. Check additional product within the unit. 4. Continue cooking until the critical limit is met. 5. DISCARD product, if necessary. 6. Evaluate the unit and call store maintenance, if necessary. 7. Document corrective action on the Corrective Action Log.	1. Periodic observation of thermometer. 2. Daily calibration of thermometer. 3. Daily review of documentation to assure that critical limits have not been exceeded.	Cooked Temperature Log
Display in hot holding unit CCP2	B-pathogen growth	B-Hot holding unit maintains product internal temperature at 135°F or higher	≥135 °F	Internal product temperature	Calibrated and sanitized stem thermometer	Every two hours	1. Retrain. 2. Notify the department manager. 3. Check additional product within the unit. 4. Remove and reheat the product if less than two hours. 5. DISCARD if temps are between 41°F and 135 °F for more than two hours. 6. Evaluate the unit and contact maintenance, if necessary. 7. Document corrective action on the Corrective Action Log.	1. Periodic observation of thermometer. 2. Daily calibration of thermometer. 3. Daily review of documentation to assure that critical limits have not been exceeded.	Holding Temperature Log

8.8 HACCP Application in Catering

8.8.1 Introduction

The HACCP principles are designed for application to any food operation in the food supply chain; however it has become a generally held belief in some quarters that HACCP will not work as effectively in catering as it does in manufacturing. These beliefs seem to have stemmed from the early days of HACCP, where the principles were often applied to the process of manufacturing individual products such that factories making a variety of different products would have individual HACCP plans for each product that they produced—product-led HACCP. Quite understandably, this led to resistance to the HACCP system in catering since taking a product-led approach where there are hundreds of different menu items to cover would be totally impractical, leading to hundreds of HACCP plans. However, the limitations of the product-led approach were also quickly realized in manufacturing, since such a linear approach to application only works well in very simple operations. As most manufacturing operations are more complex and rely on a number of different subprocesses to provide components of the individual finished products, the process-led or modular approach to HACCP has become much more common. Modular systems are practical to develop and these can be applied as effectively in catering operations as in other parts of the supply chain.

8.8.2 What Are the Hazards?

Typical hazards in catering operations include the following:

- **Microbiological:**
Pathogenic microorganisms and/or their toxins in menu items, where the risk areas are presence of pathogens/toxins in particular raw materials; growth of microorganisms/toxin formation due to temperature abuse; survival of microorganisms due to inadequate heat processing; and cross-contamination with microorganisms due to inadequate segregation or unhygienic practices.
- **Chemical:**
Presence of unlabelled allergens in menu items, which may be due to inappropriate recipe design; poor raw material control; inadequate segregation; cross-contamination during food handling operations; or mistakes in labelling/menu preparation.
Presence of toxic chemicals, e.g., cleaning or pest management chemicals, due to poor design of PRPs; inadequate storage; or inappropriate handling of chemicals.
- **Physical:**
Presence of hard or sharp items, e.g., metal or glass fragments, in menu items, which is usually to do with poor design and/or control of PRPs.

Table 8.5 Example Catering Process Groupings (*Source:* Wallace et al., 2011; adapted from US FDA, 2005)

Process Group 1 Food preparation with no cooking step	Process Group 2 Food preparation for same-day service	Process Group 3 Complex food preparation
Example foods: <ul style="list-style-type: none"> • Salad greens • Fresh vegetables • Coleslaw/dressed salads • Fish for raw consumption (sushi) • Sliced sandwich meats • Sliced/grated cheese • Meat salads (made with precooked meats) 	Example foods: <ul style="list-style-type: none"> • Fried chicken • Grilled or fried fish • Hamburgers, sausages, etc. • Roasted, fried, or grilled meats • Hot vegetables • Cooked eggs 	Example foods: <ul style="list-style-type: none"> • Soups • Gravies • Sauces • Rice dishes • Prepared meals, e.g., chilli, rice, and pasta dishes • Meat salads (made with meats that require precooking)

8.8.3 Typical Control Measures

Most chemical and physical hazards in catering operations are general rather than process-specific issues, and are therefore controlled by PRPs. It is therefore important that prerequisites are carefully designed, implemented, and verified to give confidence that these issues are under control at all times.

Control measures for microbiological hazards are generally associated with temperature, i.e., cooking, chilling, and hot/cold storage. PRPs are also involved with regard to hygienic practices and segregation.

8.8.4 Approaches Taken

The exact approach taken in applying HACCP principles in catering will depend on whether Codex HACCP (2009) or a specific simplified approach for Catering (e.g., UK FSA, 2007) is used. For caterers taking the Codex HACCP approach, one of the first steps will be to group menu items into like groups to allow a modular framework for the system to be established. For example, Table 8.5 shows a simple form of catering process groupings based on whether menu items have a cooking step or not and whether complex sets of processes are involved.

For a more detailed understanding of the modular framework, it is likely that a module map (Fig. 8.9) will need to be developed to identify all process modules and how they fit together. From this initial plan of the operation the necessary detailed process flow diagrams can be developed (Fig. 8.10). From these process flow diagrams, the application of HACCP principles normally follows in exactly the same way as in manufacturing, although it is more likely that external input, e.g., from consultants or regulatory personnel, will be needed to supplement in-house knowledge.

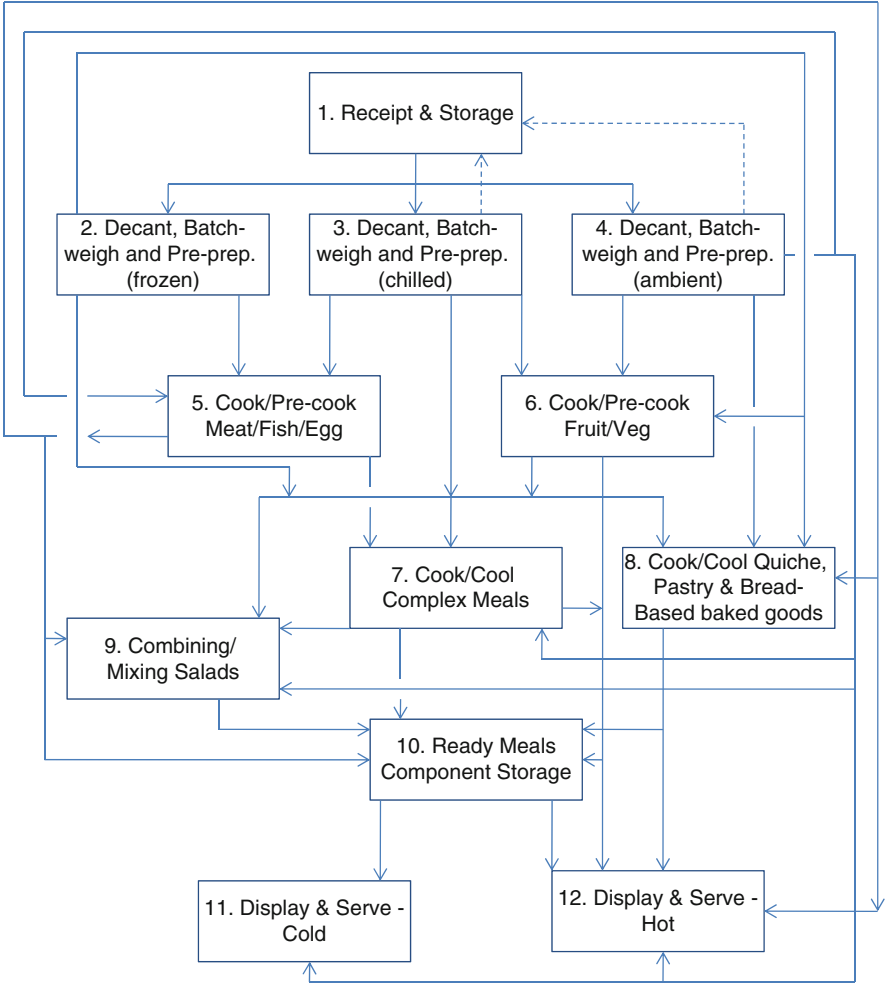


Fig. 8.9 HACCP modular system structure—refectories (reproduced with kind permission of UCLan Catering Services)

8.8.5 *Difficulties and Issues*

Apart from the issues to do with product-led versus process-led HACCP discussed above, other difficulties have been identified in catering operations with regard to resources for HACCP, both in terms of its development and ongoing management. At the development stage, there may be issues to overcome such as lack of training, not enough personnel to operate a HACCP team, or not enough knowledge of food safety hazards to take decisions about food safety. Whilst there may be fewer personnel in catering operations than in manufacturing, the personnel present are

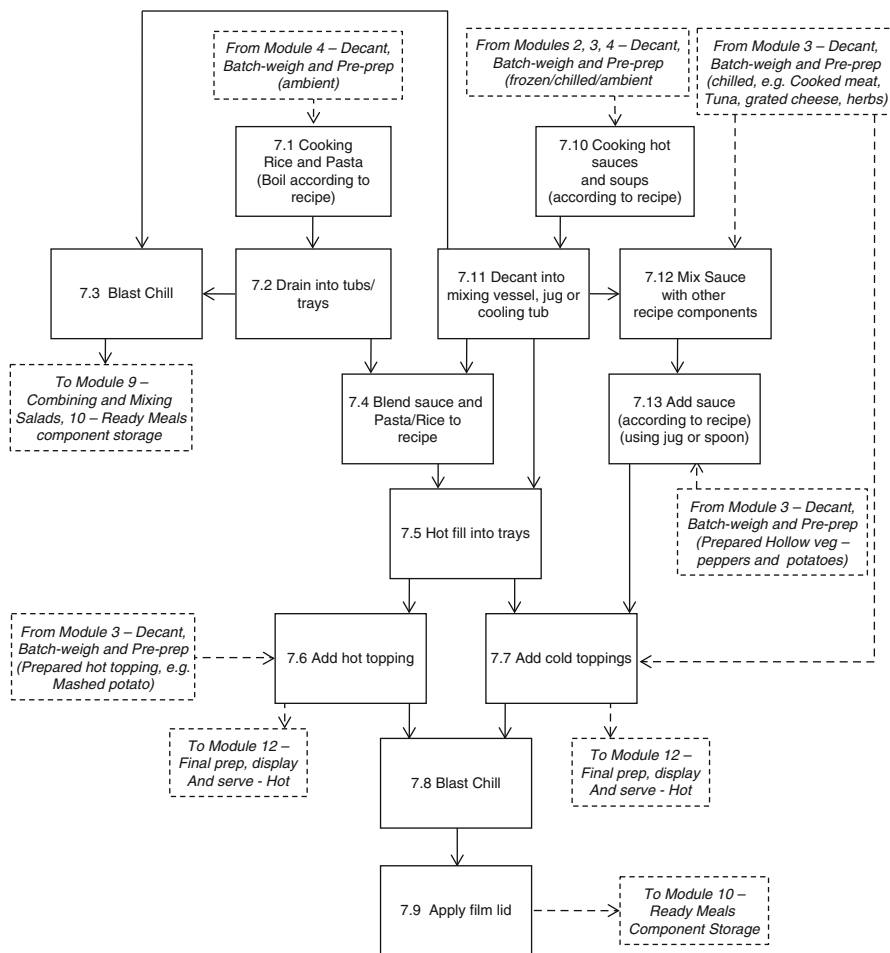


Fig. 8.10 Example module process flow diagram—Module 7 cooking and cooling activities complex meals (reproduced with kind permission of UCLan Catering Services)

often closer to the day-to-day operations with a good understanding of the processes being used; however the knowledge of HACCP and food safety hazards may be lacking, particularly in smaller catering businesses. Knowledge of HACCP principle application can be gained through training; however appropriate knowledge of all relevant food safety hazards and their control mechanisms can be more difficult to obtain and is often best achieved through consultancy arrangements. Use of consultants also brings inherent difficulty in that it can be very difficult for businesses to understand whether or not the consultant has appropriate and sufficient expertise and experience. However a good consultant acting as trainer/facilitator

to the business during HACCP development can be a very effective way to establish a strong and practical HACCP system.

Further difficulties have been identified with monitoring and recording systems for HACCP, with particular regard to time and equipment necessary to monitor CCPs (and prerequisites) and the belief that “too much paperwork” is needed for HACCP management. A key point to understand here is that there can be flexibility in how the HACCP principles are applied, and in the amount of documentation and recording that takes place, such that resources are targeted at the critical areas for food safety.

These issues have been key drivers for the development of simplified approaches to HACCP application such as *Safer Food Better Business* (UK FSA, 2007) and others. Although critics of these approaches claim that they can be too simple and are “not HACCP,” these initiatives provide simple instructions and documentation for the caterer, allowing development of a “cut and paste” food safety system using the information and templates provided. However, the minimal monitoring requirements tend to make it difficult to prove whether or not the system is/was under control.

8.9 Special Considerations for HACCP Application in Chain Restaurants⁴

Contributor:

Andy Kerridge, Burger King

8.9.1 Introduction

Foodservice or catering covers a wide range of types and sizes of operations with an equally wide range of complexity; and each has its own challenges in respect to HACCP. For chain restaurants, whether hamburger or chicken, hot dogs or pizza, the basic concepts are consistency and simplicity—so if you order the same product it should not matter whether the restaurant is in Moscow or Miami, Chicago or Shanghai, the product should be the same. This means a high level of standardization of ingredients, products, and procedures. A crew member should be able to walk into another restaurant of the same brand in any other place and feel at home with most of the items on the menu, and be able to (language aside) make most of the products.

Another feature which is important to a chain restaurant (but should be for any restaurant) is speed of service. This tends to lead to a menu which is low on complexity—which means items (dishes or pizzas or burgers) which are easy and

⁴For further detail on application in this sector please see Case study A.4 Fast Food restaurant operations.

consistent in the way they are put together, and making them involves only limited movement in the kitchen.

So, taking the above principles of consistency and simplicity, one can see that the situation in chain restaurants lends itself to the application of HACCP, especially as HACCP has matured and moved away from individual plans for each product, i.e., a product-led HACCP. The now more usual process-led or modular approach to HACCP fits well with chain restaurant operations.

In chain restaurants certain parts of the HACCP can be, and usually are, performed by head office. Centralized functions such as training, supply chain, and quality assurance mean that so long as restaurant staff follow the system, they can focus on the job to be done. There will be a systemized approach to monitoring the control points and actions in place for noncompliance. New products and processes are tested rigorously before putting into restaurant for further testing and modification, before general release. Compliance with the HACCP will be monitored and the system verified by the head office functions.

8.9.2 What Are the Key Differences?

Chain restaurants are multiple locations of similar layout, with same/similar products and equipment. The hazards and controls are therefore also very similar, with some minor differences caused by site design, or local legislation. Restaurants are very unlikely to be able to have space or the money to be able to implement automated methods of monitoring and control such as a metal detector or an X-ray. What is more likely is products would be bought in presliced (metal detected by the supplier). If contamination could still occur onsite, then it may be dealt with by inspection—e.g., fry baskets can break and lose pieces of metal due to metal fatigue/age—they are often knocked on the edge of the frying vat to remove surplus oil). A weekly check could identify fry baskets which need to be replaced, where wires are coming loose. This is not a CCP as would be the case in a production line with metal detection, but is an appropriate control in the circumstances.

8.10 HACCP in Storage and Distribution

Contributor:

Alison Gardner, Waitrose, UK

8.10.1 Introduction

The distribution and storage of food products typically occur at the end of the manufacturing process although during production each could occur at various stages, for example transferring work in progress between sites or components/ingredients

between supply chain stakeholders. The points raised in this section are applicable to all storage and distribution operations occurring anywhere in the food supply chain.

HACCP principles should be applied to the whole supply chain and normally where the processor is delivering direct to the customer it will be included in the main site HACCP study; however this is not always the case where third-party contractors are used or where the site is part of a larger group—in these examples the HACCP may be a separate document which should be referred to in the manufacturing HACCP.

The processes within storage and distribution tend to be fairly simple compared to manufacturing and therefore it is not always necessary to develop a flow diagram but all the process steps undertaken must be identified.

8.10.2 What Are the Hazards?

There are fewer hazards within storage and/or distribution than many other steps in the food supply chain; however, coming at the end of the process or between-unit operations it is important to manage this area to ensure that a safe product is not compromised. Storage and distribution of packaged products versus bulk shipment will be very different in terms of potential hazards and required controls, due to differences in packaging and transit vehicles.

Temperature abuse of product (in individual packaging or in bulk) could result in microbiological levels increasing which may cause spoilage or food poisoning on consumption. Additionally any temperature-sensitive toxins could start to develop if the temperature regime is altered.

The main chemical hazard would be unlabelled allergens if products are labelled incorrectly particularly where part processed materials are involved.

Physical hazards should be minimal if products are fully sealed in final product packaging; however, open produce, for example, could be exposed to damaged pallets or other foreign bodies in the environment. Bulk shipments (tankers and railcars) will expose product to anything that was in the container previously.

If the operator is storing product on behalf of several manufacturers it should identify any potential impact that different finished goods could have on other items, e.g., storing nuts for one customer may have impact on other customer's product.

8.10.3 Typical Control Measures

Microbiological hazards should be managed by appropriate temperature control of the environment where product is stored (chilled or frozen) and time management when product is being transferred from vehicle to storage location and vice versa.

The physical and chemical hazards should be managed by sound prerequisite programs which ensure good hygiene and maintaining product packaging integrity.

The development of a robust PRP would determine the operating procedures to be implemented ensuring that product safety is maintained during the storage and distribution chain.

Prerequisites covered by procedures in place for staff training, stock rotation, pest control, glass breakage (particularly if handling products packed in glass), and hygiene should provide the basis of the operating systems.

The operator can then determine the risks associated with the products they are handling, e.g., temperature-sensitive products and the processes undertaken such as tempering products from the frozen to chilled state. Cross-contamination during distribution (usually in bulk) has been the cause of a few significant foodborne illness events in both the human food and animal feed industries. This is where a CCP may be required, e.g., in ensuring that pasteurized liquid products are never placed in a tanker that has previously transported raw unpasteurized products or that bulk horse feed is never transported in a truck that previously hauled feeds containing ionophores (which are deadly to horses).

Additionally the operator should have a robust stock management system to ensure that it can isolate particular batches of products as the need arises.

8.10.4 Approaches Taken

To apply HACCP in the storage and distribution environment is increasingly required by operators as control of the whole supply chain needs to be maintained. Food manufacturers have been managing food safety through HACCP for many years. As stated earlier a process flow may not be required although it is advisable; however HACCP is not always a well-understood process in areas such as storage and distribution where food may only form one part of an operator's portfolio of services available.

The manufacturer who uses a third-party operator to store and/or distribute on its behalf may well work with the operator to ensure that appropriate controls are put in place and maintained. Alternatively the operator may employ the services of a consultant to implement HACCP in its operation and also to audit on a regular basis to ensure that procedures are being followed.

A typical process flow diagram for storage and distribution operations is as follows (Fig. 8.11).

8.10.5 Difficulties and Issues

Where the operator is simply storing and/or distributing product the controls should be fairly straightforward to determine and implement; however some operators offer additional services which must be incorporated into the HACCP particularly as some of these operations present the greatest risk to the product. As previously stated if providers are not experts in the food processing industry they may not be

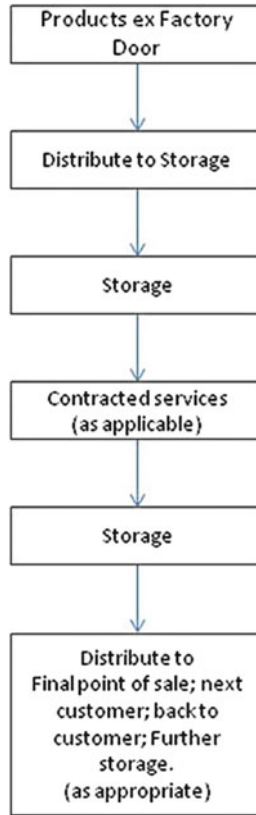


Fig. 8.11 Storage and distribution process flow diagram example (note that the above process steps could be provided by one or more providers)

capable of implementing HACCP without appropriate support and the management team of any provider should ensure that their staff understands the implications of temperature failures on product safety, etc.

Examples of services that could be offered are the following:

- (a) Changing the temperature status of the product—providing bulk freezing capability or tempering frozen product to the chilled state in preparation for delivery
- (b) Foreign body inspection—metal detection for customers
- (c) Co-packing—repacking products into larger multipacks or applying information labels for export.

In the above examples it is assumed that the products are not extracted from their packaging; otherwise the operator should consider whether they are becoming a food processor and will probably need increased standards for hygiene, fabrication, and operating procedures.

Any storage and distribution provider will require a robust traceability process particularly if storing on behalf of several manufacturers. Some may send product into storage before products have completed post-process analysis and therefore if any results require products to be withdrawn from the market the provider should be able to isolate products on a batch-by-batch basis on behalf of the manufacturer.

One further consideration is that any storage and distribution stage once the product has left the manufacturer could be provided by multiple operators and in this case the manufacturer needs to ensure that it understands the complexity of the route from its door to final customer and that each provider has a robust HACCP study in place.

8.11 The Consumer

Application of HACCP has not really progressed to cover the control of food safety hazards in consumer homes and kitchens, although there is clearly much interest in assuring the safety of consumer handling practices. As we mentioned in the Prologue, there have been a number of sociological changes in recent years that affect consumers, the food they prepare and eat, and their preparation and handling routines.

Typical hazards in the consumer operation include cross-contamination with pathogenic microorganisms, as well as chemical and physical hazards from the kitchen environment, equipment, surfaces, and other foodstuffs. The food handler is very much a vector in the potential contamination chain, e.g., through poor hand washing and handling practices, and the presence of domestic pets in the home environment can exacerbate the contamination risk. There is also a substantial risk of pathogen growth due to poor refrigeration practices, either due to equipment that is incapable of controlling temperature effectively or poor handling (hot holding and cooling) practices. Lack of education has been seen to contribute to these issues, as have changes in cooking and eating practices in various consumer groups.

Sperber (2011) provides a review and case study of food safety in the home (Sperber, 2011; in Wallace et al., 2011), and identifies a range of common-sense practices that can be used as preventative control measures in the home. Adding these practices to the use of effective cooking, refrigeration, and cleaning/disinfection gives a useful list of food safety control measures, or “House Food Safety Rules” for the Consumer (Table 8.6).

The terminology and jargon of HACCP means that it is unlikely to ever be fully adopted in the domestic environment. However the ethos and sentiment of HACCP can be adapted to meet consumer needs and, with adequate education, consumers can identify their areas of risk and use practical control measures such as the above to improve safe food handling practices in the home, thus strengthening the ultimate link in the food supply chain.

Table 8.6 House food safety rules

Principal food safety control measures in the domestic environment
<ul style="list-style-type: none">• Transport chilled and frozen food quickly between the retailer and your home. Place in fridge/freezer immediately you get back to kitchen.• Keep the fridge below 5 °C and the freezer below –18 °C. Check this regularly with an accurate thermometer.• Store cooked or ready-to-eat foods at the top of the fridge and raw foods at the bottom to avoid cross-contamination. Use separate fridges if possible.• Check date codes and use all food within the recommended period.• Use clean (potable) water for preparing foods, especially when rehydrating foods such as dried milk for consumption without heating. In many regions, limited access to potable water is a major public health issue.• Clean and disinfect bottles used for infant feeding before filling with properly heated milk or infant formulas.• Maintain allergen controls if a family member has a food allergy. Be aware of food allergies that visitors may have.• Do not store toxic chemicals in the kitchen or in other areas where foods are stored. Never store toxic chemicals in former food containers and always clearly label.• Cook food <i>thoroughly</i> and chill rapidly if not going to be used straightaway.• Adopt good hygiene practice to ensure cross-contamination control:<ul style="list-style-type: none">◦ Always wash hands before and after preparing food, going to the bathroom, and handling waste, raw foods, and pets.◦ Keep pets away from food, worktops, and utensils.◦ Keep windows and door closed or screened to prevent insect or rodent access.◦ Keep the general environment clean, and wash worktops and utensils between use for food which is raw and that which is cooked.

8.12 Reflections of HACCP Application Throughout the Food Supply Chain

When considering each of the links in the food supply chain model (Fig. 8.1) the complexity of food safety management from farm to fork starts to emerge. Whilst models invariably make the subject appear somewhat simplistic, the sheer variation of operations and hazards that may occur in the food supply chain makes it essential that effective HACCP plans and PRPs are applied throughout. Adding in the context of a truly global food supply chain and the potential for transfer of issues and hazards across the world through the food supply, we can see that food safety management is a crucial element of public health protection.

- Several recurring themes are clear through the links in the food chain:
- The need for specialist knowledge at all parts of the chain, relevant to the materials being handled and the processing operations being applied.
 - The importance of connectivity and interactivity of the different links in the chain; hazards in one link may need to be controlled at another later link and PRPs in one link may minimize problems later on. It may not be possible to fully control all hazards within each individual link, so communication of knowledge and information is vital.

- HACCP will work in all links of the food supply chain; however flexibility may be needed to develop practical systems that meet the requirements of each link.
- The need for management commitment for providing suitable resources and training that will enable the development, implementation, and maintenance of effective food safety management systems.
- The need for full traceability of all materials throughout the food supply chain.
- The need for consumer education such that they can apply practical control measures and strengthen food safety practices in the home.

Sharing of information between all the parties and stakeholders involved will be the key to effective management of food safety through the application of HACCP and prerequisites.

Epilogue

At the end of a specialist book such as this it is easy to lose sight of everything that was going on around you before you picked it up and started reading. That is, if you even had time to sit down and read the whole book. We are all so busy these days that taking time to read, absorb new concepts, come up with ideas of your own and basically just **think** is a dream that many don't get to experience—the “real” world gets in the way, with day-to-day issues to deal with, product to get out of the door, customer queries to respond to and many other demands on our time.

However, to think more strategically and to be progressive you have to make continuous improvement of food safety a priority.

“To make significant changes in food safety we need creativity and innovation. To make significant changes in food safety we need leadership. To make significant changes in food safety we need more research. To make significant changes in food safety we need collaboration”—Yiannas (2009)

In the past, HACCP and prerequisite programs (PRPs) may have been considered as separate elements from the other management systems in an operation, but it is increasingly important to consider the holistic approach to food safety management programs, incorporating best practice facility and equipment design, as well as structured management systems. Operating within the framework of a supportive food safety culture will help to make significant changes in food safety management and consumer health protection.

At the end of the book, we wanted to include some examples of commonly observed mistakes in using HACCP. This is information that we wish we had known twenty years ago and some of it has been acknowledged elsewhere (e.g., Wallace, Sperber and Mortimore, 2011; Mayes and Mortimore, 2000). In plants or other operations where there is good hygienic practice, a positive attitude towards food safety and quality, and good technical knowledge concerning safe product design, most of the elements required for a sound HACCP program will be in place. But even then there are some areas that can be difficult, and the following is the list, in no particular order, of things to beware of:

- **Overcomplicated and difficult-to-maintain systems.** As discussed in Chap. 2, time spent planning the system carefully is a wise investment. At an early stage the team should also be thinking about the maintenance of the HACCP system in order for it to stay current. There are a number of things that can help:
 - Use a modular approach which is usually easier to keep simple because it divides the plant/process up into manageable-size pieces. These can be allocated to the people who are closely associated with them and who will be more aware when something changes in their area.
 - Making sure that all HACCP documents are numbered and that the linked documents and procedures are listed on a master plan so that nothing is missed out.
 - Cross-reference documentation such as work instructions and operating procedures (to the HACCP plan). They can be more easily updated when changes occur.
 - Broad communication that HACCP is part of the company's overall food safety program.
- **Inaccurate process flow diagrams.** Many companies like to simplify process flow diagrams (PFDs), but in doing so the hazard analysis may be incomplete as steps are often missed out. Part of the reason for this simplification is to have a document to show to external parties such as customers and regulators without having to "give away" the detail of what happens on-site. In this case, our recommendation is to create a simple PFD that can be shared externally along with a very detailed PFD that can be used internally for the hazard analysis. Another reason why PFDs are often inaccurate is that there may have been changes since the PFD was originally drawn up and, hence, it is outdated. The PFD must be confirmed as being correct and complete, by walking through it in the plant. This must be done **before** the hazard analysis begins. Consider the process 24/7 and also personnel traffic patterns and air and drain flow. If there are high-hygiene zones, they can be marked on the diagrams, along with any routine manual sampling, inspection points, and even sanitation and cleaning protocols (wet vs. dry clean areas). These activities can be a source of cross-contamination and, if not called out, will be missed in the hazard analysis. Like all other HACCP documents, the PFD needs to be regularly reviewed and updated when necessary.
- **Lack of understanding of the products' intrinsic safety factors.** It is really important to understand what is making your product safe. Is it low water activity, pH, preservatives, a heat kill step, or something else? This knowledge is needed in order to make informed decisions in the event of cross-contamination or requested formula or process changes. Know what would make your product unsafe as well—if it became contaminated with "x" then would it grow, survive, etc. Many companies do not spend enough time on this.
- **Poor application of HACCP principles 1 and 2: hazard analysis and determination of CCPs.** Too many CCPs through misunderstanding the relationship

between HACCP and PRPs is a frequent error (Wallace and Williams, 2001). This is the most difficult area of HACCP and the most debated. The introduction of OPRPs has helped many companies but others find this new area even more confusing. Food safety is often not “black and white” in terms of how things are done. But there is enormous value in the rich debate that should occur amongst the HACCP team as they use their knowledge and experience to determine the best way to manage the significant hazards identified in the hazard analysis.

Another mistake, which weakens the system, but is very common, is the identification of hazards in general terms (e.g., “biological” or “pathogens”) instead of specific terms that identify the specific hazard and its manifestation. Is it “presence,” “cross contamination,” or “growth” of microbiological hazards that is the concern? If possible, identify the likely microorganism such as *Salmonella* spp., *Listeria monocytogenes*, or *Staphylococcus aureus*. Only by making a specific identification of a hazard, will you be able to determine the appropriate control measures for its prevention. Identification of hazard significance through risk evaluation (likelihood and severity) is a challenge where technical expertise is lacking.

The fundamental thing to bear in mind is that the team is tasked with identifying significant hazards which **MUST** be controlled (Fig. A.5) in order to prevent a likely foodborne illness event. Making sure that they do this thoroughly is key.

- **Poor application of HACCP principle 3: establishing critical limits.** Literature is limited in this area but experience indicates that some companies will write in the regulatory limit and many will use their actual operating specification range at this point. This indicates a lack of understanding that the critical limit is exactly what it says—the limit that is critical for food safety (i.e., the edge of the cliff)—and that this limit needs to be based on scientific data (validated). Establishing what the margin of error is between the operational and critical limit is also common sense but not always considered early on.
- **Poor application of HACCP principles 4 and 5: monitoring and corrective action procedures.** Lack of clear instructions and properly trained monitoring personnel can have catastrophic effects. The CCP monitor is in the front line and must be well informed as to his or her responsibilities. There are some practical activities that can help:
 - Ensure the monitoring frequency is appropriate.
 - Train designated CCP monitors well—be sure to verify their understanding and their ongoing behavioral competency on a periodic basis.
 - Involve the CCP monitors in the design of any forms and in writing the procedures and work instructions.
 - Use verification activities to follow up with them with regard to performance.
 - Be very clear on requirements for corrective action and required training. Ideally, “inform QA manager” will only be specified once other actions are complete. This should not be the main or the only action required. Think also about back up when the QA manager is unavailable. That same requirement



Fig. 1 "If I lose control, is it likely that a health hazard will occur?"

also applies to CCP monitors and CCP record reviewers—both the regular and back up people need to be trained.

- **Poor application of HACCP principle 6: verification.** HACCP principle 6 includes both validation and verification activities. Validation is usually the greater challenge for many. Lack of suitable references or other evidence such as challenge studies, to show that the HACCP plan will be effective against the hazards identified, is a common failure. Verification is seen as being more straightforward—many of the activities will already be familiar and in place but it is important to establish that the chosen verification activities will demonstrate effective operation of HACCP and the wider food safety management program over time. For example, problems can also arise from misunderstanding that the requirements for HACCP management also apply to PRPs, particularly in requiring validation and verification. The guidance here is to ensure sound training and education and seek reputable advice if possible.
- **Lack of management support.** Real management commitment is a key success factor in any food safety program. This has to be more than a vocal assurance of support. There needs to be a number of other signs of alignment:
 - Signed food safety or quality policy which is regularly reviewed and updated.
 - Willingness to hold people accountable in the event of failure.
 - Provision of resources for food safety activities—seeing it as a priority, and even better, as a core value to the company.
 - Frequent and visible confirmation of commitment to food safety during staff briefings.
 - Attendance at food safety-related training.
 - Proactive requests for status updates.
 - Participation in review of performance indicators such as audits and consumer complaint data.
 - Support that continues to be there once the focus shifts to something else.
- **Lack of employee commitment.** This is just as important as management commitment. Employees can sometimes have a cynical, “seen it all before” attitude and be reluctant to embrace new work practices. Good communication, an open and honest approach, sharing examples of failure and making it relevant can help. Real management commitment is an essential starting point for employee commitment and needs to be there every single day.
- **Lack of motivation once the HACCP plan is complete.** Combine this with factors such as staff turnover, illness, absenteeism, and competition for resources once new projects come along and this can be a real challenge. The vision of a proactive and sustainable program takes a lot of effort to bring to life. Again, education and genuine commitment are critical, as is making it a team effort and everyone’s responsibility. This doesn’t happen by accident—it needs to be planned and reviewed for improvement opportunities.

As you continue to develop your program, remember that you don't have to work in isolation. Make sure that you reach out to others in the industry. Go to conferences, join trade associations and networks, and attend meetings and webinars. You will want to ensure that your HACCP system, the overall food safety management program, and ultimately, your business has a long shelf-life and be capable of adapting to encompass new approaches and ideas along the way. As industry develops in this area, hopefully your business and its food safety control program will move with it.

Finally, a few thoughts to bear in mind as you embark on your HACCP endeavors whether they are for the first time or as part of continuous improvement:

- Keep it simple and focused. Over complex systems are difficult to communicate and maintain.
- Be clear on your objectives. Understand what the outcome looks like.
- Choose the right people for the job and train them properly. This is a people and science-based system.
- Ensure that your HACCP team members know what is expected of them and fully participate.
- Prepare thoroughly—to fail to prepare is to prepare to fail!
- Don't make assumptions—Always verify.
- Assign roles and responsibilities.
- Work in an organized manner. Make sure that all details are recorded, from who was on the HACCP team to capturing the thought process and discussions accurately during hazard analysis and CCP identification.
- Challenge existing beliefs—make sure that you have evidence of what is actually happening.
- Challenge current practices—are they acceptable?
- Resist the temptation to make the HACCP findings fit the existing control and monitoring schedules.
- Review and enhance your PRPs. Food Safety requires a hygienic operation environment.
- Be humble about what you know and always seek to learn. The worst mistake you can make is to think that you already have a better food safety program than anyone else.
- Constantly search for new ideas and opportunities to make your program even better. If you aren't open to learning you lose the opportunity to go from good to great and others will overtake you along the way.

We would like to wish you luck in applying HACCP to your operation and to strengthening your food safety program. We have enjoyed updating this book and, as we said at the beginning, we hope that it will be of some help as you continue on your journey.

Sara Mortimore and Carol Wallace

Appendix A Case Studies

Introduction

This appendix is split into two parts and consists of two types of HACCP and Food Safety Case Study. Part One consists of four practical case studies, which have been constructed to illustrate the application of the HACCP principles to different areas of food and drink production and preparation. Part Two consists of two case studies covering the investigation of outbreaks when food safety management has gone wrong.

The authors of these case-study examples are experts in their fields. Part One case studies come from practitioners within the food supply chain who have hands-on experience of implementing HACCP. Part Two case studies come from expert investigators of food safety incidents. Each example has been carefully chosen so that this appendix represents a wide range of processes and products, as well as providing learning points from incidents where food safety was not managed effectively.

Part One

- Case study A.1. Fancy feeds—specialist animal feed manufacturing
- Case study A.2. Flour milling
- Case study A.3. Butter town—large-scale manufacturing
- Case study A.4. Fast food restaurant operations
- Case study A.5. University catering—large-scale, complex catering

Part Two

- Case study A.6. When having a HACCP plan is not enough—Case study based on the September 2005 Outbreak of *E. coli* O157:H7 in South Wales, UK
- Case study A.7. Learning from major incidents—Salmonella in Cadbury's Chocolate 2006

Part One: Practical HACCP Application Case Studies

Note: Each case study detailed here is theoretical and the findings may not be exhaustive. The contributors are experienced in the fields concerned, but the case studies do not necessarily reflect the views or current approaches taken by their companies, nor those of the book authors. The examples are not intended as specific recommendations for similar processes/products, i.e., they are not generic HACCP plans, but as a demonstration of the application of the HACCP principles in different situations.

Case Study A.1: Fancy Feeds, USA

Kathy Haines and Anthony Vojta, Land O'Lakes Inc., USA

The case study outlined below is presented with due care in its compilation. However, it is provided without any liability whatsoever in its application and use, reflecting the personal views of the authors and not necessarily Land O'Lakes Incorporated.

Introduction

Fancy Feeds, Inc. is a fictional medium sized animal food manufacturing company specializing in Livestock products sold to retail dealers. They recently secured a contract for a local zoo which will take them into the exotic animal food market. One of their new product lines is a pelleted Kudu diet.

HACCP Team Members

- Plant Manager: 15 years of animal food manufacturing experience.
- Production Supervisor: 3 years of animal food manufacturing experience and HACCP trained.
- Quality Assurance Manager: 7 years of animal food manufacturing experience, HACCP trained, and selected as the Team Leader.
- Maintenance Manager: 1 year of animal food manufacturing experience.

Terms of Reference

The HACCP study covers all types of animal food safety hazards which include physical, chemical, and biological. The focus of this HACCP program entails Kudu diet manufactured at this facility.

Fancy Feeds, Kudu Diet Process Flow Diagram

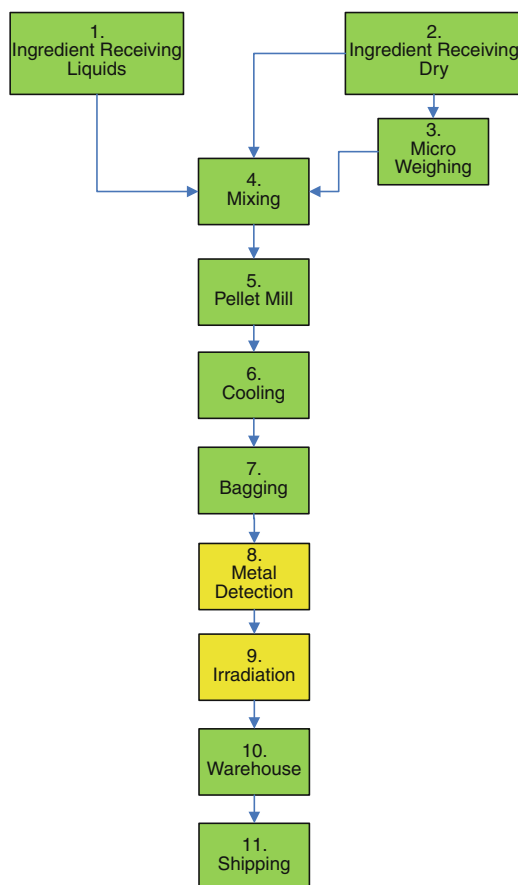


Fig. A.1 Process flow diagram

Product Description

- *General:* Kudu diet is a pelleted product that consists of corn, rice hulls, pork meat and bone meal, cane molasses, salt, trace minerals (zinc, limestone, di-calcium phosphate, manganese, and copper sulfate), and vitamins A, D, and E which provides supplemental nutrition to the Kudu's total diet.
- *Target Market:* Kudu diet is distributed to Zoo's to be fed to Kudu. Kudu are two species of antelope of the genus *Tragelaphus*.
- *Consumer/Customer Use:* Intended to be hand fed by zoo visitors.

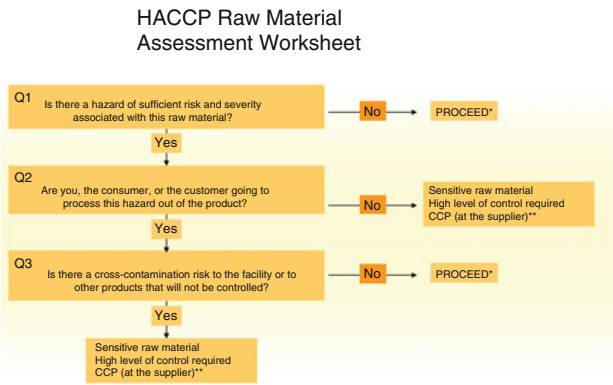


Fig. A.2 HACCP raw material decision tree (adapted from Mortimore and Wallace, 1998)

The Process

See Fig. A.1.

Ingredients are received by bulk and bag. Bulk ingredients are stored in dry storage bins or liquid storage tanks. Bagged ingredients are stored in the warehouse. Micro-ingredients are weighed by the mixer operator and added to the mixer when the formula calls for the ingredient. After the formula is mixed, the batch is sent to a storage bin for pelleting. The mixed batch is processed through a pellet mill that uses pressure and steam to form pellets. The pellets are then cooled and stored in a bin for further packaging. The packaging machine is loaded with tags and bags and the selected product flows into the bagger hopper. The packaging line is started and the product is filled into the bag, the tag is applied, and sewn onto the bag. The code date is applied to the package and the weight is verified. The filled feed bag is conveyed through a metal detector into the irradiation room where it is exposed by gamma rays for a determined amount of exposure and exits the room to be stored in the warehouse at ambient temperature. The finished product is stored until it is selected for an order.

Hazard Analysis and CCP Determination

The raw material decision tree (Fig. A.2) was used to evaluate each raw material. The results are shown in Table A.1.

Table A.1 Ingredient hazard analysis

Raw material	Hazard type	Hazard	Q1	Q2	Q3	CCP (at the supplier) ?	Rationale
Corn	Biological	Presence of Salmonella	Y	Y	N	No	Kudu diet is irradiated prior to storage
	Chemical	Presence of Aflatoxin	Y	N	–	CCP	The presence of Aflatoxin is dependent on the crop year
		Presence of DON	Y	N	–	CCP	The presence of DON is dependent on the crop year
		Presence of Fumonsin	Y	N	–	CCP	The presence of Fumonsin is dependent on the crop year
	Physical	Presence of metal	Y	Y	N	No	Protective Devices within the process
Rice Hulls	Biological	Presence of Salmonella	Y	Y	N	No	Kudu diet is irradiated prior to storage
	Chemical	Presence of Aflatoxin	Y	N	–	CCP	The presence of Aflatoxin is dependent on the crop year
	Physical	Presence of metal	Y	Y	N	No	Protective Devices within the process
Pork Meat and Bone Meal	Biological	Presence of Prohibited Animal Protein	Y	N	–	CCP	The presence of prohibited animal protein could be harmful to ruminant diets

(continued)

Table A.1 (continued)

Raw material	Hazard type	Hazard	Q1	Q2	Q3	CCP (at the supplier) ?	Rationale
		Presence of <i>E. coli</i>	Y	Y	N	No	Kudu diet is irradiated prior to storage
	Chemical	None	N	–	–	No	Hazard not likely to occur
	Physical	Presence of metal	N	–	–	No	Hazard not likely to occur
Cane Molasses	Biological	Presence of Salmonella	Y	Y	N	No	Kudu diet is irradiated prior to storage
	Chemical	None	N	–	–	No	Hazard not likely to occur
	Physical	None	N	–	–	No	Hazard not likely to occur
Salt	Biological	None	N	–	–	No	Hazard not likely to occur
	Chemical	None	N	–	–	No	Hazard not likely to occur
	Physical	None	N	–	–	No	Hazard not likely to occur
Zinc	Biological	None	N	–	–	No	Hazard not likely to occur
	Chemical	Presence of Dioxin	N	–	–	No	Hazard not likely to occur
		Presence of Heavy Metals	N	–	–	No	Hazard not likely to occur
	Physical	None	N	–	–	No	Hazard not likely to occur

(continued)

Table A.1 (continued)

Raw material	Hazard type	Hazard	Q1	Q2	Q3	CCP (at the supplier) ?	Rationale
Limestone	Biological	None	N	–	–	No	Hazard not likely to occur
	Chemical	None	N	–	–	No	Hazard not likely to occur
	Physical	None	N	–	–	No	Hazard not likely to occur
Di-calcium Phosphate	Biological	None	N	–	–	No	Hazard not likely to occur
	Chemical	Presence of Fluoride	N	–	–	No	Hazard not likely to occur
	Physical	None	N	–	–	No	Hazard not likely to occur
Manganese	Biological	None	N	–	–	No	Hazard not likely to occur
	Chemical	None	N	–	–	No	Hazard not likely to occur
	Physical	None	N	–	–	No	Hazard not likely to occur
Copper Sulfate	Biological	None	N	–	–	No	Hazard not likely to occur
	Chemical	Presence of Dioxin	N	–	–	No	Hazard not likely to occur
		Presence of Heavy Metals	N	–	–	No	Hazard not likely to occur
	Physical	None	N	–	–	No	Hazard not likely to occur
Vitamin A	Biological	None	N	–	–	No	Hazard not likely to occur

(continued)

Table A.1 (continued)

Raw material	Hazard type	Hazard	Q1	Q2	Q3	CCP (at the supplier) ?	Rationale
	Chemical	Potency of Vitamin	Y	N	–	CCP	Purchase ingredient through approved suppliers with potency verified at the time of receipt
	Physical	None	N	–	–	–	Hazard not likely to occur
Vitamin D	Biological	None	N	–	–	–	Hazard not likely to occur
	Chemical	Potency of Vitamin	Y	N	–	CCP	Purchase ingredient through approved suppliers with potency verified at the time of receipt
	Physical	None	N	–	–	–	Hazard not likely to occur
Vitamin E	Biological	None	N	–	–	–	Hazard not likely to occur
	Chemical	Potency of Vitamin	Y	N	–	CCP	Purchase ingredient through approved suppliers with potency verified at the time of receipt
	Physical	None	N	–	–	–	Hazard not likely to occur

Fancy feeds raw material hazard analysis work sheet

CCP Identification

The standard HACCP definition of Critical Control Point (CCP) was used for identification as follows: CCP is defined as a point, procedure, practice, operation, or stage in animal food production at which control can be applied and the production of internally contaminated animal food can as a result be prevented, eliminated, or reduced to acceptable levels.

The identification of the CCP was done following the decision tree (adapted from Mortimore and Wallace, 1998). The following decision tree questions were used to systematically discuss and identify CCP's in Kudu diet production:

- Q1: Is there a hazard of sufficient risk or severity to warrant its control?
- Q2: Do control measures exist for the identified hazards?
- Q2a: Is control necessary at this step to warrant safety?
- Q3: Is the **step** specifically designed to eliminate or reduce the likely occurrence of the hazard to an acceptable level?
- Q4: Could contamination occur at or increase to unacceptable level(s)
- Q5: Will a subsequent step or action eliminate or reduce the hazard to an acceptable level?

See Fig. [A.3](#) and Table [A.2](#).

CCP Management

Once all CCPs were identified the team established how they would be monitored, the corrective action to be taken in the event of failure, and what verification procedures would be appropriate. This was all captured on a HACCP Control Chart (Table [A.3](#)).

HACCP Plan Implementation and Maintenance

Since this is Fancy Feeds first HACCP plan, the HACCP team determined that a review after 3 months of implementation was needed.

Regular audits will be carried out every 6 months and an annual audit will be carried out by a third-party certification organization. The audit will include a review of all HACCP records including Hazard Analysis, Process Flow Diagram, Prerequisite Programs (PRPs), Monitoring Records, and Corrective Actions. The results of the audits will be reviewed during the facility management meetings.

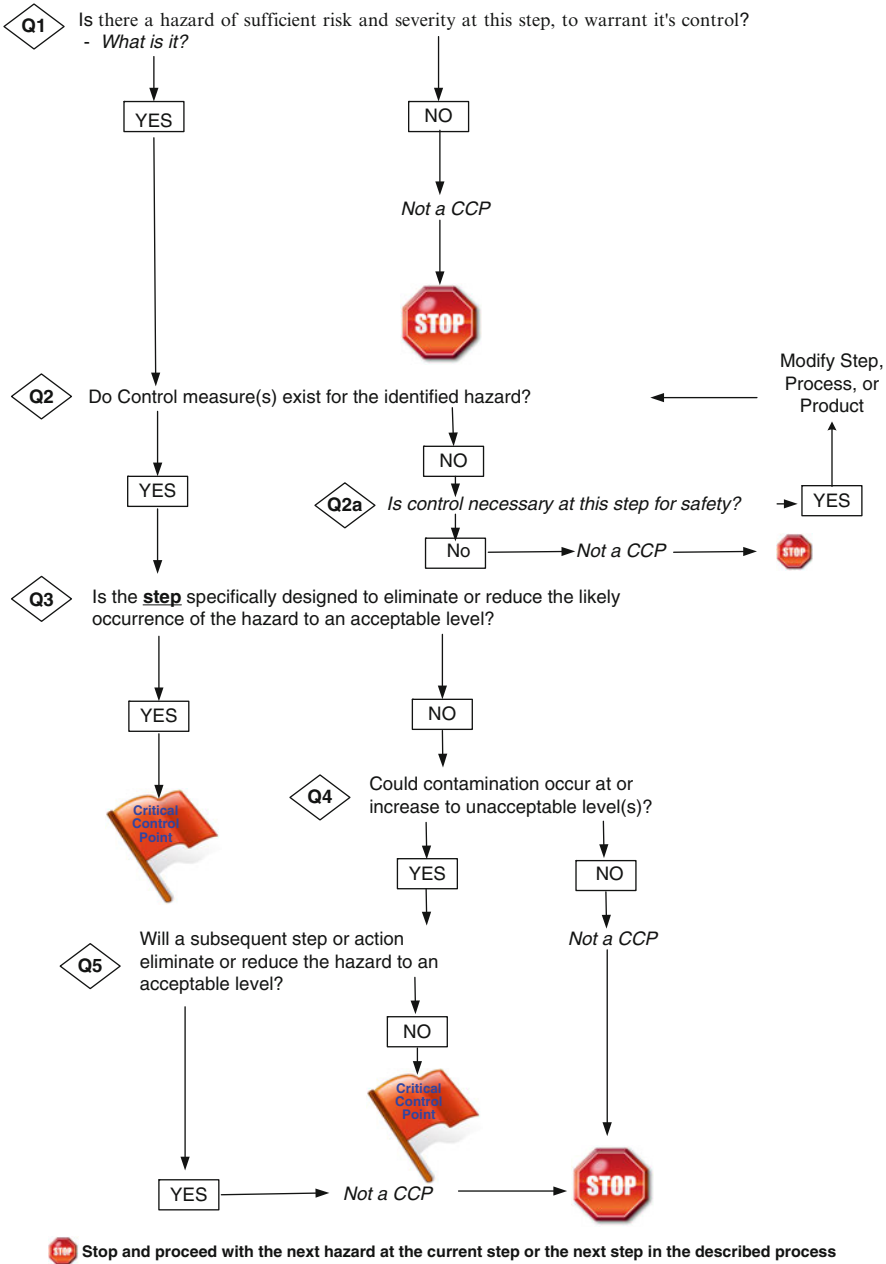


Fig. A.3 Process step CCP decision tree (adapted from Mortimore and Wallace, 1998)

Table A.2 Process step hazard analysis

	Fancy feed												
HACCP plan	Kudu												
Revised date:	1/25/2012												
Superseding date:	New												
Revision number 1													
Process step #	Process step	Hazard category	Hazard and source	Likelihood	Severity risk	Control measure	Q1	Q2	Q2a	Q3	Q4	Q5	CCP
1	Ingredient receiving liquids	Biological	Presence of Salmonella and <i>E. coli</i> O157:H7 in the transfer hoses	M	H	Housekeeping and sanitation	Yes	Yes	–	No	Yes	Yes	No
		Chemical	Potential cross-contamination of wrong ingredient received	L	M	Shipping documentation verification and visual inspection	No	–	–	–	–	–	No
		Physical	Foreign matter—metal from ingredient and equipment	L	L	Strainer check after each load/PM program	No	–	–	–	–	–	No
2	Ingredient receiving dry	Biological	Presence of Salmonella and <i>E. coli</i> O157:H7 in the receiving environment	M	H	Housekeeping and sanitation Irradiation of finished product	Yes	Yes	–	No	Yes	Yes	No
		Chemical	Presence of Aflatoxin from	M	L	Supplier control	No	–	–	–	–	–	No ^a

(continued)

Table A.2 (continued)

Process step #	Process step	Hazard category	Hazard and source	Likelihood	Severity risk	Control measure	Q1	Q2	Q2a	Q3	Q4	Q5	CCP
3	Micro-ingredients weighing		ingredient (crop year dependent)			Mycotoxin testing on each load							
		Physical	Foreign matter—metal from ingredient and equipment	M	L	Visual inspection of the magnet at the point of receiving	No	–	–	–	–	–	No
		Biological Chemical	None Cross-contamination from wrong ingredient used	– M	– M	– Micro-ingredients are verified through scanning program	– Yes	–	Y	N	Y	N	Yes
4	Mixing	Physical	Contamination from tools	L	L	Tool handling program	No	–	–	–	–	–	No
		Biological	None	–	–	–	–	–	–	–	–	–	–
		Chemical	None	–	–	–	–	–	–	–	–	–	–
5	Pellet mill	Physical	Metal contamination from equipment	M	H	Magnets/PM program (Later metal detection)	Yes		Y	N	Y	Y	No
		Biological	None	–	–	–	–	–	–	–	–	–	–
		Chemical	Cross-contamination from	H	L	PM boiler tests and use of food	No	–	–	–	–	–	No

(continued)

Table A.2 (continued)

Process step #	Process step	Hazard category	Hazard and source	Likelihood	Severity risk	Control measure	Q1	Q2	Q2a	Q3	Q4	Q5	CCP
6	Cooling		boiler chemicals through steam at pelleting										
			Cross-contamination from lubricants at pelleting	H	L	PM and use of food grade lubricants	No	-	-	-	-	-	No
			Metal contamination from equipment	M	H	Metal detection downstream of the process	Yes	Yes	-	No	Yes	Yes	No
		Biological	Presence of Salmonella in the air supply	M	H	Housekeeping and sanitation Later irradiation	Yes	Yes	-	No	Yes	Yes	No
7	Bagging	Chemical	None	-	-	-	-	-	-	-	-	-	-
		Physical	Metal contamination from equipment	M	H	Metal detection downstream of the process	Yes	Yes	-	No	Yes	Yes	No
		Biological	None	-	-	-	-	-	-	-	-	-	-
		Chemical	None	-	-	-	-	-	-	-	-	-	-
		Physical	Metal contamination from equipment	M	L	Metal detection downstream of the process	No	-	-	-	-	-	No

(continued)

Table A.2 (continued)

Process step #	Process step	Hazard category	Hazard and source	Likelihood	Severity risk	Control measure	Q1	Q2	Q2a	Q3	Q4	Q5	CCP
8	Metal detection	Biological	None	–	–	–	–	–	–	–	–	–	–
		Chemical	None	–	–	–	–	–	–	–	–	–	–
		Physical	Presence of metal contamination from equipment from previous process steps	M	M	Metal detection	Yes	Yes	–	Yes	–	–	Yes
9	Irradiation	Biological	Presence of <i>Salmonella</i> and <i>E. coli</i> O157:H7 from previous process steps	M	H	Irradiation	Yes	Yes	–	Yes	–	–	Yes
		Chemical	None	–	–	–	–	–	–	–	–	–	–
		Physical	None	–	–	–	–	–	–	–	–	–	–
10	Warehouse	Biological	None	–	–	–	–	–	–	–	–	–	–
		Chemical	None	–	–	–	–	–	–	–	–	–	–
		Physical	None	–	–	–	–	–	–	–	–	–	–
11	Shipping	Biological	None	–	–	–	–	–	–	–	–	–	–
		Chemical	None	–	–	–	–	–	–	–	–	–	–
		Physical	None	–	–	–	–	–	–	–	–	–	–

Fancy feeds process step hazard analysis work sheet
^aMay be managed as an OPRP during a poor crop year.

Table A.3 HACCP control chart

Process step	CCP, no.	Hazard	Control measure	Control measure limit	Monitoring			Corrective action	Verification
					Procedure	Frequency	Responsibility		
Micro-ingredients weighing	1	Incorrect ingredients addition leading to under or over consumption	Scanning of ingredient bar code	All ingredients are scanned with a functioning scanner	1. Assure scanner is functional 2. Automated reconciliation of ingredients to formula	1. At start and end of run 2. By batch	1. Weigh up operator 2. Weigh up operator cross-check	1. At start—change to manual recording with supervisory oversight 2. At end—hold all product produced	1. Daily supervisor records review 2. Daily supervisor records review
Metal detection	2	Presence of metal contamination from process equipment	Metal detection	All product passes through a properly functioning metal detector	1. Assure that all product passes through a metal detector 2. Assure machine is calibrated to the standards 3. Properly document on the recording chart and CCP monitoring sheet	Minimum of every 4 h	Bagging operator	The QA manager will segregate and hold all affected product. Follow all standard operating procedures for disposition of metal detected product	The bagging operator will verify that the metal detector is on and calibrated at the start of production, at a minimum of every 4 h, and at the end of production using the test spheres supplied by the metal detector manufacturer
Irradiation	3	Presence of <i>Salmonella</i> Enteritidis (Se), <i>E. coli</i> O157:H7 from ingredients	Irradiation	Minimum absorbed dose; 1.5 k Gray/Maximum absorbed dose; as found in the CFR	Irradiation operator will monitor the data log printout from the irradiation control board for each irradiated batch	Every batch	Irradiation operator	The QA manager will segregate and hold all affected products. Follow all standard operating procedures for disposition of irradiated product	QA manager will verify that absorbed doses received by product are within the minimum and maximum limits from the results of dose mapping

Case Study A.2: HACCP Plan for a Wheat Flour Milling Facility

J. Shebuski, Cargill, Minneapolis, MN, USA

The case study outlined below is presented with due care in its compilation. However, it is provided without any liability whatsoever in its application and use, reflecting the personal views of the author and not Cargill, Incorporated.

The HACCP plan described below was created as a generic model of a flour milling process. It may lack some processing steps which are unique to some flour mills. However, the hazards identified in the raw materials and the process and the evaluation of those hazards are not likely to be different for most flour milling facilities.

There are a number of preliminary steps that precede the actual development of the HACCP plan.

Step 1: Create a HACCP team

A HACCP team must be created involving individuals from many different roles. It is typical that personnel working in the following functions will be part of this team; processing, quality and food safety, sanitation, maintenance, procurement, research and development, and sales. These team members can all provide unique insights and perspectives on the product and process and can assist with the HACCP program development process.

Step 2: Evaluate intended and unintended use

Once the team is assembled it is important to understand how the wheat flour being produced will be used. Both intended and unintended uses must be considered. Traditional uses of wheat flour have involved its' incorporation into baked products such as cakes, breads, and other products which may be cooked or fried. However, in some instances flour may be used in dough-based products which are not consumed as intended, e.g., the consumption of unbaked cookie dough. Once this is complete a process flow diagram must be created which indicates each step in the milling process, with inputs to the process and outputs from the process indicated.

Step 3: Create a Process Flow diagram (Fig. A.4)

A process flow diagram must be created to identify each process step with all inputs and outputs identified.

Conduct a Hazard Analysis

After completing the preliminary steps, the first step in creating the HACCP plan, the hazard analysis can be started. This involves identification of the biological, chemical, and physical hazards associated with the raw materials used and the hazards involved at each step of the milling process.

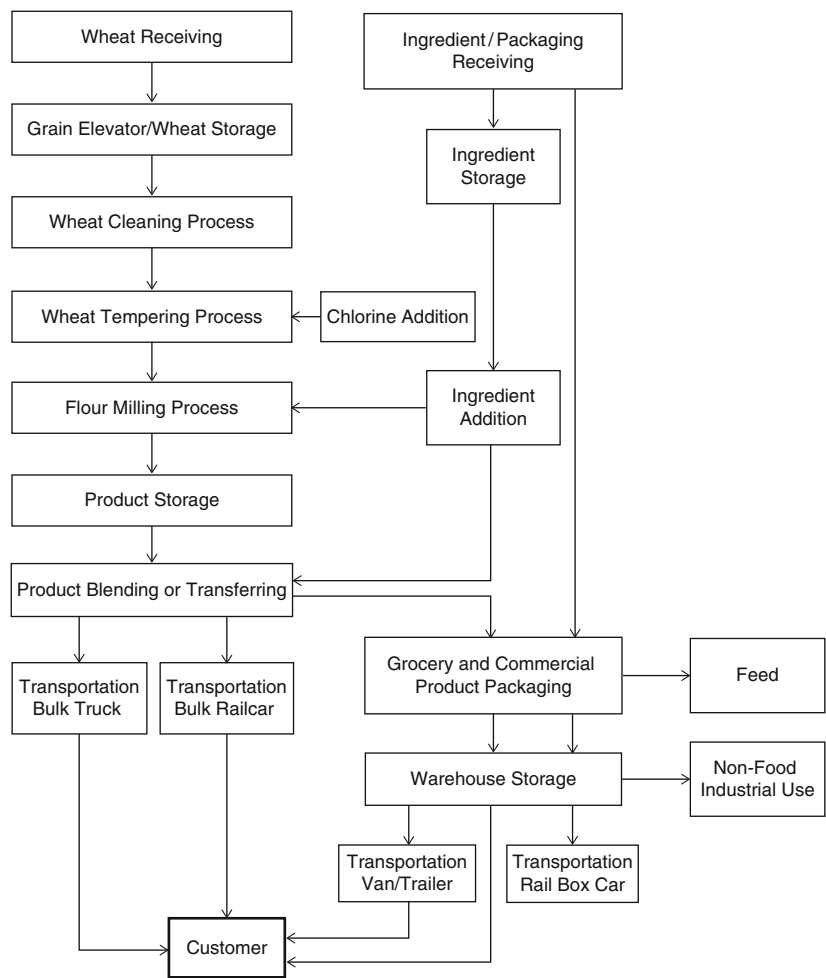


Fig. A.4 Process flow diagram for wheat flour

Raw Materials

Wheat is the primary ingredient of concern but other minor ingredients, such as a vitamin/mineral enrichment, potassium bromate, ascorbic acid, azodicarbonamide, benzoyl peroxide, malted barley flour, etc., must also be considered.

Biological Hazards

The wheat, from which wheat flour is produced, is a raw agricultural commodity. Like many agricultural commodities it is grown in an open environment accessible

to the elements in which it is grown. During its growth it is subject to a variety of weather conditions and is easily accessible to birds, rodents, and other wild and domesticated animals also living in the same environment. This environment allows for the possibility that the wheat may become contaminated with pathogenic organisms. Therefore the presence of these biological hazards should be considered likely in wheat intended to be milled into flour. The most commonly identified biological hazard associated with wheat and wheat flour is *Salmonella*. *E. coli* O157:H7 has also been mentioned as a possible hazard of concern, however its' presence in wheat appears to be very, very low.

Within the exception of malted barley flour, which should be evaluated in a manner similar to wheat, there are no biological hazards of concern associated with the other minor ingredients used in the production of wheat flour.

Chemical Hazards

Again, because of the environment in which wheat is grown and stored it is subject to contamination by insects and molds. Pests can impact the yield and quality of the growing wheat therefore it may be necessary to periodically treat the growing wheat with pesticides to minimize these concerns. Other pesticides may be used to minimize the growth of undesirable plants which are competing with the wheat for nutrients and water. Insecticides may again be applied to the wheat after it has been harvested and stored. The use of unapproved pesticides or residual pesticide levels in excess of regulatory limits must be considered chemical hazards of concern. The presence of molds is not of themselves a concern; however, the production of mycotoxins on the wheat by contaminating molds can create additional chemical hazards. The mycotoxins may be produced while the wheat is growing in the field or after harvesting during storage. The mycotoxin of greatest concern is deoxynivalenol (DON), also commonly referred to as vomitoxin.

Chemical hazards of concern involving the minor ingredients are related to overdosing of these materials. Under addition or no addition in some cases could also create regulatory or labeling issues.

Physical Hazards

There are a number of physical hazards that can be associated with wheat. Anything that could be introduced from the growing fields, during harvesting, or through transport and storage may be present. Hazards such as animal hair/fur, bird feathers, bones, stones, metal, rubber, wood, and glass would not be unexpected.

Physical hazards of concern involving the minor ingredients would be metal, glass, rubber, or plastic.

The Milling Process

The objective of the milling process is to separate the components of the wheat kernel and convert the desired components into flour. This involves the separation

of the bran layer from the endosperm and the subsequent reduction of the endosperm to flour. The milling of wheat into wheat flour is fairly straightforward process but involves several steps.

- Cleaning of the wheat

Removal of non-wheat material, e.g., corn, weed seed, sand, stones, straw, chaff, wood, glass, etc. through the use of physical separation (screening), aspiration, and scouring.

Removal of ferrous material through the use of a magnet.

- Tempering of the Wheat

Water is added to the wheat and is absorbed by the wheat for ~8–16 h in order to reach a consistent moisture level. This step aids in the removal of the bran from the endosperm. Sodium hypochlorite may be added to the tempering water in an attempt to control microbial growth during this step.

- Grinding of the wheat kernels (first break).

The wheat kernels are broken into coarse particles by passing them between corrugated rolls.

- Sifters and Purifiers

These particles are then further size reduced and segregated through multiple passages through sifter screens of increasingly smaller size.

The bran is removed at this point through the use of air separation.

- Size reduction of the endosperm.

The endosperm/flour particles are then passed through a series of roll mills and sifters to gradually reduce them to the size that we traditionally recognize as flour (135 μm).

- Blending and Packaging

Previously produced flours are then blended to create a final product with the appropriate characteristics, based on analytical and rheological tests and baking performance evaluations, necessary for a given application. The finished blended flour is placed into a variety of different types of packages ranging in size from 2# paper bags to railcars.

During the milling process there may be flour produced that has been determined to be unacceptable for quality or food safety reasons. In some cases it may be acceptable for some of this material to be added back to the process stream; however, in other cases, where this is not acceptable, this flour must be sold for non-food, industrial use. The handling of this material must be documented in the flow diagram and also considered when conducting the hazard analysis.

Following the traditional milling process it is likely there has been an overall reduction in microbial load of approximately 1–2 logs. However, there is no step(s) in

the milling process specifically designed for the destruction of pathogenic hazards such as *Salmonella*. Therefore there are no critical control points (CCPs) in the milling process for the control of the biological hazards identified in the wheat or that may be introduced during processing. These hazards are managed through a number of PRPs such as sanitation, pest control, careful management of water and condensation, packaging, transportation and maintenance, and preventative maintenance programs. These programs are focused on minimizing the introduction of pathogens and the possibility of pathogen growth in the milling equipment and in the mill environment. The control of biological hazards must be carried out by the end user of the flour.

The chemical hazards identified in the wheat, pesticides and mycotoxins, are managed through PRPs and are not managed as CCPs. The pesticide hazards are managed through contractual agreements with the growers and storage elevators to ensure only approved pesticides are used and only at the appropriate times. This is verified through a scheduled pesticide testing program. Mycotoxins are managed by regular evaluations of the wheat during the growing season and in storage. If mycotoxins levels are found to be of concern the wheat will be segregated and not milled into flour. The mycotoxin levels are further verified through a regularly scheduled testing program at the mill. Other chemical hazards which may be introduced during processing could be materials such as equipment grease or oil and underdosing/overdosing of minor ingredients, minerals/vitamins. These potential hazards are managed through PRPs such as the procurement program, the supplier qualification program, and the maintenance and preventative maintenance programs.

Physical hazards may be not only originate with the wheat but may also be introduced from the addition of the minor ingredients, during the process, from processing equipment, or through human errors. These hazards are managed during the milling process starting at the wheat cleaning step and throughout the process through the use of magnets, sifters, and screens as well as through the maintenance and preventative maintenance programs. These are PRPs, not CCPs. Metal detectors or magnets may also be used at the point of packaging. The metal detectors and magnets are typically not considered CCPs at this point because the possibility of metal of a size significant enough to cause a food safety concern is extremely remote. All of the sieving and sifting that precedes this step is adequate to prevent food safety hazards due to metal. The function of the metal detectors at this point in the process is to prevent the presence of metal which would cause quality problems but would not be food safety hazards.

Overall, there are no CCPs in the processing of wheat to flour. All potential hazards associated with this process are managed through PRPs with the exception of the biological hazard, *Salmonella*. This hazard must be managed by the end user since here is no step in the traditional milling process to eliminate it. The end user has the final responsibility for making this product safe.

Wheat flour should be considered a minimally processed agricultural product. It is not a fully processed product and it is not a ready-to-eat product after milling.

Case Study A.3: Buttersville, USA

Judy Fraser-Heaps, Jeff Balousek, Land O'Lakes Inc., USA

The case study outlined below is presented with due care in its compilation. However, it is provided without any liability whatsoever in its application and use, reflecting the personal views of the authors and not necessarily Land O'Lakes Incorporated.

Introduction

The Butter category within fats and oils historically has quite a safe history. Many countries allow sodium chloride and lactic acid cultures as the only non-milk additives in butter. The scope of this study is churned, salted butter, from pasteurized cream. It is important to note that the structure of butter is not homogeneous. The salt in the water phase droplets (from the churning process) with the compartmentalization of the water droplets within the oil phase inhibits outgrowth of *Listeria monocytogenes* as the primary potential microbial hazard with the product (Lavender et al., 2008).

HACCP Team Members

The HACCP team is composed of a multidisciplinary team consisting of employees from the Quality, Operations, Human Resource, Engineering, and Maintenance functions. Each member brings forth their own set of expertise in butter manufacturing. In addition to plant personnel, the HACCP team is directly linked to corporate Quality Assurance and Food Safety and Microbiology team members to strengthen the development and review of the program. HACCP team members have gone through an internationally recognized HACCP training program prior to their participation on the team. The plant quality assurance manager was designated the HACCP team leader, and the quality assurance supervisor was designated as the Deputy HACCP team leader.

Terms of Reference

The HACCP study covers all types of food safety hazards, namely, biological, chemical, and physical. The HACCP study also includes review of the required PRPs that lead to a successful implementation of a HACCP plan including Good Manufacturing Practices, Sanitation, Chemical Control, Pest Control, Trace Recall, Specification Control, Allergen, and Supplier Control and Employee Training.

Product/Process Description

Product	Butter (Salted).
Target market	Butter is sold to both retail and food service customers and then distributed to the general public domestically and internationally.
Consumer/customer use	Refrigerated and ready to consume.
Base ingredients	Salted Butter–Cream, Salt.
Raw materials	Allergen Present: MILK. Micro-sensitive ingredients: dairy ingredients: Salmonella, <i>Listeria</i> , <i>Staph</i> , <i>B cereus</i> are controlled through pasteurization and temperature control.
Packaging	1 lb. Butter quarters.
Process description	Milk is separated into cream or cream is obtained and pasteurized at $\geq 185^{\circ}\text{F}$ for ≥ 15 s. Cream is refrigerated to $\leq 45^{\circ}\text{F}$ for curing for ≥ 6 h. Cream is tempered to 52°F and continuously churned. Salt brine is injected into the butter stream. Butter is packaged and placed in the cooler set at $\leq 40^{\circ}\text{F}$. Buttermilk coming off of the churning operation is cooled and further processed.
Formulation/food preservation and safety attributes	Typically salted butter is a minimum of 80 % fat with 2 % salt, 1 % curd, and 17 % moisture. Formulation can vary slightly, however, butter by definition is a minimum 80 % fat.
Labeling/Label Instructions	Included product code, ingredient statement, lot number, manufacturer, plant number, allergen declaration, and instructions to keep refrigerated.
Shelf life	150–180 days at $<40^{\circ}\text{F}$. Limiting factor is sensory.
Storage and distribution	Products are maintained at less than or equal to 45°F during storage and transportation.

Hazard Analysis

Process Flow Diagrams:

A multilevel process flow diagram system was developed to show varying levels of detail.

“National Map” Flow Diagram (Fig. A.5)—A high level overview of the process broken down into major process stages. The Flowchart includes a general timeline of processing. CCPs shall be labeled. CCPs are determined at the end of the hazard analysis.

“Regional Map” Flow Diagram (Fig. A.6)—A one page overview of the entire process broken down into detailed process steps—showing flow of materials, ingredients, rework, process air, culinary steam, process water, etc. CCPs shall be labeled after the Hazard Analysis has been completed.

“Local Map” Flow Diagram (Fig. A.7)—A multi-page document consisting of one flow diagram for each of the major process stages. The Local Map Flow Diagram includes—Detailed breakdown of process steps within major process stage.

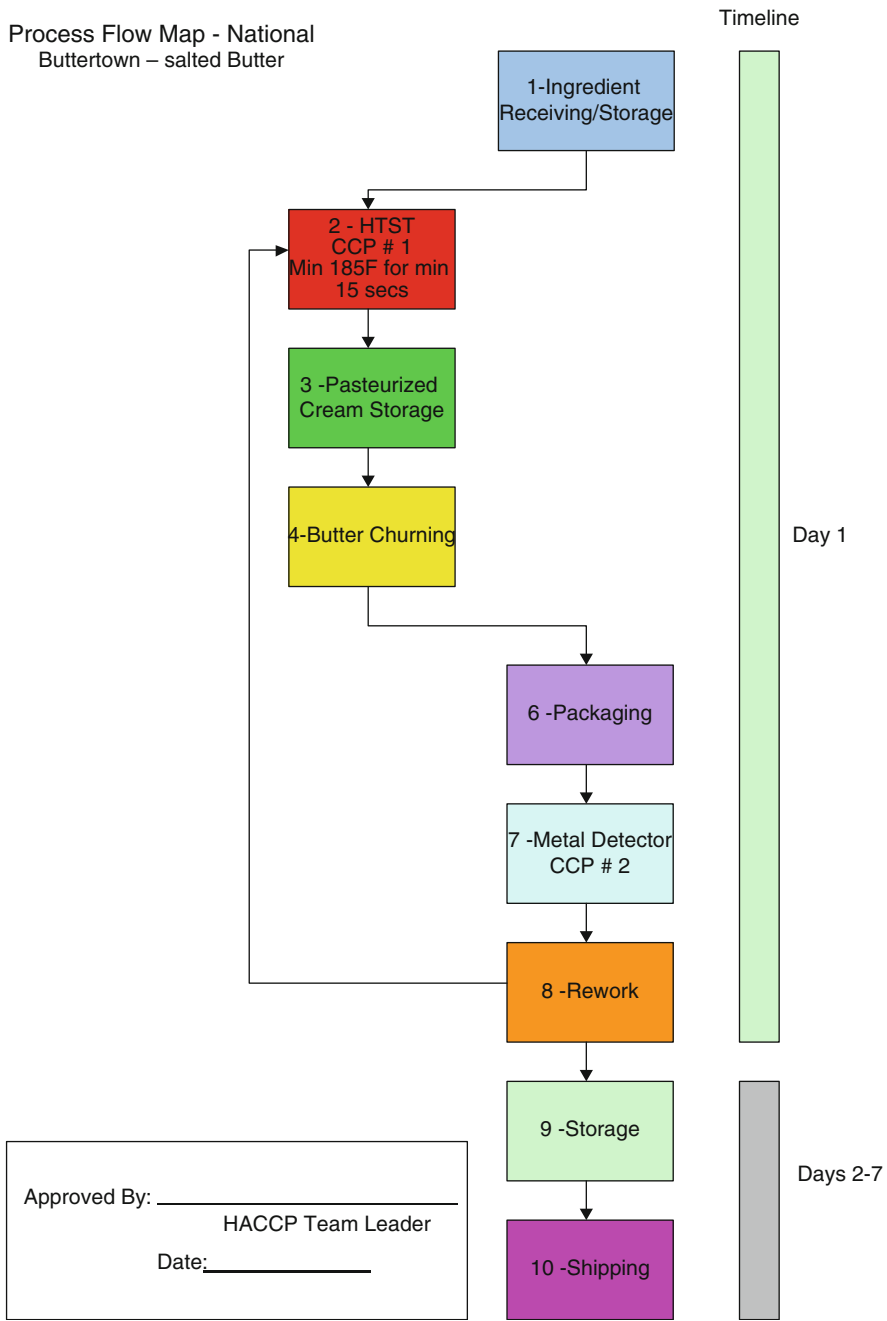


Fig. A.5 “National Map” flow diagram

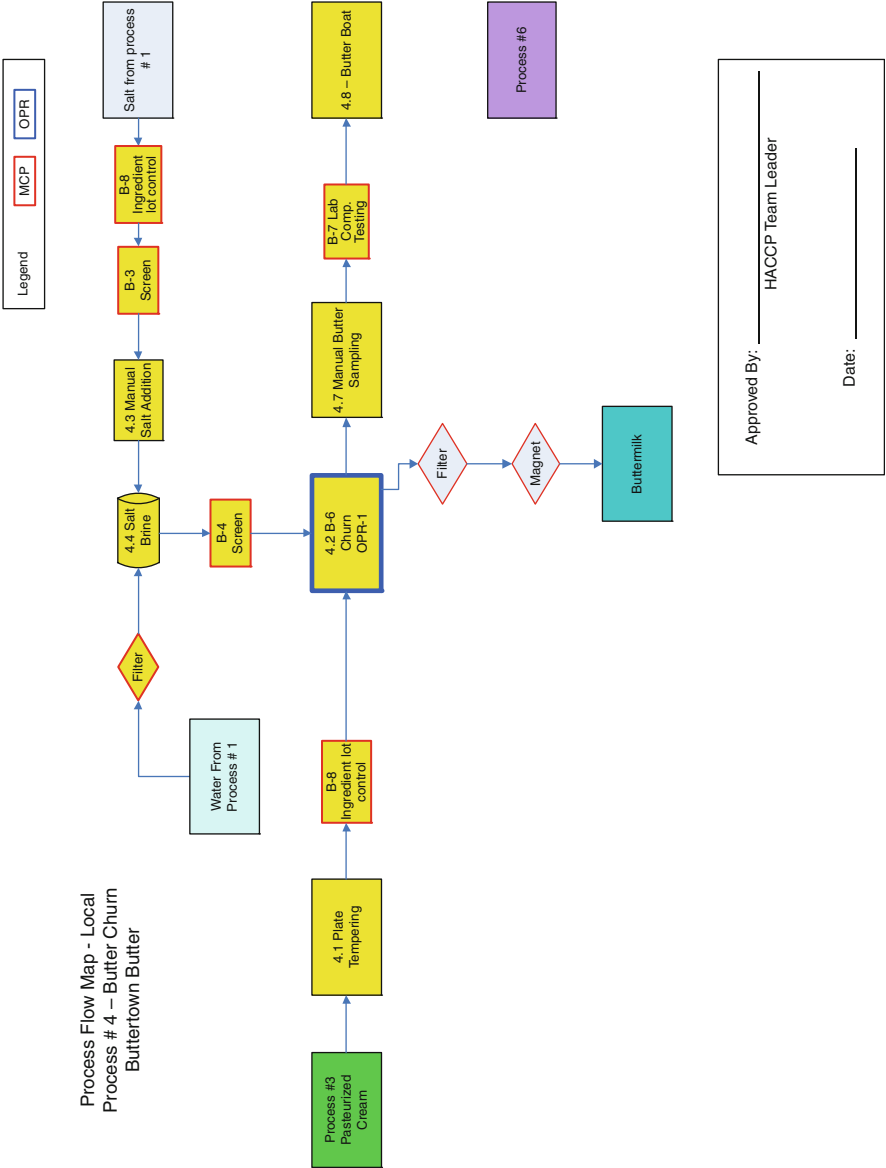


Fig. A.7 “Local Map” flow diagram

All detailed process steps are included in the plant Hazard Analysis and are labeled with the respective Hazard Analysis step number. Included are

- Process and Hold times and temperatures.
- Manufacturing Control Points (MCPs) which are the procedures and practices that affect the overall quality of the product. These control points should include criteria for operational PRPs (e.g., Pasteurizer and Metal Detection Operational Limits, Physical Safety Systems, Food Security, Specification Compliance, Lot Trace, Rework and Regulatory requirements).
- Include flow of materials, ingredients, rework, process air, culinary steam, process water, etc.
- Any manual intervention into the process shall be noted on the flow chart.
- CCP's shall be labeled after the hazard analysis has been completed.
- Operational Prerequisite Programs shall be noted.

All the Process Flow Diagrams (PFDs) are created and managed by the plant HACCP team. The flow diagrams are verified onsite and approved, signed, and dated by the HACCP team leader. Verification of the PFD is completed prior to undertaking the hazard analysis (refer to the local churn process map as an example).

After completing the preliminary steps in the HACCP process, the next step in creating the HACCP plan is to conduct a Hazard Analysis. The Hazard Analysis consists of identifying potential biological, chemical, and physical hazards at each process step of the local flow diagram. As the overall process is evaluated, potential hazards are identified for product and process, the likelihood and severity are ranked, and control measures identified. Sources and vectors of microbial cross-contamination are also considered, especially in review of each process intervention. As potential hazards are identified, the control measures should also be documented on the chart. The likelihood and severity are first considered “in the absence of control” so that the proper control provided by PRPs and work procedures are not overlooked. The CCP decision tree is used as a tool to determine critical control points. The CCP documentation chart is then filled out with the critical and operational limits (to allow a measure of safe operation) to assure the process is in control, and documenting the procedures to follow if there is a deviation. All procedures and verification steps are documented. Persons monitoring CCPs must also have completed HACCP training in addition to their work procedures training.

Two significant hazards in the manufacturing of butter exist, extraneous metal controlled through metal detection and vegetative pathogens controlled through pasteurization.

The Product by nature is a dairy allergen.

Critical Control Point Identification

This was done using a decision tree (Figure A.8) and the team findings are listed in Table A.4.

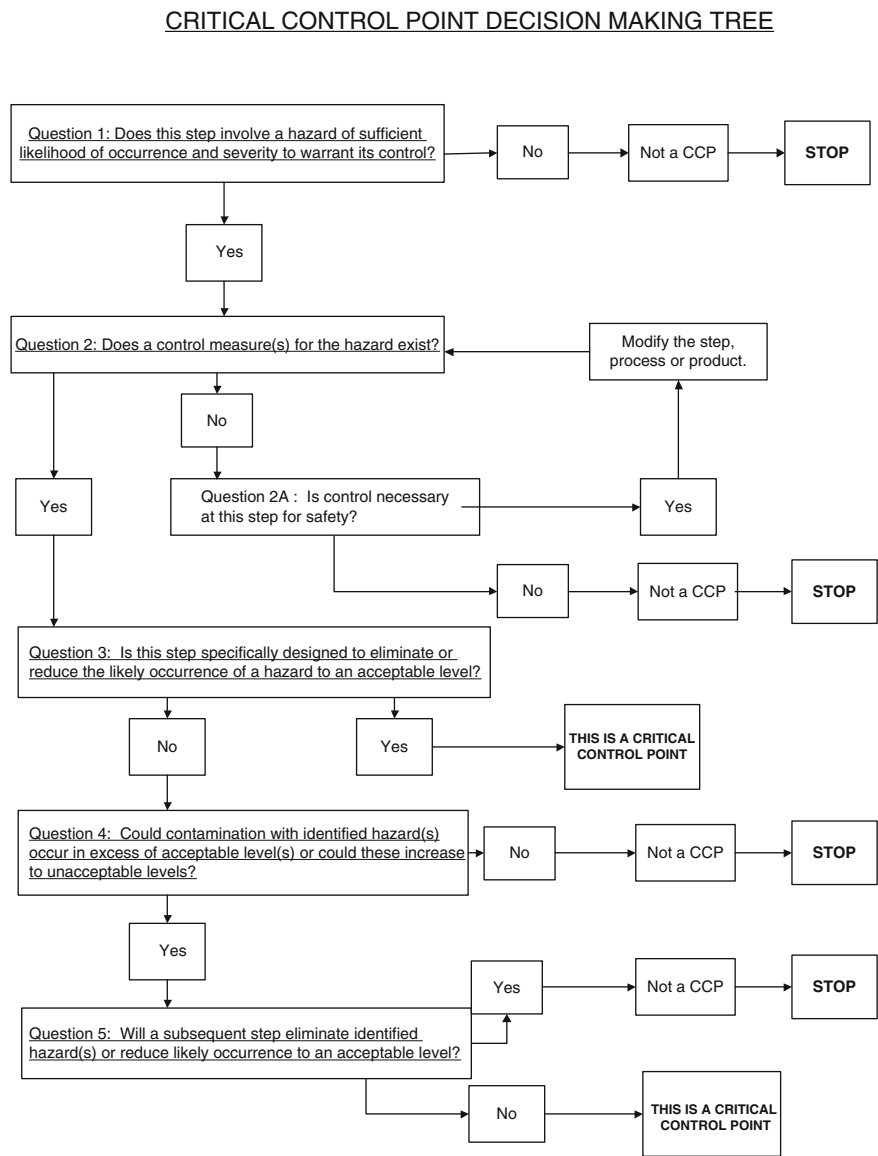


Fig. A.8 Critical control point decision-making tree (Adapted from Mortimore and Wallace 1998)

CCP Management

The Butternut HACCP team established monitoring, corrective action and verification procedures, and documented this in Table A.5.

Table A.4 Example of a completed hazard analysis for the raw milk receiving step

Plant: HACCP plan		Land O'Lakes—Buttertown, USA		Severity of Risk: High (H) = Potential Severe Health Risk, Medium (M)—Mild Illness with recovery, Low (L) - Likelihood of Risk to Occur: High (H) = High Likelihood, Medium (M)—Medium Likelihood, Low (L)—Low Likelihood											
Product/process/line:		Butter		Q1: Does this step involve a hazard of sufficient likelihood of occurrence and severity to warrant its control?											
Revised date:		1/27/2010		Q2: Does a control measure for the hazard exist?											
Superceding date:		4/21/2009		Q2a: Is control necessary at this step for safety?											
				Q3: Is this step specifically designed to eliminate or reduce the likely occurrence to an acceptable level?											
				Q4: Could contamination with identified hazard(s) occur in excess of acceptable levels(s) or could these increase to unacceptable levels?											
				Q5: Will a subsequent step eliminate the identified hazard(s) or reduce its likely occurrence to an acceptable level?											
Process step #	Process step	Hazard category	Hazard and source	Control measure	Likelihood	Severity risk	Q1	Q2	Q2a	Q3	Q4	Q5	CCP?	CP?	Rationale
1.1	Raw cream receiving	Biological	1. Presence, growth, and outgrowth of microorganisms from temperature abuse. <i>(Salmonella, Listeria, E. coli, staph, and B. cereus)</i> 2. Cross-contamination from unclean equipment	1. Temperature control <45 °F 2. Proper sanitation Sensory evaluation and acidity test. Not inserting CIP spray wand until tanker is empty	L	M	No	—	—	—	—	—	No	Yes (IR-3)	Significant hazard not likely to occur due to temperature control prerequisite. High level of growth to form toxin
		Chemical	Contamination from cleaning chemicals		L	L	No	—	—	—	—	—	No	Yes (IR-5)	Significant hazard not likely to occur. Acidity test very sensitive
		Physical	Foreign material from pump and environment	Visual, Supplier control, Breather Filter on dome prior to unloading	L	L	No	—	—	—	—	—	No	Yes (IR-2)	Significant hazard not likely to occur

Table A.5 HACCP control chart

Buttertown, USA									
Critical control point (CCP) documentation									
Product/Process name: Butter									
CCP no	Process step	Hazard	Source	Control measure	Critical limits	Monitoring Procedure	Frequency	Responsibility	Corrective action
CCP 1	HTST cream pasteurization	Biological vegetative pathogens	Incoming ingredients and pre-pasteurization cross-contamination	Heat treatment Seal state seal report	A minimum of 185 °F for a minimum of 15 s	1. Measure temperature at the exit of the holding tube	Continuous during operation	Pasteurizer operator	Manually divert flow of product Isolate the affected product. Assess risk; Mgmt will submit a product safety incident (PSI) and corporate QA. Disposition of product will be recorded on the PSI report Document actions
CCP 2	Metal detector	Physical presence of extraneous metal	From equipments and ingredients	Metal detector	All products pass through a properly functioning metal detector	Assure product passes thorough metal detector Assure machine is calibrated to the standards	Minimum of every 4 h	Line operator	1. When metal detector alarms, hold the product. Notify a supervisor and/or a lead person to determine root cause and assess risk. Document on CCP Monitoring sheet 2. If verification of calibration and reject test fails, hold the product back to the last good verification and retest. Mgmt will determine disposition of product. Document on CCP monitoring sheet CCP Failures are considered Hazardous Holds

Date: 1/27/2012

A. Daily record review and sign off by HACCP trained reviewer to verify:
1. All critical limits for Cut In/Cut Out (CICO) were met and done before production begins
2. The standards to be used to verify the calibration are documented on the LQMS Metal Detection Approved Standard Form
3. Daily record review by a HACCP trained reviewer

HACCP Plan Maintenance

The HACCP plan is reviewed on an annual basis as a minimum by the plant HACCP team. In addition to the annual review, the plan must be reviewed with any additions of new ingredients, products, process changes, or equipment changes in the facility. The corporate quality assurance department also conducts a full “deep dive” HACCP review every 3 years to ensure that potential hazards are identified.

Reference

B. Lavender, Philip A. Voysey, K.J. Bridgwater, L. Watson and P. Anslow, Campden and Chorleywood Food Research Association, Station Road, Chipping Campden, Gloucestershire, UK, The Behavior of *Listeria monocytogenes* in Butter, www.foodprotection.org/files/annual.../2008-poster

Case Study A.4: Hamburger Preparation in a Fast Food Restaurant

D.J. Phillips (retired) and A. Kerridge, Burger King

Introduction

This case study was first developed in 1994 (in Mortimore and Wallace, 1994) and has been updated to reflect changes in the industry.

It may appear more difficult to apply HACCP to restaurant operations if one is used to food manufacturing situations where there are usually a number of discrete processing steps. In general terms, there tends to be more direct product handling in a restaurant operation than in a manufacturing situation, fewer “process steps”, and perhaps a greater opportunity for cross-contamination. It is therefore essential that proper precautions are taken to ensure that food is safe when presented to the consumer. Bryan (1981) quoted a survey carried out in the USA, which identified the ten most common contributory reasons for food poisoning associated with all types of restaurant operations as being:

- Improper cooling
- Twelve hours or more between preparation and eating
- Infected people handling food
- Inadequate reheating
- Improper hot holding
- Contaminated ingredients

- Food from unsafe sources
- Improper cleaning of equipment
- Raw/cooked cross-contamination
- Inadequate cooking

A HACCP approach aimed at identifying all potential hazards associated with materials, recipes, processes, and product handling, and establishing Critical Control Points to eliminate or reduce the hazards to an acceptable level, is as relevant in restaurant management as it is in food manufacturing.

Hazard Analysis of Product Formulation

A HACCP Study of the recipe should be used to identify:

1. Any potential hazardous ingredients which would require processing in the restaurant to make them safe.
2. The potential for any of the ingredients to become hazardous during storage in the restaurant or as a result of cross-contamination.
3. All of the time/temperature profiles for both storage, processing, and product holding.

The two most important factors affecting product safety of ingredients before their use in the restaurant are the adequacy of the Supplier Quality Assurance procedures and the distribution and storage conditions. Ingredients must only be purchased according to strict specifications from suppliers that are capable of managing food safety, and who are applying HACCP to their own manufacturing processes. Suppliers must be audited regularly to ensure their compliance with the product specification and their overall quality system. A third-party audit scheme such as those benchmarked by GFSI can be a very useful management tool to supplement first-party audits.

As can be seen from the ingredients table in the example given, the meat and the bun are the only ingredients that are actually further processed in the restaurant and therefore the integrity of the ingredients at delivery plays a major part in ensuring that the finished product is safe for the consumer. A hazard analysis of the individual ingredients and the preventative measures required at the supplier are shown in Table [A.6](#).

Critical Control Points in Product Preparation

An example of the process steps that could occur during hamburger preparation is shown in Table [A.7](#).

As with any HACCP Process it is very important to validate that the process sequence is correct and is actually what is happening in the restaurant, particularly to ensure that no steps have been omitted. Similarly, it is important to see how

Table A.6 Ingredient hazard analysis—hamburger preparation

Ingredients	Hazards	Preventative measures
Beef patties	Contamination with <i>Salmonella</i> , <i>E. coli</i> , <i>S. aureus</i>	GMP: Product and environmental monitoring Finished product specifications for minimizing pathogen levels
	Foreign matter	Bone elimination devices. In-line metal X ray, in-line metal detector
Buns	Pathogen contamination	GMP. Bake temperature >85 °C
	Foreign matter	GMP. Metal detection
Mayonnaise	Salmonella from eggs	GMP. Positive release/certificates of analysis
	Growth of pathogens	pH <4.0
Sliced lettuce/onion	Pathogens	Chlorination (where allowed) Shelf life, Storage/distribution 1–4 °C
	Foreign matter	GMP. Metal detection
Whole tomatoes	Pest infestation/foreign matter	GMP. Metal detection

Table A.7 Process step table—hamburger preparation

Stage	Mayonnaise	Lettuce	Tomato	Bun	Meat	Pickles	Ketchup	Onion
1 Deliver	1–4°C	1–4°C	Ambient	Ambient	–18°C max	Ambient	Ambient	1–4°C
2 Storage	Ambient	1–4°C	Ambient	Ambient	–18°C max	Ambient	Ambient	1–4°C
3 Pre-preparation	Transfer to clean, sanitized pans	Transfer to pans	Wash and slice	None	Transfer to freezer cabinet	Transfer to pans	Transfer to dispenser	Transfer to pans
4 Cooking				Toast	Cook			
5 Hold	4 h max at ambient	4 h max at ambient	4 h max at ambient		Hot hold			4 h max hold
6 Preparation								
7 Assembly/wrap					Hamburger			
8 Hold					Hot hold 10 min max			
9 Service					Customer			

product is moved around the restaurant, how the hygienic practices of the employees is working, and how equipment is cleaned and stored before use.

Each step of the process must then be studied in detail to identify the presence of hazards or factors that could lead to hazards occurring, and identify the points at which control can be applied, together with the Critical Limits, the Monitoring Procedures, and Corrective Actions. A hazard analysis of the process is shown in Table A.7.

The hazard analysis confirms that the critical control points fall into three categories.

1. Prevention of cross-contamination of bacteria or foreign matter either by product-to-product or people-to-product routes.
2. Prevention of microbiological growth through abuse of storage holding times and temperatures.
3. Cooking of raw products such as beef to destroy any pathogenic organisms that may be present. In fact, beef is the only product used for hamburgers in the restaurant that is processed to make it safe and this fact reinforces the importance of an effective Supplier Assurance program for all products to ensure that all potentially hazardous foods and ingredients are properly identified and processed by the supplier to ensure their safety.

Cross-contamination of products with microorganisms from raw unprocessed food or from staff poses one of the major potential hazards in any restaurant and must be prevented by identifying:

- (a) Procedures and practices which may contaminate potentially hazardous foods.
- (b) Environmental conditions that may allow the growth and transfer of microorganisms on food contact surfaces.

Typically, such cross-contamination is prevented by:

- Use of color-coded tongs for handling raw and cooked meat, chicken, and fish.
- Three-sink system for washing, rinsing, and sanitizing all utensils.
- Regular use of sanitizers for wiping all product contact surfaces.
- Stringent application of hand washing and hand sanitizers.
- Wherever possible, avoiding the introduction of potentially hazardous raw foods such as whole eggs, raw chicken, or fish into the restaurant.

Control of storage times and temperatures is essential to avoid the uncontrolled multiplication of any bacteria that may be present. This is achieved through:

- (a) Defining shelf lives and storage conditions of all incoming ingredients, and ensuring that these are adhered to during distribution.
- (b) Operating to strict “First in, First out” (FIFO) principles.
- (c) Defining maximum preparation times and discard times for all products within the restaurant, at all relevant stages of preparation and providing an easy-to-follow system for restaurant staff.
- (d) Providing hot holding units capable of maintaining temperatures above that required for safety (no specific temperature given as the legal limits vary from country to country).

For beef patties, which are produced from 100 % beef that has been minced, formed, and frozen, cooking in the restaurant is the major control point assuring the absence of pathogens in the finished burger. Raw beef may contain *Salmonella* spp., *Staph. aureus*, and *E. coli* O157, all of which will be destroyed by thorough cooking. However, control still has to commence with the patty manufacturer and with the suppliers of the original beef to minimize the presence of pathogens, and monitoring programs, specifications, and auditing of Good Manufacturing Practices at the manufacturer should all be in place. Cooking temperatures are therefore

strictly controlled with all of the meat being cooked to a specified minimum internal temperature. Broilers are calibrated before start-up and cooked burger temperatures are regularly checked throughout the day.

Monitoring

Monitoring of all food safety control points can be carried out through the use of check lists which can be used by the restaurant manager. Monitoring of product quality is also carried out throughout the supply and distribution chain to ensure that product specifications, shelf life, and temperature criteria are being rigidly complied with. All of the operating procedures are detailed in an Operations Manual which specifies all food safety items, operating procedures, and corrective actions.

The information regarding the HACCP study is captured on Table [A.8](#).

Record Keeping

The monitoring of the CCPs must be properly documented and recorded in a suitable format, validated, and signed by the responsible person. Records should be kept for at least 1 year.

Verification

HACCP systems must be verified to ensure that they are working effectively and should aim to establish that:

- (a) Appropriate control points have been established to control all known potential hazards.
- (b) Control measures are working effectively.

Verification is carried out in a number of ways. Firstly, verification of control points associated with supplier and distribution control is carried out by regular audits of all suppliers and distributor records, quality systems, HACCP systems, as well as GMP audits. Secondly, at the restaurant level, a team of independent auditors carry out regular audits of every restaurant, checking that every control point is in place and that all Critical Limits are being adhered to. These audits are very detailed and any critical safety factors are highlighted for immediate attention. Thirdly, any customer complaints are systematically analyzed to ensure that all hazards have been identified and are being controlled.

Managing food safety effectively is crucial for the success of fast-food businesses; the HACCP principles of identifying potential hazards and implementing appropriate control measures provide the most efficient means of maintaining such management.

Table A.8 HACCP control chart—hamburger preparation

CCP	Process step	Hazard	Preventative measure	Critical limits	Monitoring procedure	Corrective action
1	Delivery	Microbiological growth if temperature abused Foreign materials	Temperature control Packaging intact	Meat patties –18 °C Lettuce 1–4 °C Onion 1–4 °C All packs undamaged and secure	Each delivery (Check per Operations Manual procedures) As above	Reject if outside limit. Notify distributor As above
2	Storage	Cross-contamination (a) Foreign material (b) Microbiological growth if temperature abused	Complete covering of product Covering (to prevent contamination) Temperature control restricts growth Stock control	No exposed product As above Meat patties –18 °C Lettuce 1–4 °C Onion 1–4 °C Within dates	Visual As above Daily temperature checks and record Use FIFO Daily stock check	Cover, discard if contamination is evident As above Alert engineer. Discard if outside limit Discard products exceeding shelf life
3	Pre-preparation (i) Mayonnaise (a) Decant into holding pans	Foreign material Chemical/ microbiological Cross-contamination	Complete covering of product Clean and sanitized utensils Clean, sanitized pans, and spatulas	No exposed product Cleaned and sanitized before use As above	Visual Visual Visual	Cover, discard if contamination is evident Do not use. Retraining As above
	(b) Storage (before transfer to preparation table)	Foreign material	Covering of product	No exposed product	Visual	Cover, discard if contamination is evident

(continued)

Table A.8 (continued)

CCP	Process step	Hazard	Preventative measure	Critical limits	Monitoring procedure	Corrective action
(ii) Lettuce/onion/pickles	(a) Fill holding pans	Microbiological growth if contaminated	Temperature control (1–4 °C)	4 °C max	Daily temperature checks and record	Alert engineer. Discard if outside limit
		Foreign material	Complete covering of product	No exposed product	Visual	Cover, discard if contamination is evident
			Clean and sanitized utensils	Cleaned and sanitized before use	Visual	Do not use. Retraining
	(b) Storage	Foreign material	As above	As above	As above	As above
	(iii) Tomatoes					
(b) Coring/slicing	(a) Wash	Cross-contamination	Use of dedicated, clean, and sanitized sink	Cleaned and sanitized before use	Visual	Do not use. Retraining
	(b)	Cross-contamination	Clean, sanitized utensils			
		Foreign material	Equipment clean, sanitized, and in good repair	Cleaned and sanitized before use	Visual	Do not use. Retraining
(iv) Bun Storage		Foreign material	Complete covering of product	No exposed product	Visual	Cover, discard if contamination is evident
			Store 15 cm off floor	Food stored off floor	Visual	Put on trolley. Discard if contamination is evident
(v) Meat patties Storage		Foreign material	Complete covering of product	No exposed product	Visual	Cover, discard if contamination is evident

(vi) Ketchup					
4	Decant into bottles	Foreign material	As above	As above	As above
		Clean and sanitized utensils	Cleaned and sanitized before use	Visual	Do not use. Retraining
	Cross-contamination	Clean and sanitized bottles	As above	As above	As above
4	Meat cooking	Microbiological survival	Correct cooking time/temp	Meat cook-out to required temperature	Checks completed minimum 4 × day; record and sign
		Cross-contamination	Separate handling of raw and cooked product	Keep raw and cooked meats separate	Visual
				Do not handle raw/cooked meats	Discard if seen. Retraining
				Color-coded tongs used to handle cooked meat	As above
	Bun toasting	Cross-contamination	Correct handling	Staff not handling uncooked food	As above
5	Holding	Microbiological growth if temperature abused	Temperature	Salad products maximum 4 h at ambient	Use of discard times
				Bun/meat held at required temperature	Daily temperature checks; record; and sign
			Covering of steamer	Covered	Alert engineer. Reject if outside limit
6					Cover if seen
	Microwaving of bun and meat	Cross-contamination			
		(a) Foreign material	Clean and sanitized	Clean and sanitize before use and ongoing	Visual
6		(b) Microbiological	Clean and sanitize contact surfaces (hand/work)	Clean and sanitize before use and ongoing (e.g., handle/buttons)	Visual
					Do not use. Retraining
(continued)					

Table A.8 (continued)

CCP	Process step	Hazard	Preventative measure	Critical limits	Monitoring procedure	Corrective action
7	Preparation	Cross-contamination Microbiological/ chemical/foreign bodies	(i) Personal hygiene (ii) Clean and sanitized surfaces	Clean and sanitized hands Clean and sanitized before use and ongoing regularly	Visual Visual	Do not use. Retraining. Do not use. Retraining.
8	Assembly/wrap	Cross-contamination Foreign material	Wrap intact	Product undamaged and secure	Visual	Discard if contamination is evident. Retraining
9	Holding	Microbiological growth if temperature abused	Temperature/time heat chute min 73 °C	Max holding time 10 min Serving temperature 66 ± 17 °C	Daily checks; record, and sign Discard times	Discard product. Troubleshoot procedure. Alert engineer
10	Service (if eaten on premises)	Cross-contamination (a) Foreign material (b) Chemical	General restaurant cleanliness Care taken with the use of chemicals	Restaurant clean and tidy Use away from customers	Visual Signed daily checklist Visual	Rectify/retrain As above

Case Study A.5: University Catering Services HACCP Plan

Compiled by Carol Wallace with thanks to UCLan Catering Services, University of Central Lancashire, UK.

Note: Whilst this HACCP plan is based on University Catering Services operations it does not necessarily reflect the current practices or processes at the University of Central Lancashire (UCLan).

HACCP Steering Group

Facilities Manager

Catering Manager

Principal Lecturer, Food Safety Management (HACCP Specialist)

Senior Lecturer, Environmental Health

HACCP Team

Assistant Catering Manager

Chef Manager

Catering Supervisor

Principal Lecturer—Consultant Member

Senior Lecturer—Consultant member

Scope

The manufacture and service of ready-to-eat hot and cold prepared meals and snacks.

Terms of Reference

- The HACCP plan will cover all relevant microbiological, physical, and chemical hazards.
- This HACCP plan covers all processes from raw material intake to service to the customer or delivery to venue (buffets).

Description of Product

Ready-to-eat hot and cold prepared meals are manufactured from fresh, frozen, and dried raw materials. Raw materials contained in the recipes include dairy products, fish and prawns, chicken, turkey, beef, lamb, bacon, and pork.

Allergens are used onsite and are controlled through PRPs. The HACCP plan includes a detailed allergen risk assessment (not reproduced here) but no claims are currently made. Ingredients are sourced through approved suppliers.

All cooked prepared meals are heated to pasteurization temperatures, then either moved straight to hot display/service or are blast chilled and stored chilled for reheated/cold service within 3 days. Buffet items may be served in restaurants or transferred to meeting locations across campus via delivery vehicle.

Intended Consumer Use

- The products are intended for the general population which may include high risk groups, e.g., food for crèche.
- Products may contain allergens so no claims are currently made; however, nuts as an ingredient are no longer used and we are working towards providing allergen information for the menu rotation.
- Products may be consumed at refectories/outlets or taken away for immediate consumption.

Envisaged Consumer Misuse

- Potential temperature abuse of take-away or buffet items.

Prerequisites

This HACCP study operates in conjunction with PRPs designed using guidance of the *Codex General Principles of Food Hygiene* (Codex, 2009).

Hazard Analysis Procedure

A two-step high/low significance assessment procedure was used to identify the significant hazards from the list of potential hazards at each process step. The likelihood of occurrence and severity of effect were considered and, since a significant hazard is defined as one that is both likely to occur and cause an adverse health effect (Mortimore and Wallace, 1998), those hazards considered “high” both for likelihood and severity were deemed significant hazards. All significant hazards were passed through the Codex decision tree (Codex, 2009) to identify CCPs.

HACCP Review

The HACCP plan will be reviewed annually and updates made to the plan as required.

A hazard analysis will be carried out before any new processes or ingredients are implemented. This will include an authorization sign-off procedure.

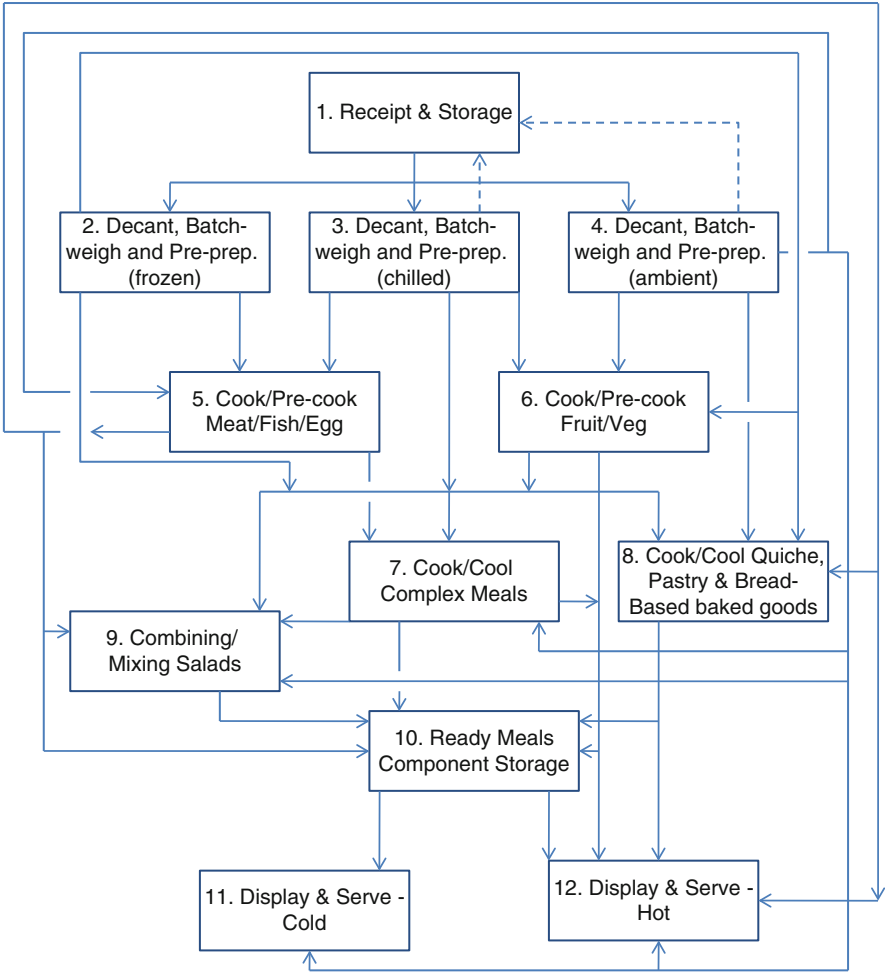
References

Codex Committee on Food Hygiene (2009). *Food Hygiene Basic Texts*. 4th Edition, Rome: Food and Agriculture Organisation of the United Nations, World Health Organisation. <http://www.fao.org/docrep/012/a1552e/a1552e00.htm>

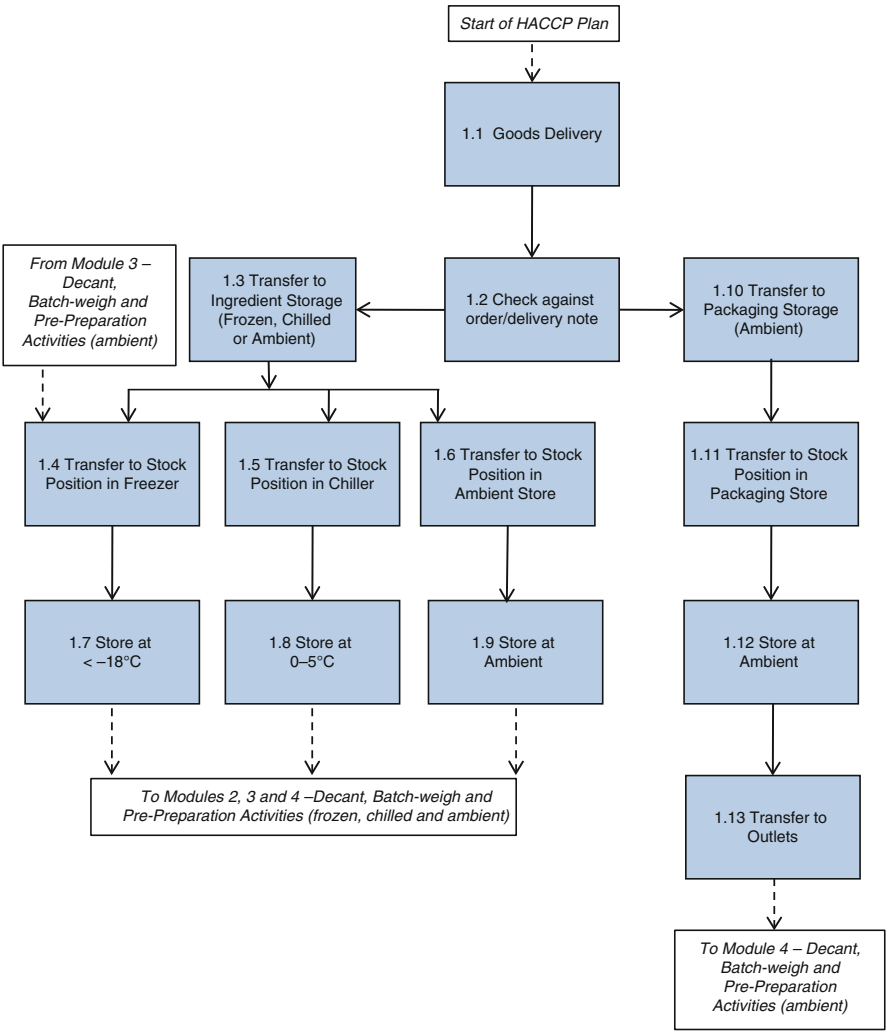
Mortimore, S.E. & Wallace, C.A., 1998, *HACCP—a practical approach* 2nd Ed., Aspen Publishers Inc (now Springer), Gaithersburg, USA

Process Flow Diagrams

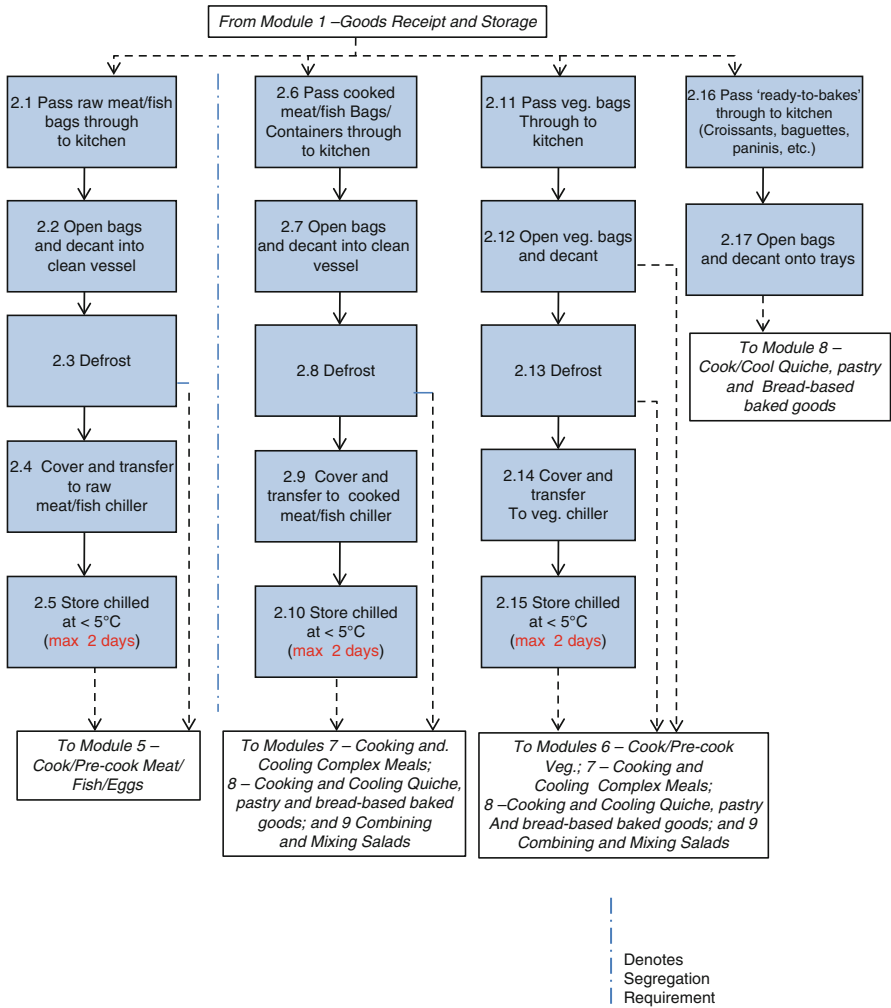
Catering Services Modular Flow Diagram



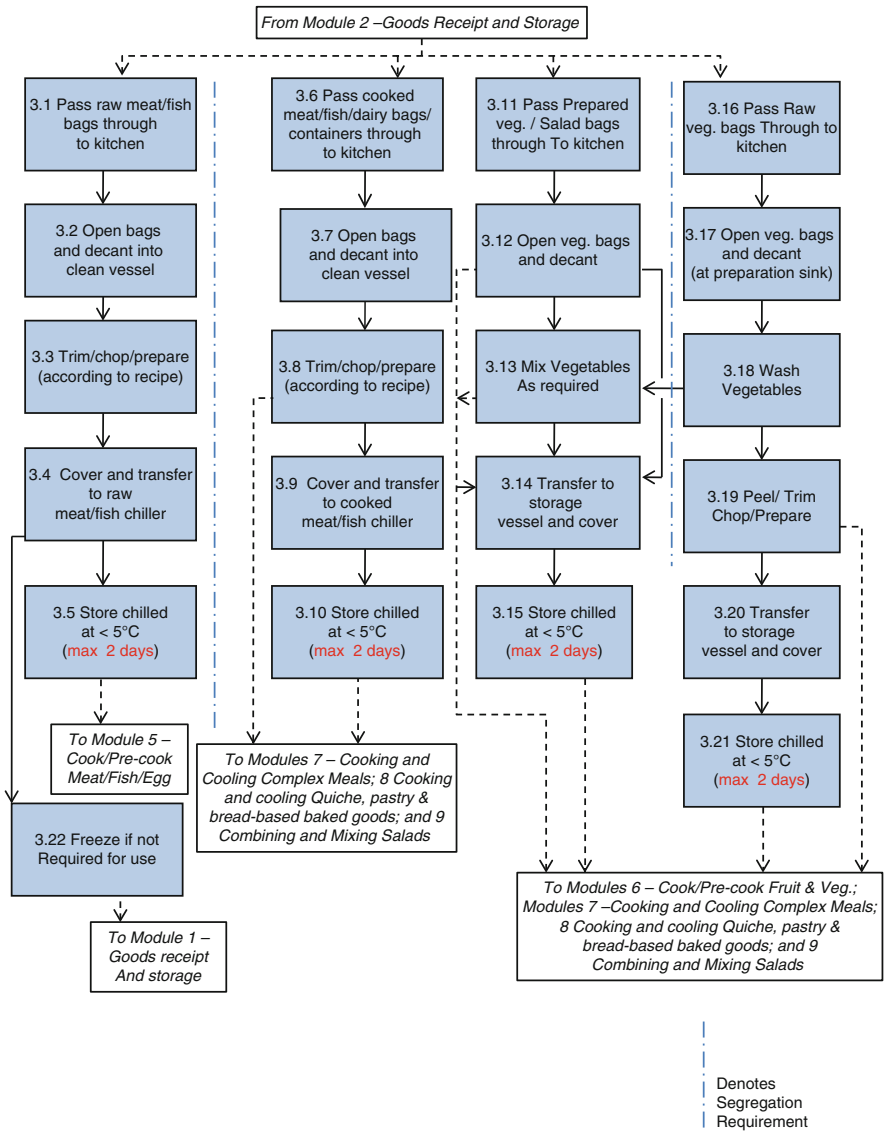
Module 1 Goods Receipt and Storage



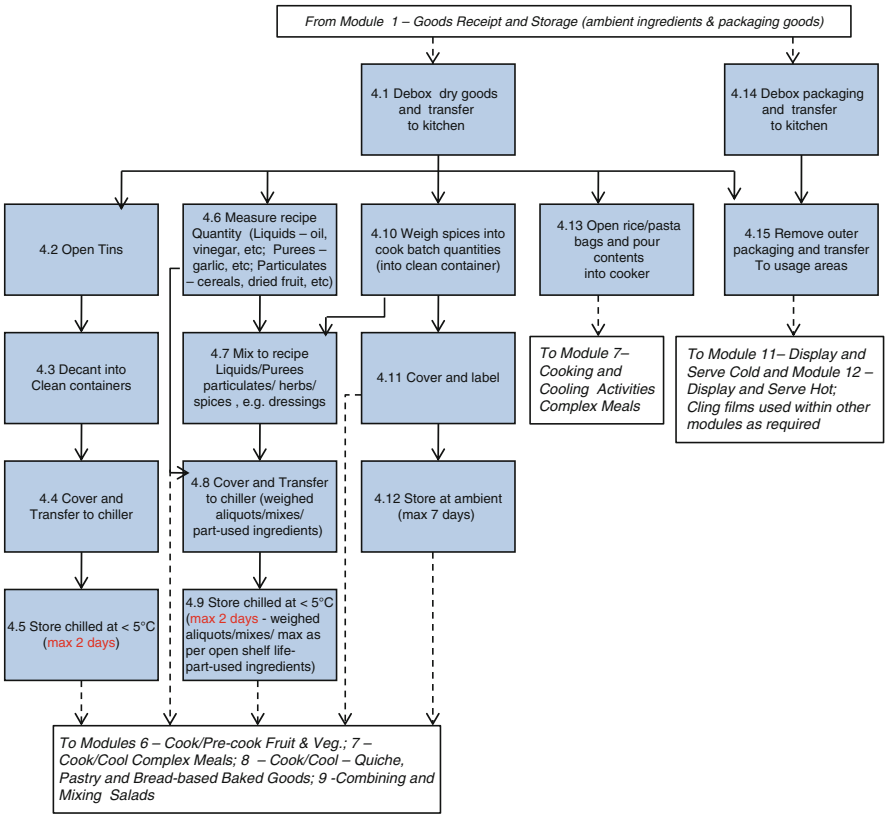
Module 2 Decant, Batch-weigh and Pre-Preparation Activities – Frozen Goods



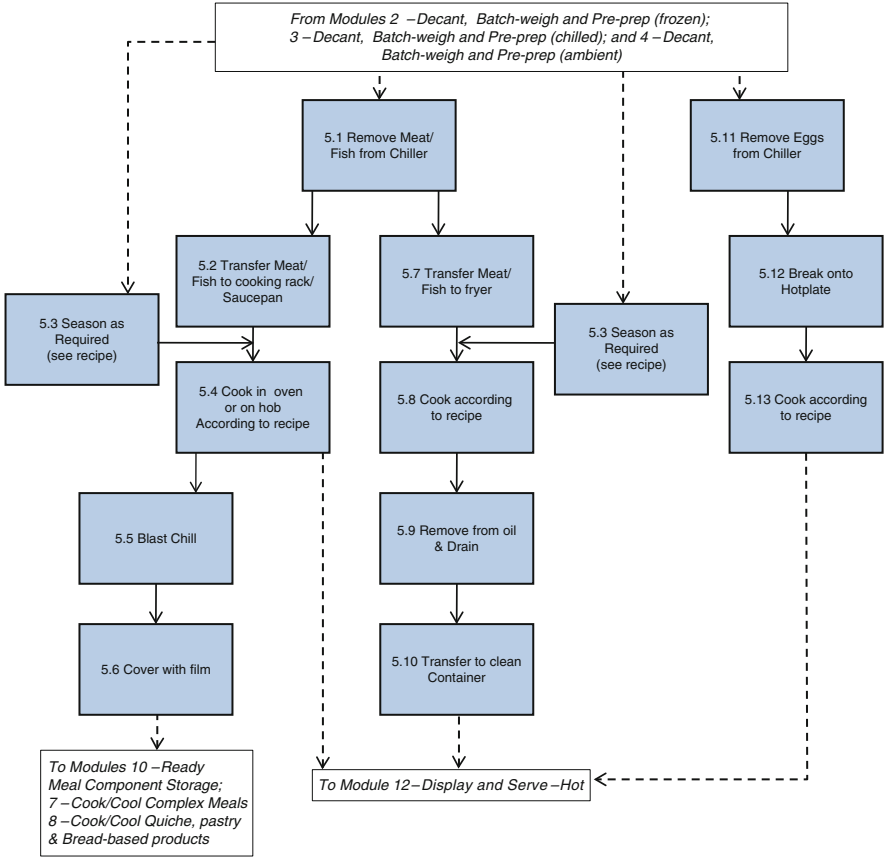
Module 3 Decant, Batch-weigh and Pre-Preparation Activities – Chilled Goods



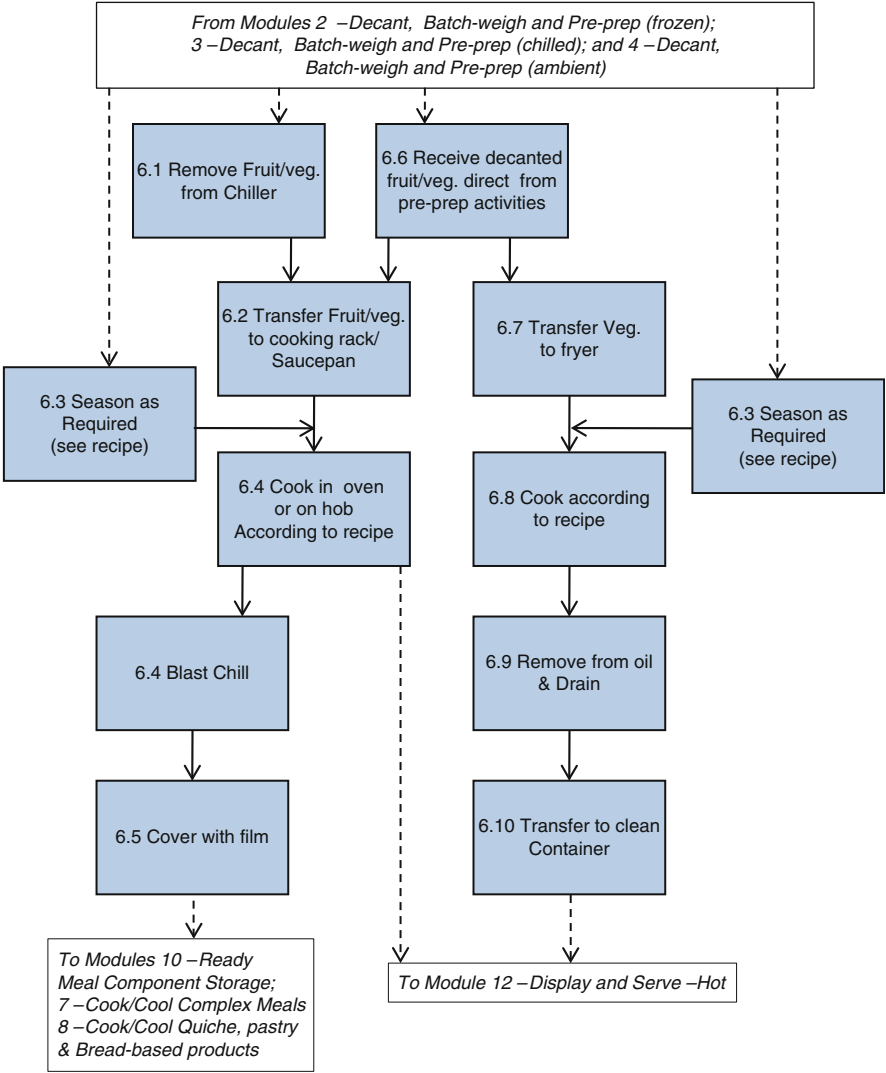
Module 4 Decant, Batch-weigh and Pre-Preparation Activities – Ambient Goods



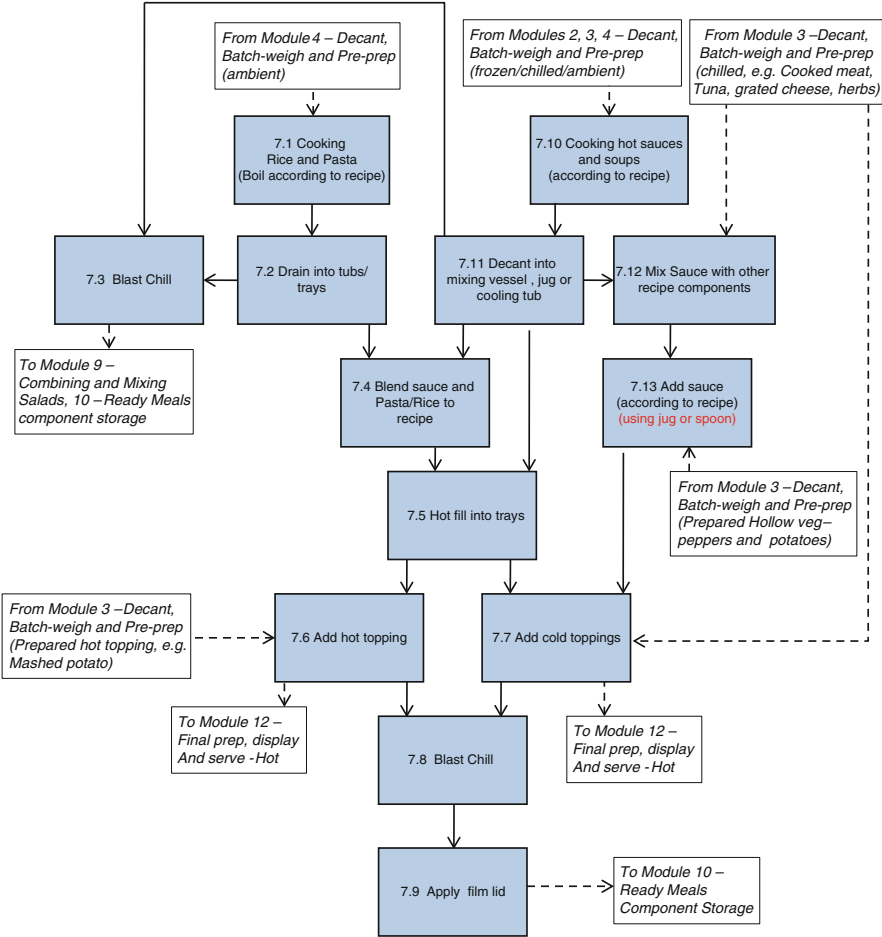
Module 5 Cook/Pre-cook Meat/Fish/Egg



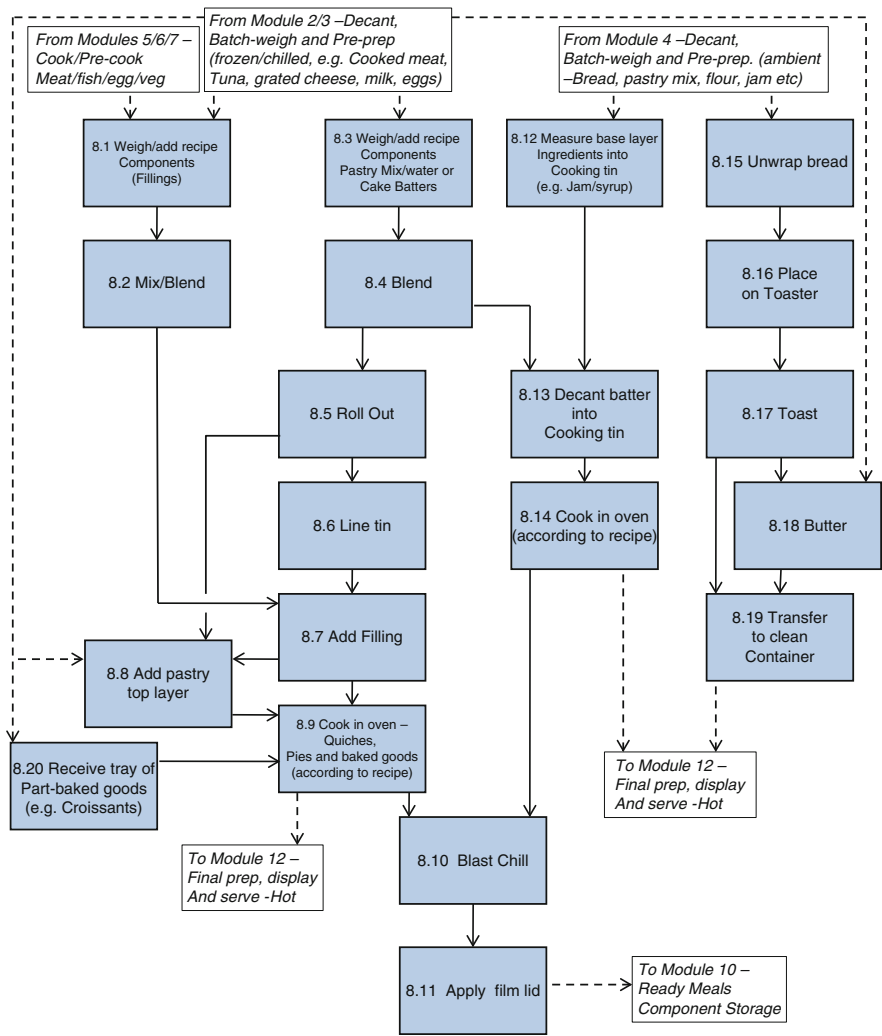
Module 6 Cook/Pre-cook Fruit & Vegetables



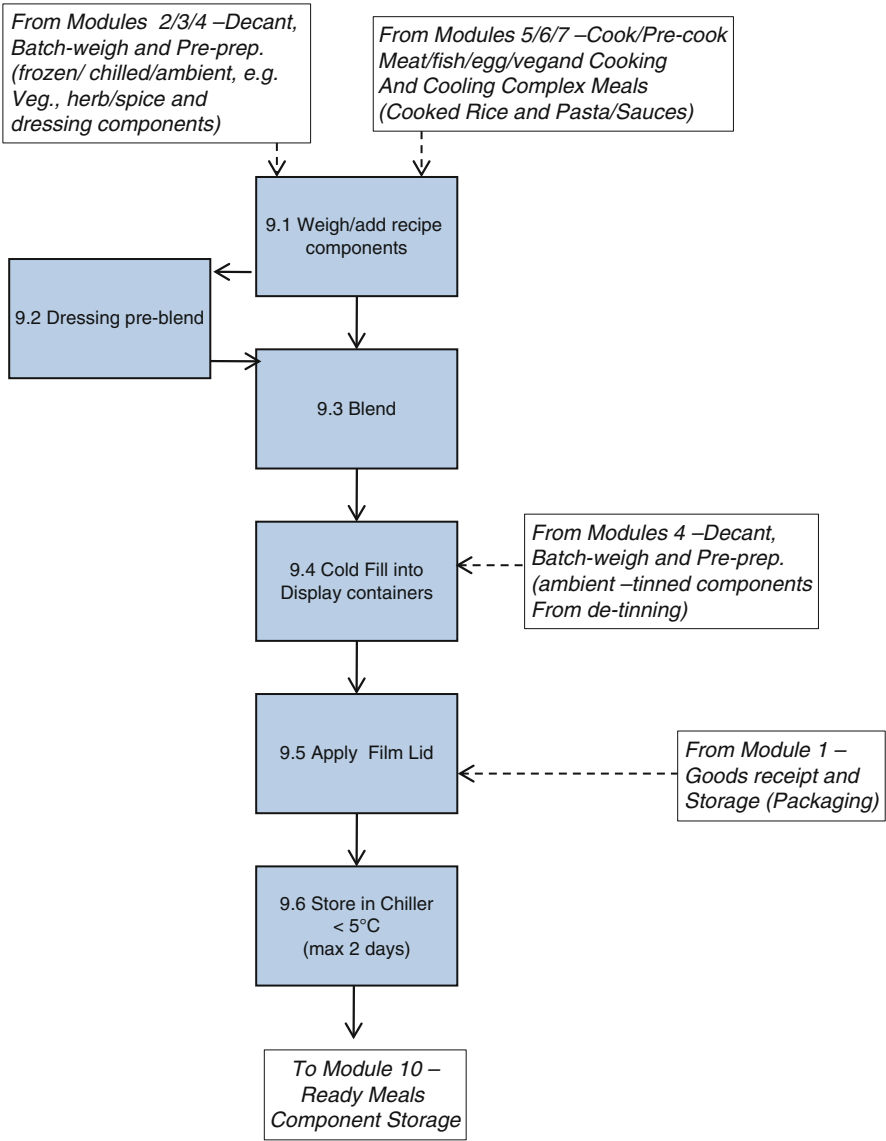
Module 7 Cooking and Cooling Activities Complex Meals– Soups, Sauces, Pasta and Savoury Bakes



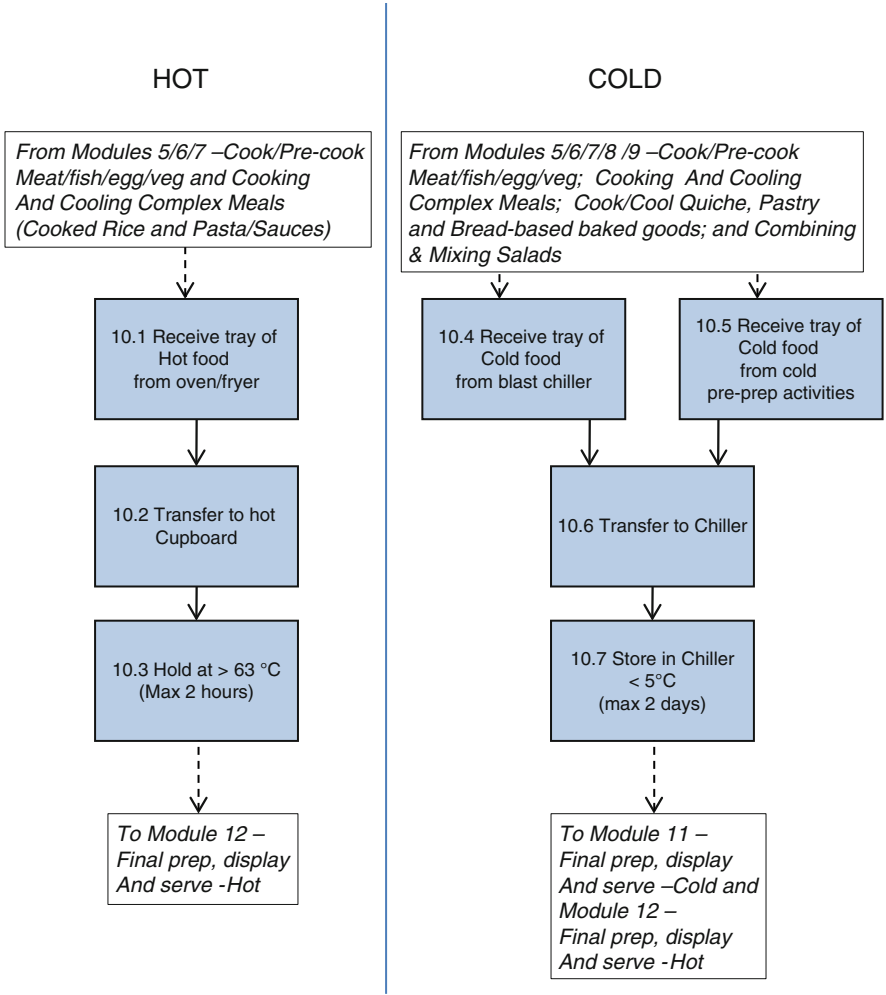
Module 8 Cook/Cool Quiche/Pastry and Bread-based Baked Goods



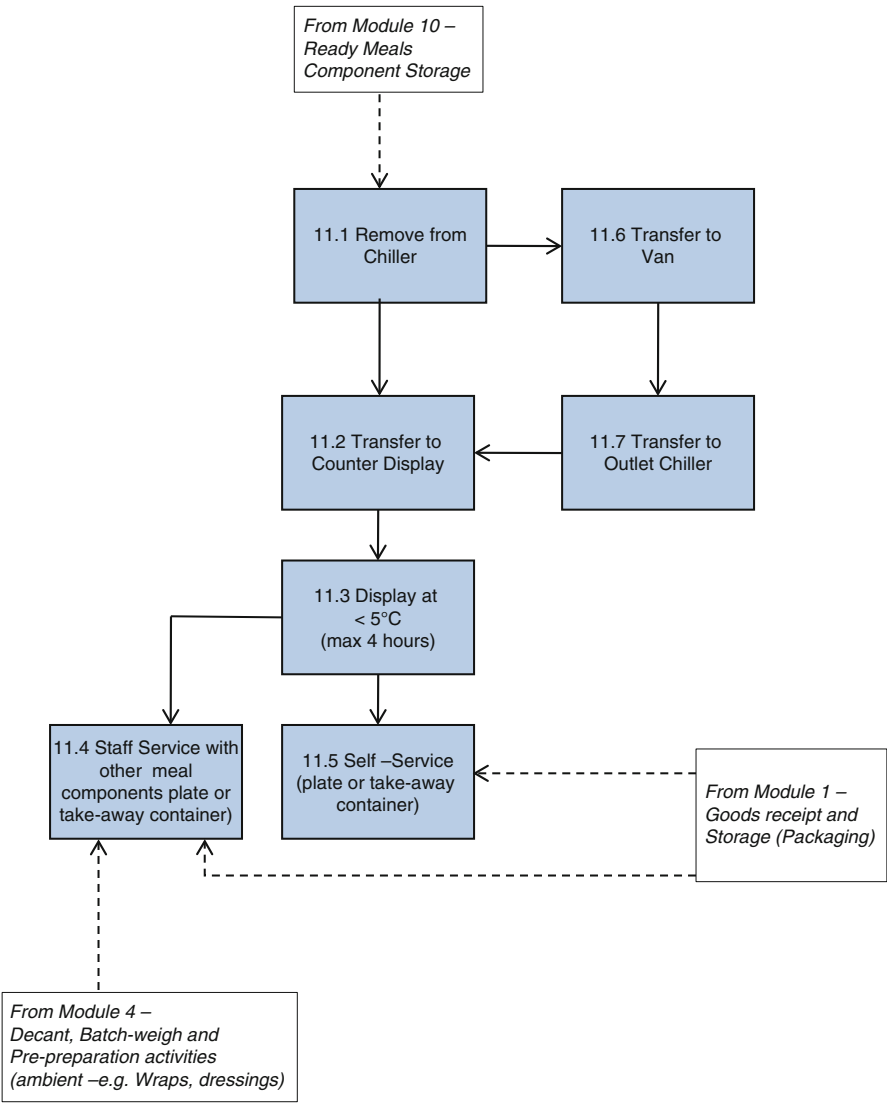
Module 9 Combining and Mixing Salads



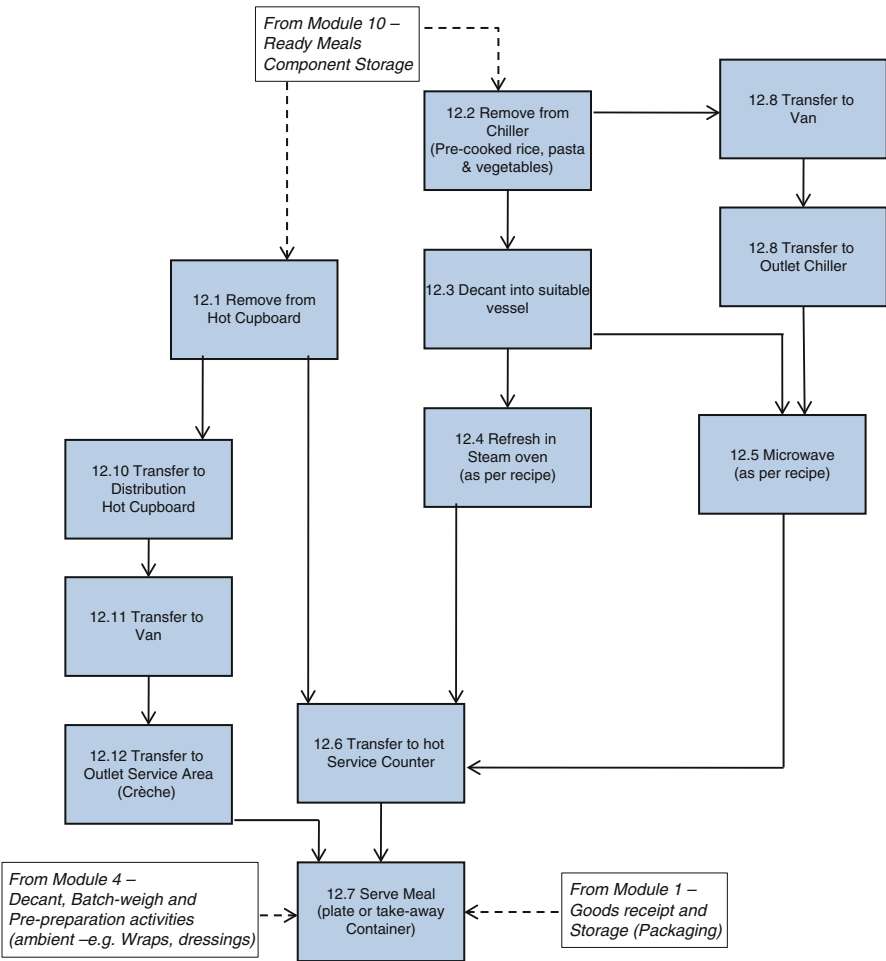
Module 10 Ready Meals Component Storage



Module 11 Display and Serve - Cold



Module 12 Display and Serve - Hot



University Catering Services Hazard Analysis

Process step	Hazard	Hazard analysis			Control measure	Justification
		Likelihood	Severity	Significant Hazard?		
<i>Module 1: Goods receipt and storage</i>						
1.1 Goods delivery	Foreign material from damaged packaging	High	Low	No	Goods intake prerequisite. Rejection of damaged goods	Unlikely to cause harm to the consumer
	Presence of pathogenic microorganisms in raw products	High	High	Yes	Cooking at later step	Separate full ingredient hazard analysis performed to identify specific issues. All raw products likely to contain pathogenic microorganisms to be segregated (prerequisite programs) and cooked/processed before use
	Growth of microorganisms due to temperature abuse of refrigerated goods in transit	Low	Low	No	Rejection of material outside of specified limits <5 °C	Risk of growth deemed to be low
1.2 Check against order/delivery note	Introduction of unknown allergens due to wrong product supplied	Low	High	No	Approved product specifications and goods intake procedures	Allergens managed by prerequisite programs, which rely on knowledge of all allergens in materials supplied as per specifications and allergenic ingredients risk assessment. No allergen claims currently made but recipe rotation contains no nut ingredients
1.3 Transfer to ingredient storage (frozen, chilled, or ambient)	Possible growth of pathogenic microorganisms	Low	Low	No	Rapid transfer. Managed by prerequisite programs	

(continued)

Process step	Hazard	Hazard analysis			Control measure	Justification
		Likelihood	Severity	Significant Hazard?		
1.4 Transfer to stock position in freezer	No hazard identified	n/a	n/a	n/a	n/a	
1.5 Transfer to stock position in chiller	No hazard identified	n/a	n/a	n/a	n/a	
1.6 Transfer to stock position in ambient store	No hazard identified	n/a	n/a	n/a	n/a	
1.7 Store at < −18 °C	No hazard identified	n/a	n/a	n/a	n/a	Temperature control and stock rotation is part of prerequisite programs
1.8 Store at 0–5 °C	Possible growth of pathogenic microorganisms	Low	Low	No	Managed by prerequisite programs	Likelihood is low. Temperature control and stock rotation is part of prerequisite programs
1.9 Store at ambient	No hazard identified	n/a	n/a	n/a	n/a	
1.10 Transfer to packaging storage (Foster stores—ambient)	No hazard identified	n/a	n/a	n/a	n/a	
1.11 Transfer to stock position in packaging store	No hazard identified	n/a	n/a	n/a	n/a	
1.12 Store at ambient	No hazard identified	n/a	n/a	n/a	n/a	
1.13 Transfer to Outlets	No hazard identified	n/a	n/a	n/a	n/a	

(continued)

Process step	Hazard	Hazard analysis			Control measure	Justification
		Likelihood	Severity	Significant Hazard?		
<i>Module 2: Decant, batch-weigh, and pre-preparation activities—frozen goods</i>						
2.1 Pass raw meat/fish bags through to kitchen	No hazard identified	n/a	n/a	n/a	n/a	
2.2 Open bags and decant into clean vessel	No hazard identified	n/a	n/a	n/a	n/a	Cross-contamination less likely due to frozen state
2.3 Defrost	No hazard identified	n/a	n/a	n/a	n/a	
2.4 Cover and transfer to raw meat/fish chiller	No hazard identified	n/a	n/a	n/a	n/a	
2.5 Store chilled at <5 °C (max 2 days)	Possible growth of pathogenic microorganisms	Low	Low	No	Managed by prerequisite programs	Likelihood is low. Temperature control and stock rotation is part of prerequisite programs
2.6 Pass cooked meat/fish bags/containers through to kitchen	No hazard identified	n/a	n/a	n/a	n/a	
2.7 Open bags and decant into clean vessel	No hazard identified	n/a	n/a	n/a	n/a	
2.8 Defrost	No hazard identified	n/a	n/a	n/a	n/a	
2.9 Cover and transfer to cooked meat/fish chiller	No hazard identified	n/a	n/a	n/a	n/a	

(continued)

Process step	Hazard	Hazard analysis			Control measure	Justification
		Likelihood	Severity	Significant Hazard?		
2.10 Store chilled at <5 °C (max 2 days)	Possible growth of pathogenic microorganisms	Low	Low	No	Managed by prerequisite programs	Likelihood is low. Temperature control and stock rotation is part of prerequisite programs
2.11 Pas veg. Bags through to kitchen	No hazard identified	n/a	n/a	n/a	n/a	
2.12 Open veg. Bags and decant	No hazard identified	n/a	n/a	n/a	n/a	
2.13 Defrost	No hazard identified	n/a	n/a	n/a	n/a	
2.14 Cover and transfer to veg. chiller	No hazard identified	n/a	n/a	n/a	n/a	
2.15 Store chilled at <5 °C (max 2 days)	Possible growth of pathogenic microorganisms	Low	Low	No	Managed by prerequisite programs	Likelihood is low. Temperature control and stock rotation is part of prerequisite programs
2.16 Pass “ready-to-bakes” through to kitchen (Croissants, baguettes, paninis, etc.)	No hazard identified	n/a	n/a	n/a	n/a	
2.17 Open bags and decant onto trays	No hazard identified	n/a	n/a	n/a	n/a	
<i>Module 3: Decant, batch-weight, and pre-preparation activities—chilled goods</i>						
3.1 Pass raw meat/fish bags through to kitchen	No hazard identified	n/a	n/a	n/a	n/a	

(continued)

Process step	Hazard	Hazard analysis			Control measure	Justification
		Likelihood	Severity	Significant Hazard?		
3.2 Open bags and decant into clean vessel	Possible cross-contamination with pathogenic microorganisms to other materials	Low	High	No	Controlled transfer. Managed by prerequisite programs	All raw products likely to contain pathogenic microorganisms to be segregated (prerequisite programs) and cooked/processed before use
3.3 Trim/chop/prepare (according to recipe)	Possible cross-contamination with pathogenic microorganisms to other materials	Low	High	No	Controlled transfer. Managed by prerequisite programs	All raw products likely to contain pathogenic microorganisms to be segregated (prerequisite programs) and cooked/processed before use. Knives controlled as part of prerequisite programs
3.4 Cover and transfer to raw meat/fish chiller	No hazard identified	n/a	n/a	n/a	n/a	
3.5 Store chilled at <5 °C (max 2 days)	Possible growth of pathogenic microorganisms	Low	High	No	Managed by prerequisite programs	Likelihood is low. Temperature control and stock rotation is part of prerequisite programs
3.6 Pass cooked meat/fish/dairy bags/containers through to kitchen	No hazard identified	n/a	n/a	n/a	n/a	
3.7 Open bags and decant into clean vessel	No hazard identified	n/a	n/a	n/a	n/a	
3.8 Trim/chop/prepare (according to recipe)	No hazard identified	n/a	n/a	n/a	n/a	Knives controlled as part of prerequisite programs

(continued)

Process step	Hazard	Hazard analysis			Control measure	Justification
		Likelihood	Severity	Significant Hazard?		
3.9 Cover and transfer to cooked meat/fish chiller	No hazard identified	n/a	n/a	n/a	n/a	
3.10 Store chilled at <5 °C (max 2 days)	Possible growth of pathogenic microorganisms	Low	High	No	Managed by prerequisite programs	Likelihood is low. Temperature control and stock rotation is part of prerequisite programs
3.11 Pass prepared veg./salad bags through to kitchen	No hazard identified	n/a	n/a	n/a	n/a	
3.12 Open veg./salad bags and decant	No hazard identified	n/a	n/a	n/a	n/a	
3.13 Mix vegetables/salads as required	No hazard identified	n/a	n/a	n/a	n/a	
3.14 Transfer to storage vessel and cover	No hazard identified	n/a	n/a	n/a	n/a	
3.15 Store chilled at <5 °C (max 2 days)	Possible growth of pathogenic microorganisms	Low	High	No	Managed by prerequisite programs	Likelihood is low. Temperature control and stock rotation is part of prerequisite programs
3.16 Pass raw veg. Bags through to kitchen	No hazard identified	n/a	n/a	n/a	n/a	

(continued)

Process step	Hazard	Hazard analysis			Control measure	Justification
		Likelihood	Severity	Significant Hazard?		
3.17 Open veg. Bags and decant (at preparation sink)	Possible cross-contamination with pathogenic microorganisms to other materials	Low	High	No	Controlled transfer. Managed by prerequisite programs	Segregation of raw veg./salad materials. Types of materials being used mean that likelihood of contamination/cross-contamination is low
3.18 Wash veg.	Possible cross-contamination with pathogenic microorganisms to other materials	Low	High	No	Managed by prerequisite programs	Segregation of raw veg./salad materials. Types of materials being used mean that likelihood of contamination/cross-contamination is low
3.19 Peel/trim/chop/prepare	No hazard identified	n/a	n/a	n/a	n/a	Knives controlled as part of prerequisite programs
3.20 Transfer to storage vessel and cover	No hazard identified	n/a	n/a	n/a	n/a	
3.21 Store chilled at <5 °C (max 2 days)	Possible growth of pathogenic microorganisms	Low	High	No	Managed by prerequisite programs	Likelihood is low. Temperature control and stock rotation is part of prerequisite programs
3.22 Freeze if not required for use	No hazard identified	n/a	n/a	n/a	n/a	Freezing controlled by prerequisite programs—one time freezing only on product with sufficient life after defrost
<i>Module 4: Decant, batch-weigh, and pre-preparation activities—ambient goods</i>						
4.1 Debox dry goods and transfer to kitchen	Contamination with packaging	Low	Low	No	Prerequisite programs and work instructions	Unlikely to harm consumer

(continued)

Process step	Hazard	Hazard analysis			Control measure	Justification
		Likelihood	Severity	Significant Hazard?		
4.2 Open tins	Contamination with packaging—metal swarf	Low	Low	No	Prerequisite programs and work instructions	Unlikely to occur. Any fragments unlikely to be of dimensions that could harm consumer
4.3 Decant into clean containers	No hazard identified	n/a	n/a	n/a	n/a	
4.4 Cover and transfer to chiller	No hazard identified	n/a	n/a	n/a	n/a	
4.5 Store chilled at <5 °C (max 2 days)	Possible growth of pathogenic microorganisms	Low	High	No	Managed by prerequisite programs	Likelihood is low. Temperature control and stock rotation is part of prerequisite programs
4.6 Measure recipe quantity	No hazard identified	n/a	n/a	n/a	n/a	
4.7 Mix to recipe	No hazard identified	n/a	n/a	n/a	n/a	
4.8 Cover and transfer to chiller	No hazard identified	n/a	n/a	n/a	n/a	
4.9 Store chilled at <5 °C (max 2 days)	Possible growth of pathogenic microorganisms	Low	High	No	Managed by prerequisite programs	Likelihood is low. Temperature control and stock rotation is part of prerequisite programs
4.10 Weigh spices into cook batch quantities	No hazard identified	n/a	n/a	n/a	n/a	
4.11 Cover and label	No hazard identified	n/a	n/a	n/a	n/a	
4.12 Store at ambient (max 7 days)	No hazard identified	n/a	n/a	n/a	n/a	

(continued)

Process step	Hazard	Hazard analysis			Control measure	Justification
		Likelihood	Severity	Significant Hazard?		
4.13 Open rice/pasta bags and pour contents into cooking vessel	No hazard identified	n/a	n/a	n/a	n/a	
4.14 Debox packaging and transfer to kitchen	No hazard identified	n/a	n/a	n/a	n/a	
4.15 Remove outer packaging and transfer to usage areas	No hazard identified	n/a	n/a	n/a	n/a	
<i>Module 5: Cook/pre-cook meat/fish/egg</i>						
5.1 Remove meat/fish from chiller	Possible cross-contamination with pathogenic microorganisms to other materials	Low	High	No	Controlled transfer. Managed by prerequisite programs	All raw products likely to contain pathogenic microorganisms to be segregated (prerequisite programs) and cooked/processed before use
5.2 Transfer meat/fish to cooking rack/saucepan	Possible cross-contamination with pathogenic microorganisms to other materials	Low	High	No	Controlled transfer. Managed by prerequisite programs	All raw products likely to contain pathogenic microorganisms to be segregated (prerequisite programs) and cooked/processed before use
5.3 Season as required	No hazard identified	n/a	n/a	n/a	n/a	
5.4 Cook in oven or on hob (according to recipe)	Survival of pathogenic microorganisms due to inadequate heat processing	High	High	Yes	Approved cooking methods—times and temperatures	

(continued)

Process step	Hazard	Hazard analysis			Control measure	Justification
		Likelihood	Severity	Significant Hazard?		
5.5 Blast chill	Germination and outgrowth of spore forming pathogens	High	High	Yes	Approved procedures for handling and cooling. Time and temperature parameters set	Size of vessels being chilled increases likelihood of growth
5.6 Cover with film	No hazard identified	n/a	n/a	n/a	n/a	
5.7 Transfer meat/fish to fryer	Possible cross-contamination with pathogenic microorganisms to other materials	Low	High	No	Controlled transfer. Managed by prerequisite programs	All raw products likely to contain pathogenic microorganisms to be segregated (prerequisite programs) and cooked/processed before use
5.8 Cook according to recipe	Survival of pathogenic microorganisms due to inadequate heat processing	High	High	Yes	Approved cooking methods—times and temperatures	
5.9 Remove from oil and drain	No hazard identified	n/a	n/a	n/a	n/a	
5.10 Transfer to clean container	No hazard identified	n/a	n/a	n/a	n/a	
5.11 Remove eggs from chiller	Possible cross-contamination with pathogenic microorganisms to other materials	Low	High	No	Controlled transfer. Managed by prerequisite programs	All raw products likely to contain pathogenic microorganisms to be segregated (prerequisite programs) and cooked/processed before use. Although UK eggs less likely to be contaminated with <i>Salmonella</i> spp. due to vaccination of flocks, considered that contamination with pathogens may still be possible

(continued)

Process step	Hazard	Hazard analysis			Control measure	Justification
		Likelihood	Severity	Significant Hazard?		
5.12 Break onto hotplate	Possible cross-contamination with pathogenic microorganisms to other materials	Low	High	No	Controlled transfer. Managed by prerequisite programs	All raw products likely to contain pathogenic microorganisms to be segregated (prerequisite programs) and cooked/processed before use
5.13 Cook according to recipe	Survival of pathogenic microorganisms due to inadequate heat processing	High	High	Yes	Approved cooking methods—times and temperatures	
Module 6: Cook/pre-cook fruit and vegetables						
6.1 Remove fruit/veg. From chiller	No hazard identified	n/a	n/a	n/a	n/a	
6.2 Transfer fruit/veg. to cooking rack/saucepan	No hazard identified	n/a	n/a	n/a	n/a	
6.3 Season as required (see recipe)	No hazard identified	n/a	n/a	n/a	n/a	
6.4 Cook in oven or on hob according to recipe	Survival of pathogenic microorganisms due to inadequate heat processing	High	High	Yes	Approved cooking methods—times and temperatures	
6.5 Blast Chill	Germination and outgrowth of spore forming pathogens	High	High	Yes	Approved procedures for handling and cooling. Time and temperature parameters set	Size of vessels being chilled increases likelihood of growth
6.6 Cover with film	No hazard identified	n/a	n/a	n/a	n/a	

(continued)

Process step	Hazard	Hazard analysis			Control measure	Justification
		Likelihood	Severity	Significant Hazard?		
6.7 Transfer veg. to fryer	No hazard identified	n/a	n/a	n/a	n/a	
6.8 Cook according to recipe	Survival of pathogenic microorganisms due to inadequate heat processing	High	High	Yes	Approved cooking methods—times and temperatures	
6.9 Remove from oil and drain	No hazard identified	n/a	n/a	n/a	n/a	
6.10 Transfer to clean container	No hazard identified	n/a	n/a	n/a	n/a	
<i>Module 7: Cooking and cooling activities complex meals—soups, sauces, pasta, and savory bakes</i>						
7.1 Cooking rice and pasta (boil according to recipe)	Survival of pathogenic microorganisms due to inadequate heat processing	High	High	Yes	Approved cooking methods—times and temperatures	
7.2 Drain into tubs/trays	No hazard identified	n/a	n/a	n/a	n/a	
7.3 Blast chill	Germination and outgrowth of spore forming pathogens	High	High	Yes	Approved procedures for handling and cooling. Time and temperature parameters set	Size of vessels being chilled increases likelihood of growth
7.4 Blend sauce and pasta/rice to recipe	Germination and outgrowth of spore forming pathogens	Low	High	No	Immediate through process	Normal process is rapid cook-blend-fill, therefore there is no time to allow temperature drop to danger zone for growth. If any process delay, work procedure is to blast chill

(continued)

Process step	Hazard	Hazard analysis			Control measure	Justification
		Likelihood	Severity	Significant Hazard?		
7.5 Hot fill into trays	Germination and outgrowth of spore forming pathogens	Low	High	No	Immediate through process	Normal process is rapid cook-blend-fill, therefore there is no time to allow temperature drop to danger zone for growth. If any process delay, work procedure is to blast chill
7.6 Add hot topping	Germination and outgrowth of spore forming pathogens	Low	High	No	Immediate through process	Normal process is rapid cook-blend-fill, therefore there is no time to allow temperature drop to danger zone for growth. If any process delay, work procedure is to blast chill
7.7 Add cold toppings	No hazard identified	n/a	n/a	n/a	n/a	
7.8 Blast chill	Germination and outgrowth of spore forming pathogens	High	High	Yes	Approved procedures for handling and cooling. Time and temperature parameters set	Size of vessels being chilled increases likelihood of growth
7.9 Apply film lid	No hazard identified	n/a	n/a	n/a	n/a	
7.10 Cooking hot sauces and soups (according to recipe)	Survival of pathogenic microorganisms due to inadequate heat processing	High	High	Yes	Approved cooking methods—times and temperatures	
7.11 Decant into mixing vessel, jug, or cooling tub	No hazard identified	n/a	n/a	n/a	n/a	
7.12 Mix sauce with other recipe components	Germination and outgrowth of spore forming pathogens	Low	High	No	Immediate through process	Normal process is rapid cook-blend-fill, therefore there is no time to allow temperature drop to danger zone for

(continued)

Process step	Hazard	Hazard analysis			Control measure	Justification
		Likelihood	Severity	Significant Hazard?		
						growth. If any process delay, work procedure is to blast chill
7.13 Add sauce according to recipe	Germination and outgrowth of spore forming pathogens	Low	High	No	Immediate through process	Normal process is rapid cook-blend-fill, therefore there is no time to allow temperature drop to danger zone for growth. If any process delay, work procedure is to blast chill
<i>Module 8: Cook/cool quiche/pastry and bread-based baked goods</i>						
8.1 Weigh/add recipe components (fillings)	No hazard identified	n/a	n/a	n/a	n/a	Potential for cross-contamination covered by prerequisite programs. All fillings fully cooked
8.2 Mix/blend	No hazard identified	n/a	n/a	n/a	n/a	
8.3 Weigh/add recipe components (pastry mix/flour/water/cake batters)	No hazard identified	n/a	n/a	n/a	n/a	Potential for cross-contamination covered by prerequisite programs. All fillings fully cooked
8.4 Blend	No hazard identified	n/a	n/a	n/a	n/a	
8.5 Roll out	No hazard identified	n/a	n/a	n/a	n/a	
8.6 Line tin	No hazard identified	n/a	n/a	n/a	n/a	
8.7 Add filling	No hazard identified	n/a	n/a	n/a	n/a	
8.8 Add pastry top layer	No hazard identified	n/a	n/a	n/a	n/a	
8.9 Cook in oven (according to recipe)	Survival of pathogenic microorganisms due to inadequate heat processing	High	High	Yes	Approved cooking methods—times and temperatures	

(continued)

Process step	Hazard	Hazard analysis			Control measure	Justification
		Likelihood	Severity	Significant Hazard?		
8.10 Blast chill	Germination and outgrowth of spore forming pathogens	High	High	Yes	Approved procedures for handling and cooling. Time and temperature parameters set	Size of vessels being chilled increases likelihood of growth
8.11 Apply film lid	No hazard identified	n/a	n/a	n/a	n/a	
8.12 Measure base layer ingredients into cooking tin	No hazard identified	n/a	n/a	n/a	n/a	
8.13 Decant batter into cooking tin	No hazard identified	n/a	n/a	n/a	n/a	
8.14 Cook in oven (according to recipe)	Survival of pathogenic microorganisms due to inadequate heat processing	High	High	Yes	Approved cooking methods—times and temperatures	
8.15 Unwrap bread	No hazard identified	n/a	n/a	n/a	n/a	
8.16 Place on toaster	No hazard identified	n/a	n/a	n/a	n/a	
8.17 Toast	No hazard identified	n/a	n/a	n/a	n/a	
8.18 Butter	No hazard identified	n/a	n/a	n/a	n/a	
8.19 Transfer to clean containers	No hazard identified	n/a	n/a	n/a	n/a	
8.20 Receive tray of part-baked goods	No hazard identified	n/a	n/a	n/a	n/a	
<i>Module 9: Combining and mixing salads</i>						
9.1 Weigh/add recipe components	Cross-contamination with pathogenic	Low	High	No	Prerequisite programs	High standards of hygiene for production environment and utensils

(continued)

Process step	Hazard	Hazard analysis			Control measure	Justification
		Likelihood	Severity	Significant Hazard?		
	microorganisms—vegetative or spore formers—from environment or utensils					
	Germination and outgrowth of spore forming pathogens	Low	High	No	Immediate through process	As all components are chilled then limited opportunity for temperature rise into danger zone
9.2 Pre-blend dressing	No hazard identified	n/a	n/a	n/a	n/a	
9.3 Blend	No hazard identified	n/a	n/a	n/a	n/a	
	Cross-contamination with pathogenic microorganisms—vegetative or spore formers—from environment or utensils	Low	High	No	Prerequisite programs	High standards of hygiene for production environment and utensils
	Germination and outgrowth of spore forming pathogens	Low	High	No	Immediate through process	As all components are chilled then limited opportunity for temperature rise into danger zone
9.4 Cold fill into display containers	Germination and outgrowth of spore forming pathogens	Low	High	No	Immediate through process	As all components are chilled then limited opportunity for temperature rise into danger zone
9.5 Apply film lid	No hazard identified	n/a	n/a	n/a	n/a	
9.6 Store in chiller at <5 °C (max 2 days)	Possible growth of pathogenic microorganisms	Low	High	No	Managed by prerequisite programs	Likelihood is low. Temperature control and stock rotation is part of prerequisite programs

(continued)

Process step	Hazard	Hazard analysis			Control measure	Justification
		Likelihood	Severity	Significant Hazard?		
<i>Module 10: Ready meals component storage</i>						
10.1 Receive tray of hot food from oven/fryer	No hazard identified	n/a	n/a	n/a	n/a	
10.2 Transfer to hot cupboard	No hazard identified	n/a	n/a	n/a	n/a	
10.3 Hold at >63 °C (max 4 h)	Possible growth of pathogenic microorganisms	Low	High	No	Managed by prerequisite programs	Low likelihood of growth due to temperature buffer above growth zone. Temperature control and stock rotation is part of prerequisite programs
10.4 Receive tray of cold food from blast chiller	No hazard identified	n/a	n/a	n/a	n/a	
10.5 Receive tray of cold food from cold pre-prep activities	No hazard identified	n/a	n/a	n/a	n/a	
10.6 Transfer to chiller	No hazard identified	n/a	n/a	n/a	n/a	
10.7 Store in chiller at <5 °C (max 3 days)	Possible growth of pathogenic microorganisms	Low	High	No	Managed by prerequisite programs	Likelihood is low. Temperature control and stock rotation is part of prerequisite programs
<i>Module 11: Display and serve—cold</i>						
11.1 Remove from chiller	No hazard identified	n/a	n/a	n/a	n/a	
11.2 Transfer to counter display	No hazard identified	n/a	n/a	n/a	n/a	

(continued)

Process step	Hazard	Hazard analysis			Control measure	Justification
		Likelihood	Severity	Significant Hazard?		
11.3 Display at <5 °C (max 4 h)	Possible growth of pathogenic microorganisms	Low	High	No	Managed by prerequisite programs	Likelihood is low. Temperature control and stock rotation is part of prerequisite programs
11.4 Staff service with other meal components (plate or take-away container)	No hazard identified	n/a	n/a	n/a	n/a	
11.5 Self-service (plate or take-away container)	No hazard identified	n/a	n/a	n/a	n/a	Cross-contamination risk is low, managed by prerequisite programs—customer instructions and counter/utensil design
11.6 Transfer to outlet distribution van	No hazard identified	n/a	n/a	n/a	n/a	
11.7 Transfer to outlet chiller	Possible growth of pathogenic microorganisms	Low	High	No	Managed by prerequisite programs	Likelihood is low since refrigerated van used wherever possible. If non-refrigerated van, then delivered to final venue in <1 h. Temperature control and stock rotation is part of prerequisite programs
<i>Module 12: Display and serve—hot</i>						
12.1 Remove from hot cupboard	No hazard identified	n/a	n/a	n/a	n/a	
12.2 Remove from chiller	No hazard identified	n/a	n/a	n/a	n/a	
12.3 Decant into suitable vessel	No hazard identified	n/a	n/a	n/a	n/a	

(continued)

Process step	Hazard	Hazard analysis			Control measure	Justification
		Likelihood	Severity	Significant Hazard?		
12.4 Refresh in steam oven (according to recipe)	No hazard identified	n/a	n/a	n/a	n/a	
2.5 Microwave (according to recipe)	No hazard identified	n/a	n/a	n/a	n/a	
12.6 Transfer to hot service counter	No hazard identified	n/a	n/a	n/a	n/a	
12.7 Serve meal (plate or take-away container)	No hazard identified	n/a	n/a	n/a	n/a	
12.8 Transfer to outlet distribution van	No hazard identified	n/a	n/a	n/a	n/a	
12.9 Transfer to outlet chiller	Possible growth of pathogenic microorganisms	Low	High	No	Managed by prerequisite programs	Likelihood is low since refrigerated van used wherever possible. If non-refrigerated van, then delivered to final venue in <1 h
12.10 Transfer to distribution hot cupboard	No hazard identified	n/a	n/a	n/a	n/a	
12.11 Transfer to outlet distribution van	No hazard identified	n/a	n/a	n/a	n/a	
12.12 Transfer to outlet service area (Crêche)	No hazard identified	n/a	n/a	n/a	n/a	No likelihood of growth due to temperature buffer above growth zone and effectiveness of distribution of hot cupboards. Delivery is to Crêche within <1 h

University Catering Services HACCP Control Chart

Process step	Hazard	Control measure	Critical limits	Monitoring	Monitoring responsibility	Corrective action	Corrective action responsibility	Record
Steps: 5.4, 6.4, 7.1, 7.10, 8.9, 8.14 (Cook in oven or hob); Steps: 5.8, 6.8 (Cook in fryer); Step: 5.13 (Cook on hotplate)	Survival of pathogenic microorganisms due to inadequate heat processing	All cooked components cooked to min time and temperature	All product achieves core temperature 75 °C minimum	Temperature checks with calibrated probes	Chef/ catering assistant	Continue to heat until required temperature (75 °C minimum) is reached	Chef/ catering assistant	Cooking records
Steps: 5.5, 6.5, 7.3, 7.8, 8.10 Blast Chilling	Germination and outgrowth of spore forming pathogens	Effective blast chill process reduces temperature within safe time limit (normally achieves <5 °C within 90 min)	All product to be cooled below 5 °C within 120 min	Center temperature checks with calibrated probes at entry and exit from Chiller Residence time checked and recorded	Chef/ catering assistant	Discard batch. Investigate and repair any fault with blast chiller	Chef/ catering assistant Catering Manager/ Assistant Catering Manager	Production records

Part Two: Outbreak Investigation Case Studies

Note: These case studies are based on real foodborne disease outbreaks and include information provided to the outbreak investigators at the time.

Case Study A.6: When Having a HACCP Plan Is Not Enough—Do Businesses Cause the Foodborne¹ Disease They Deserve?

Professor Chris Griffith, Emeritus Professor at Cardiff Metropolitan University, UK

A case study based upon the South Wales Public Inquiry (Pennington, 2009) into an outbreak of *E. coli* O157 which primarily affected school children will be used to prove that; just having a HACCP plan is not enough to guarantee food safety and that to a large extent a business gets the foodborne disease it deserves.

Background

In September 2005 Wales had its largest outbreak of illness caused by *E. coli* O157. In total 157 cases were identified, 118 were microbiologically confirmed of which 109 were a strain that was unique to the outbreak. Tragically a 5-year-old boy, Mason Jones, died as a result. A public inquiry was held “to enquire into the circumstances that led to the outbreak” and its report was published in March 2009 (Pennington, 2009). The delay between the outbreak and the report publication was due in part to a police investigation undertaken to determine the possibility of prosecuting the owner of the business, J. Tudor and Sons, with criminal charges including manslaughter. Ultimately the owner William Tudor was not charged with manslaughter but was sentenced to 12 months in prison after pleading guilty to seven food hygiene offences. The outbreak was caused by cooked meat that had been contaminated with *E. coli* O157. There was an interesting microbiological chain of connections. The same strain of *E. coli* O157 that was isolated from infected victims was also found in samples of cooked meats recovered from schools, a sample of raw meat removed from the premises of J. Tudor and Sons and from cattle faeces on the farm that supplied him with raw meat. A key focus of the inquiry was the management of food safety within the business including its HACCP plan and its prerequisite programs (PRPs) coupled with the potential/likelihood for cross-contamination to have taken place. Beyond the main brief of this case study, but of interest to note, was that the inquiry looked further into other

¹ Depending upon which definitions are used, there are differences between the terms food poisoning and foodborne disease; however, for the purposes of simplicity and consistency the term foodborne disease will be used throughout.

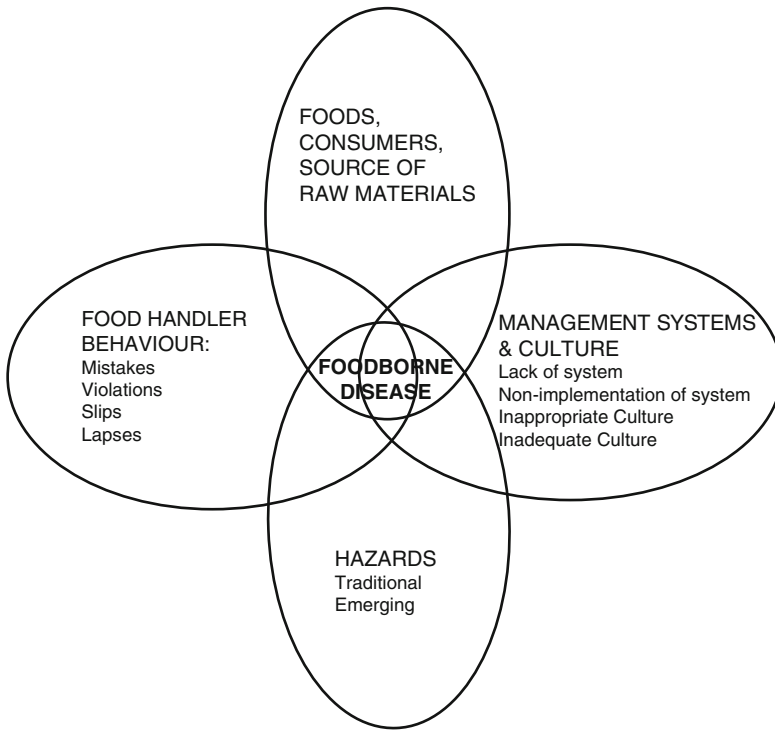


Fig. A.9 Interacting components of food safety

elements of the food chain, including the abattoir that supplied J. Tudor and Sons with raw meat, the regulatory food hygiene inspections carried out by the local authority and the procurement of meat for use in schools by the local authorities.

The Potential for Any Food Business to Cause Foodborne Disease

The absolute guarantee that food will not make a consumer ill (i.e. zero risk) is impossible to give however all involved in the food chain (suppliers, processors, purchasers, and enforcement agencies) must do their utmost to ensure that the risk is minimized.

Whether a business is likely to cause food poisoning will depend upon the interaction of four key factors (see Fig A.9) including the types of food it produces/serves, hazards associated with those foods, the behavior of food handlers working in the business, and how that business manages food safety. It is on the latter that this case study will concentrate.

The business supplied ready-to-eat meats (high risk foods known to be implicated previously in *E. coli* O157 outbreaks involving high risk consumers).

E. coli O157 has been described as an “emerging pathogen” giving rise to the first identified and confirmed outbreak in 1982 in the USA. Since then many outbreaks have been reported worldwide. The organism is of particular concern to food producers: having a relatively low infective dose—with a particularly low dose response in children. Some of whom can go on to develop complications including hemolytic uremic syndrome (HUS) leading to kidney damage and/or death. Foods that can give rise to this type of illness therefore should be handled/processed with particular care.

Food handler behavior is increasingly recognized as an important factor in the causation of foodborne disease. How hygienic food handlers are and the non implementation of known food safety practices has received considerable attention in recent years (see, for example, Clayton et al., 2002; Clayton and Griffith, 2008) and is dependent both on individual and group factors. A key factor recognized by the South Wales Inquiry was the importance of food safety culture and its role in the management of food safety within the business.

In order to manage food safety a business must have appropriate systems in place. This has led over the past 40 years or so worldwide to the increased use of HACCP or HACCP-based systems in conjunction with relevant PRPs. This book is designed to inform the reader, in detail, about such systems. The recognition of the importance of food safety culture is much more recent and the South Wales Inquiry was probably the first to report it as a risk factor in an outbreak, closely followed by the report in Canada into the 2008 Listeriosis outbreak involving Maple Leaf. Food safety culture has been defined as (Griffith et al, 2010a)

the aggregation of the prevailing relatively constant, learned, shared attitudes, values and beliefs contributing to the hygiene behaviours used in a particular food handling environment.

The operational food safety performance (i.e., extent and thoroughness of the hygiene practices used) can be viewed as an interaction of the food safety management systems with the prevailing food safety culture.

Assessing Food Safety Management at J. Tudor and Sons

The normal method for investigating a foodborne disease outbreak or assessing the food safety management within a business would be to inspect or audit the premises. Even under normal circumstances this may not be without problems. In the case of William Tudor (owner of J. Tudor and Sons) his dishonesty was cited as a problem by the inquiry. The evidence of the environmental health officers to the inquiry was that on a number of occasions the HACCP plan was unavailable for scrutiny by the EHO.

Table A.9 Desirable requirements for investigating cross-contamination in a business compared to the possible opportunities at J. Tudor and Sons

Desirable	Possible opportunities at J. Tudor and Sons
On-site investigation	Premises shut
Meet managers	Not possible, under police investigation
Produce flow diagram	Possible to construct
Interview workers	Not possible
Observe operations	Not possible
Take readings, e.g., ATP, microbial counts	Not possible

Table A.10 Audit approach used to assess the potential for, and management of, cross-contamination

Hygiene practice assessed relating to	Evidence examined with report section numbers		
	Witness and other statements	Video and pictorial evidence	Management documentation
3.1 Design, organization, construction, and maintenance of premises	3.1.1	3.1.2	3.1.3
3.2 Personal hygiene	3.2.1	3.2.2	3.2.3
3.3 Cleaning	3.3.1	3.3.2	3.3.3
3.4 Documented management system	3.4.1	3.4.2	3.4.3
3.5 Food safety organizational culture	3.5.1	3.5.2	3.5.3
3.6 Training	3.6.1	3.6.2	3.6.3
3.7 Handling / preparation practices	3.7.1	3.7.2	3.7.3

For the purpose of the initial police investigation and later the deliberation of the inquiry a report was specifically required assessing the potential for cross-contamination at the premises (Griffith, 2005). This type of assessment maybe required by auditors and inspectors but they would normally have access to the premises, documents, and to the people working in the plant. To undertake the assessment retrospectively, as required in the J. Tudor and Sons outbreak, posed additional major problems. Table A.9 indicates some of the normal requirements for an assessment of cross-contamination and what was/was not possible at J. Tudor and Sons.

Many of the classic requirements for an assessment of cross-contamination were not possible. An audit-based approach was therefore developed using the materials that were available. These included the documented systems of the business, a video made by the police of the premises, and witness statements from staff working in the plant (Table A.10).

Factors leading/contributing to cross-contamination were identified, e.g., personal hygiene, work flow, cleaning, and using an approach based on content

analysis² the evidence available was examined. This formed the basis of an audit “look at” and “look for” approach (see Table A.10). The section numbers in the table refer to those of the report.

Food Safety Management (Including HACCP, PRPs, and Culture) at J. Tudor and Sons

J. Tudor and Sons had a HACCP plan. At the time of the outbreak it was a legal requirement for them to do so as part of the Butcher’s Licensing Initiative and the owner William Tudor had been on a HACCP training course and held an advanced food hygiene qualification.

The business’ HACCP plan was dated January 2005. The two independent experts who examined the HACCP plan considered it entirely inadequate and inappropriate. Table A.11 identifies some of the faults identified with the business’ food safety documentation including the HACCP plan and associated records. One of the main conclusions of the report was that the plan was fundamentally flawed and that these flaws should have been detected during routine environmental health inspections.

Another important element of HACCP—other than the documentation itself is that food handlers are aware of it, understand what its purpose is and their roles in it, to ensure safe food. The inquiry was presented with clear evidence that none of these were a reality.

HACCP does not work in a vacuum and needs to be supported by appropriate, well managed PRPs. There was evidence (see Table A.11) that this was not the case. Many of PRPs designed to mitigate the risk of foodborne disease and in particular cross-contamination were either absent or badly documented and implemented.

Food safety management systems should outline in precise detail what needs to be done to ensure that safe food is produced. As such it provides food handlers with the information for them to act hygienically. Food safety culture reflects the collective attitudes and beliefs giving rise to the specific practices used by food handlers. A detailed analysis of food safety culture is beyond the scope of this case study and readers are directed to recent publications on the subject (Griffith, 2010; Griffith et al., 2010a, b). Every business has a food safety culture and strongly positive food safety cultures have to be “earned” by time, effort, appropriate resources, and crucially leadership. This depends upon the person in charge and their food safety goals and standards. In the case of J. Tudor and Sons the staff were told by the owner to reprocess meat that had been returned as unfit. The overall evidence presented to the inquiry suggested that the food safety culture at J. Tudor and Sons was completely inappropriate for a business serving high risk food to vulnerable customers. The inquiry report summarized the culture “as one of little

² Content Analysis: A set of procedures or a process for collecting and organizing non-structured information into a standardized format that allows references to be made about the characteristics and meaning of written, spoken, or other recorded materials.

Table A.11 Some problems noted with J Tudor and Sons food safety management system

HACCP plan
<ul style="list-style-type: none"> • Lacked details of relevant foods, e.g., processing vacuum packed meats not included • Lacked proper product description. Shelf life and other details missing • Inadequate hazard analysis • Process flow chart lacked details • Flaws with section on chilling and storage of product—unrealistic cooling times given equipment available • Lacked monitoring details • Often no proper critical limits—under critical limit column the reader was referred back to the flow chart • Inadequate corrective actions • No validation, verification, or review details
HACCP Records
<ul style="list-style-type: none"> • Doubts over the authenticity of the records—batch completion, e.g., for cooking for one whole year always started at exactly the same time • Written statement that auditing was performed yet there was no audit records, checklists, or staff trained in auditing • Examples of critical limits exceeded with no corrective action taken
PRP Documentation
<ul style="list-style-type: none"> • Missing policies, e.g., personal hygiene, hand hygiene, employee medical questionnaire. No glass policy, job descriptions, stock control policy/methods • Cleaning schedule—incomplete, lacking in detail, incorrect information—some items required daily cleaning all week but cleaner only worked 2 days a week. No defined and separate storage area for cleaning materials
Training
<ul style="list-style-type: none"> • Staff not trained in hygiene and cleaning. No training policy/records
Cross-contamination
<ul style="list-style-type: none"> • No strategy for the prevention of cross-contamination
Design, construction, and maintenance of premises
<ul style="list-style-type: none"> • Poor in all aspects
Work flow
<ul style="list-style-type: none"> • Poor, a lot of evidence to show mixing of raw and cooked product and surfaces common to both

regard for the importance of food safety but where making and saving money was the priority.” This type of negative food safety culture is not unique nor is it necessarily restricted to small businesses. There are numerous examples in large businesses where deliberately/knowingly selling pathogen contaminated product or altering the expired date codes of foods has occurred. The evolution of a negative food safety culture starts etc food safety culture starts with the subject being ignored and ends with deliberate breaching of food safety requirements. One of the problems in difficult economic times is that spending on food safety is cut and this maybe the start of an erosion or shift in food safety culture. Although, at the time of the J. Tudor and Sons outbreak the economy was flourishing.

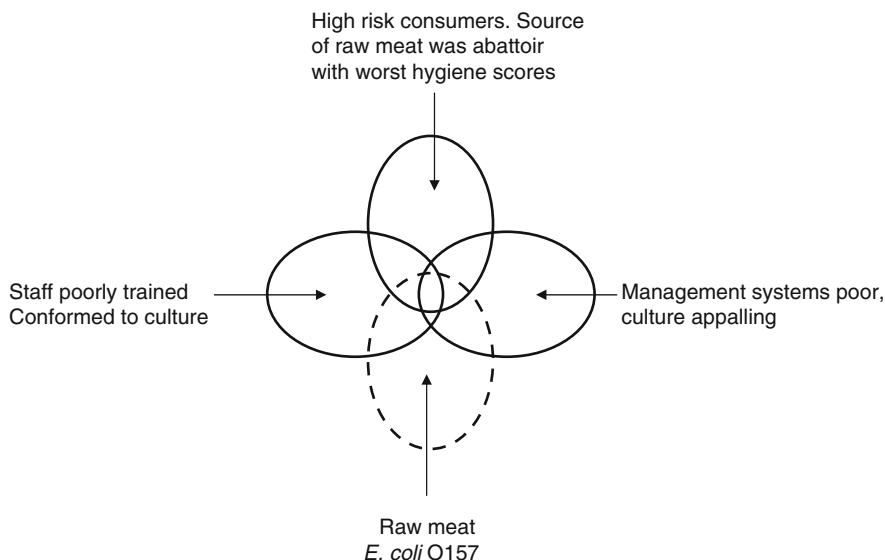


Fig. A.10 Factors influencing safety: case study J. Tudor

It has been said that every management system is perfectly designed to achieve the results it gets. In the case of J. Tudor and Sons with its poor HACCP and PRP systems coupled with a negative food safety culture this was certainly true and as a consequence the systems delivered unsafe products. The factors influencing Safety at J. Tudor are summarized in Fig. A.10.

Lessons Learned from the Outbreak

Various lessons for both producers and people involved in auditing/inspecting food safety systems can be learned. These include:

- Cross-contamination is an increasingly important risk factor and has been implicated in as many as 38 % of foodborne disease outbreaks (Griffith and Redmond, 2009). However, given the way outbreaks are investigated even this is likely to be an underestimate. People are likely to remember if food was undercooked but not to know or remember if, for example, a knife used to cut raw food was subsequently used to cut ready-to-eat food without proper cleaning and disinfection. It is also likely to be more of a problem with organisms that can have a low infectious dose, including not only *E. coli* O157 but also *Campylobacter* (estimated to be the most important cause of bacterial foodborne disease and norovirus possibly the single largest cause of food-related stomach upsets).
- The consequences of foodborne disease can be very severe and include the victim's death. This has been known for many years but what is new are the increased possibilities for criminal prosecutions including manslaughter. Although this charge was not brought in the J. Tudor and Sons outbreak it

illustrates that the police are prepared to use this in cases of foodborne disease. UK laws on corporate manslaughter have changed recently and since the Tudor outbreak, making prosecutions easier and at least one foodborne disease manslaughter charge is currently being considered in the UK. Successful manslaughter prosecutions have also been brought elsewhere in the world.

- There is a need for HACCP and food safety culture training for producers, inspectors, and auditors of food safety management systems.
- Having a HACCP plan in itself does NOT guarantee safe food. It needs to be validated, appropriate, accurate, ideally externally verified and embedded into the food safety culture of the business.
- Food safety culture is likely to be increasingly reported as a factor in foodborne disease outbreaks. The subject is still in the infancy and more research is needed.
- Food safety leadership is crucial and producers must develop a positive food safety culture within their business and show commitment and strong food safety leadership. This to an extent depends on having the correct food safety goals and standards and these must not be compromised by economic considerations. Every business needs to be profitable but the literature is littered with business examples of a poor food safety culture being more expensive and costing more money than the cost of trying to achieve it.
- Those who inspect, audit, or verify food safety management systems have a fundamental responsibility in food safety and they must try to objectively assess what is happening when they are not present, i.e., assess objectively the food safety culture.
- Businesses, based on their systems and culture, in relation to the foods they sell and to whom, will to an extent get the level of foodborne disease they deserve.

This case study has been used in teaching food safety giving rise to one problem. Trainees hearing the case study think it is useful but have sometimes then dismissed it believing the business was so badly run with so many faults it was not relevant to them. In the author's experience exactly the same problems have been encountered in some businesses across five continents and some have shown an equal level of disregard for consumer safety.

Businesses with poor food safety systems and practices may “get away” with it for a time but longer term they are likely to be found out—possibly resulting in someone's death. One of the most difficult things for an expert witness to do in court is to give evidence whilst the parent's of a dead child are crying during the testimony.

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Case Study A.7: HACCP in Manufacturing—Learning from Major Incidents: Cadbury Salmonella Outbreak Investigation

Transcribed and expanded by Carol Wallace from a presentation contributed by Nick Lowe, Food Safety Team Leader, Birmingham City Council, UK (originally delivered at *Food Manufacture* Product Recall Conference, Warwick, UK, 2008).

Incident Context

This was a large incident of *Salmonella* Montevideo infection, affecting both adults and children and including several severe cases although no deaths were reported. The incident occurred in a multinational food company, Cadbury Schweppes, with multiple sites in the UK making chocolate, chocolate products, and other confectionery items for supply to retail and other manufacturers. Global brands were involved.

The incident was due to contamination of a chocolate precursor known as “crumb,” which was manufactured at one site (Marlbrook) for supply to other Cadbury sites and third-party sales.

The incident was investigated by Birmingham City Council Environmental Health team led by Nick Lowe, following notification that *S. Montevideo* had been found in Cadbury products.

The Outbreak Epidemiology and Outbreak Control Team

Following a national increase in *Salmonella* Montevideo infections in England and Wales between March and July 2006, an outbreak investigation was set up. The data collected during these investigations were presented to the *S. Montevideo*

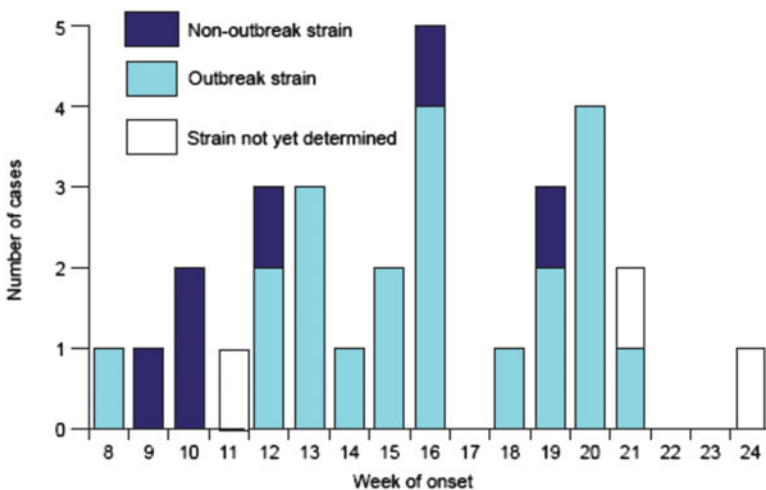


Fig. A.11 Epidemic curve by week of onset (Source: HPA, 2006a)

Table A.12 Outbreak control team evidence

Evidence considered by the outbreak control team (HPA, 2006b)
• Clinical isolates of <i>S. Montevideo</i> confirmed by Cfi in the period preceding the start of the outbreak were distributed across a range of PFGE profiles
• The excess in cases generated by the outbreak were attributable to a single PFGE profile designated as <i>SmvdX07</i>
• The <i>S. Montevideo</i> strains isolated from samples taken from the factories of Cadbury were also confirmed as PFGE profile <i>SmvdX07</i>
• The dates of positive tests for products made by Cadbury (January and February 2006)
• The dates of onset of illness for the cases (February to June)
• The geographical distribution of cases suggests that the outbreak was caused by a nationally distributed food
• The food histories taken from cases
• 87 % (13 of 15) of cases definitely reported consumption of products made by Cadbury in the days preceding the onset of symptoms
• No other common brands, retail outlets, catering chains, or single food types were identified as common factors
• The decrease in the frequency of cases of <i>S. Montevideo</i> PFGE <i>SmvdX07</i> following the voluntary recall of a number of chocolate products, produced by Cadbury. These were considered as potentially contaminated with <i>S. Montevideo</i> PFGE <i>SmvdX07</i> after a risk assessment of the results of microbiological sampling and environmental investigations at a number of factory premises

National Outbreak Control Team (OCT). The team included representatives from the Health Protection Agency (HPA), the Food Standards Agency (FSA), the Department for Food, Agriculture and Rural Affairs (DEFRA), and selected local authorities, including Birmingham City Council.

The onset profile for the epidemic showing details of 30 cases where onset dates were available is portrayed in Fig. A.11.

The Outbreak Control Team considered a range of evidence (Table A.12).

After carefully considering all the available evidence the OCT concluded that consumption of products made by Cadbury Schweppes was the most credible explanation for the outbreak of *S. Montevideo*.

Investigating the Incident at Cadbury's

Following initial notification of the national increase in *S. Montevideo* infection, Birmingham City Council Environmental Health team was notified of a product withdrawal since the organism had been found in Cadbury products. There was some suggestion at the time that Cadbury personnel were aware of the contamination but had still distributed the product.

Initial questions and concerns raised by the investigation team included:

- How could this happen?

- What was the company explanation for release of product?
- Why had there been no notification and liaison with local environmental health officers? This was a concern
- Were there any ongoing contamination problems in current production?
- Had all the affected products been identified or could others be involved?

Preliminary investigation of the process revealed that crumb was transported to the Bournville factory in bulk road tankers from Marlbrook (having been sampled before departure) and was emptied into one silo. From this silo it was manufactured into product within 24 h and thus the affected Crumb and chocolate would quickly be distributed throughout the factory. Although the crumb was tested for *Salmonella* spp., there was no positive release procedure for crumb and so, by the time the positive result was identified, the product had already been made into chocolate products.

The origin of the problem was found to be *S. Montevideo* contamination of the Crumb at the Marlbrook factory, which was eventually attributed to a leaking drainpipe. *S. Montevideo* was found in the drain and in drain water, and a seal breach in the crumb system was also thought to have contributed.

It was revealed that *S. Montevideo* had been identified in liquid chocolate and that this had led to an increase in end product sampling. Sampling was raised from two per line per shift to four per line per shift—a 100 % increase. However, to put this in context, the increase meant moving from 52 samples to just 104 over 300 tones of chocolate produced or 60,000,000 50 g bars. In addition to the end product testing, samples of liquid chocolate and chocolate crumb were taken plus environmental swabs—300 samples overall. A traceability study was also conducted to identify all the products made from the salmonella positive liquid chocolate.

Findings indicated that fundamental errors had been made by the company regarding the risk of levels of *S. Montevideo* in the end product. Referring to a report provided by the UK Biscuit, Cake, Chocolate & Confectionery Alliance (BCCCA) on microbiological risk analysis (Pusey report, 2003), the company had aimed to establish the levels of salmonella in product using the Most Probable Number (MPN) Method³ of microbiological testing and to compare this to levels that had caused infection in previous confectionery incidents. The incorrect assumption was that if the level of salmonella was lower than that of previous confectionery incidents then products should be safe for consumption. However, during the outbreak investigation, the UK Health Protection Agency reconfirmed the expert view that ready-to-eat food should be free from salmonella (Table A.13).

When questioned about the use of this method and sampling protocol, the company informed investigators that the MPN method had originated from Campden &

³ MPN works by taking the original positive sample and diluting by a factor of 10 then testing for the presence of bacteria. Dilutions are repeated until the bacteria not found and the data are fed into a statistical equation to obtain the most probable number in the sample. In the Cadbury version of this test, for a positive sample a further 50 samples were taken and the number of positives was used to determine MPN. In reality this gave an average figure rather than the MPN.

Table A.13 HPA view on FSA food alert announcing the recall of a number of confectionery products (*Source*: HPA, 2006)

The UK Food Standards Agency issued a Food Alert on 23 June 2006 (Food Standards Agency, 2006) announcing the recall of a number of confectionery products due to potential contamination with *Salmonella* Montevideo. The Health Protection Agency is of the view that processed ready-to-eat foods should be free from salmonella species and their presence, even in small numbers, results in such foods being of unacceptable or potentially hazardous quality (HPA, 2000). Published guidelines also recommend the absence of salmonella species in confectionery products such as chocolate (ICMSF, 1986; IFST, 1999)

References referred to in HPA view:

- Food Standards Agency. Cadbury Schweppes Plc recalls a range of its own brand chocolate products due to possible contamination with salmonella. Food Alert for Action (Ref 36/2006). FSA, 23 June 2006: London. Available at: <<http://www.food.gov.uk/enforcement/alerts/2006/jun/cadburychoc>>
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Chorleywood Food and Drink Research Association, who “had been consulted and had given their scientific endorsement.” Use of this method ignored previous guidance from the Public Health Laboratory Service (PHLS) and the International Commission for Microbiological Specifications for Foods (ICMSF), as noted in Table A.12, and also went against Cadbury internal requirements, such as:

- Ingredient specifications, which required ingredients to be negative for *Salmonella* spp.
- Internal microbiological documents, which referred to zero *Salmonella* spp.
- Positive release procedures for crumb and liquid chocolate going to third-party sales, which tested for the presence of *Salmonella* spp.

During this phase of the investigation, in addition to the issues around lack of authority notification, key questions for the investigators included the validity of the MPN method, the interpretation of the Pusey report regarding the level of risk from salmonella, and the role of Campden and Chorleywood Food Research Association in the decisions taken. A further nagging question was “what had prompted the introduction of the MPN policy?” since this was such an unusual testing approach. Findings related to this latter question revealed that there had been three further *Salmonella* spp. incidences between April 2002 and January 2003 where all products had been disposed of and this had been described in an internal report. The project names that had been given by the company to the later contamination incidents—Project Ivan at Bourmville and Project Jade at Somerdale—led to a question about whether there had been other projects with names starting with A–H. In fact, it was found that there had been eight further contamination incidents where the MPN method had been used and the product had been released (Table A.14).

Table A.14 Previous contamination incidents where MPN method was used

January 2005	Project <i>Alex</i>	<i>S. Montevideo</i> CDM 49g
March 2005	Project Becks	<i>S. Carmel</i> in double decker
April 2005	Project Charlie	<i>S. Carmel</i> in drinking chocolate
April 2005	Project Donald	<i>S. Carmel</i> in double decker
April 2005	Project Eden	<i>S. Brackenridge</i> in double decker with nuts
May 2005	Project Flash	<i>S. Brackenridge</i> in curly wurly
June 2005	Project Gomez	<i>S. Brookfield</i> in CDM buttons
October 2005	Project Hector	<i>S. Bonariensis</i> in curly wurly

Detail of the Wider Investigation

In addition to the investigation of Cadbury itself, further key areas investigated included the role of Campden and Chorleywood Food Research Association, the suitability of the MPN Method, the epidemiological study performed by the Health Protection Agency, and the individual outbreak cases.

A collation of relevant information was undertaken; searches were carried out under warrant after liaison with the police and included the use of computer forensic experts. Records, including computer records, copies of relevant meeting notes, reports, letters and E-mails, and microbiological results going back to 2002 were all seized. Statements from key personnel were taken and their notebooks seized. Individual computers were seized and embedded electronic trails investigated. Mirror images of on-site servers were taken including e-mail servers and these were sampled and interrogated using key words. Personnel were interviewed under caution and expert witness evidence was sought. A nominated expert witness from the UK Advisory Committee on the Microbiological Safety of Food (Professor Paul Hunter, lecturer at University of East Anglia) was appointed to report on *Salmonella*, the most probable number and any other relevant discussions, and the ACMSF minutes were introduced as part of the data. As part of the wider investigation, outbreak cases were identified via the Health Protection Agency and these witnesses were visited by local government officers to confirm the facts.

The Health Protection Agency confirmed the outbreak by DNA matching using Pulse-Field Gel Electrophoresis and matched country wide cases in nationally distributed product. They also conducted a review of previous *S. Montevideo* samples and Campden samples were highlighted. The DNA match was confirmed and notification was given to both Campden and the FSA.

The advice and instruction given by Campden regarding *Salmonella* was investigated along with the appropriateness of the MPN procedure and questions were raised as to whether Campden had knowledge of the full circumstances when asked to provide the MPN method, including how the company proposed to use it—this was concluded to be unlikely.

The key conclusion was that, whilst the Most Probable Number (MPN) is a suitable method for homogenous spread of bacteria, it is **not** suitable for

Salmonella in chocolate. Further to this the interpretation of the Pusey report by the company regarding levels of salmonella in ready-to-eat product was highlighted as a misinterpretation of the data and, as shown in Table A.12, the expert position that ready-to-eat foods should be free from salmonella was reiterated.

Charges Brought against Cadbury were the Following (Lowe, 2008; Food Production Daily, 2007):

1. In contravention of Article 14 of 178/2002, Cadbury “placed on the market ready-to-eat chocolate products which were unsafe, in that they were injurious to health and unfit for human consumption due to the presence of Salmonella organisms.”
2. In contravention of Article 19 of 178/2002, Cadbury “failed to immediately inform the competent authorities that they had reason to believe that ready-to-eat chocolate products, placed on the market, may be injurious to human health due to the presence of Salmonella organisms.”
3. In contravention of Article 5 of 852/2004, Cadbury “failed to identify hazards from ready-to-eat chocolate products contaminated with Salmonella and failed to identify critical control points and corrective actions in line with HACCP (Hazard Analysis and Critical Control Points) principles.”

Outcome

The company was fined £1 million and spent a further approximately £20 million on recalling affected products and rectifying the problem.

Key learnings from the incident demonstrated not only the errors and inadequacy of food safety management at the company but also highlighted the importance of positive relationships and cooperation between businesses and local authorities. The importance of multi-agency collaboration in investigating the outbreak has also been highlighted, with particular reference to the positive cooperation that took place between Local Authorities at Birmingham City Council and in Herefordshire, the Health Protection Agency, Food Standards Agency, and the Advisory Committee on Microbiological Specifications for Foods.

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HPA, 2006b, Communicable Disease Report Weekly, Volume 16 Number 29, 21 July 2006

Lowe, N., 2008, Learning from Major Incidents—Cadbury Salmonella Outbreak, presentation delivered at *Food Manufacture* Product Recall Conference, Warwick, UK, 2008

Appendix B Pathogen Profiles

These pathogen profiles have been constructed to provide an easy-to-use source of material on growth and survival characteristics of some major food pathogens. The base information for these profiles has been sourced from currently available resources on microorganisms in foods, e.g., ICMSF (1996) and, whilst correct at the time of construction, may be superseded by future research. The information within the tables is intended as an introduction to the properties of these pathogens and should be used as a general guide only.

The authors would like to thank the following contributors for their valued input to the updating of the pathogen profiles for this edition of the book:

Bacterial Pathogens—Dr R. Bruce Tompkin, Retired (Con Agra) food safety system expert, LaGrange, Illinois, USA.

Toxigenic Fungi—Dr Ailsa Hocking, CSIRO Animal, Food and Health Sciences, CSIRO Riverside Life Sciences Centre, 11 Julius Avenue, North Ryde NSW 2113, Australia.

Viruses—Dr Gail Greening, ESR (Institute of Environmental Science and Research Food Group), Kenepuru Science Centre, PO Box 50-348, Porirua, 5240, New Zealand.

Additional coordination support—Cathy Moir, CSIRO Animal, Food and Health Sciences, CSIRO Riverside Life Sciences Centre, 11 Julius Avenue, North Ryde NSW 2113, Australia.

Pathogen Profiles—Part 1: Bacterial Pathogens

Organism	<i>Yersinia enterocolitica</i> (Ye)	<i>Bacillus cereus</i> (Bc)	<i>Campylobacter</i> spp. (C)
Taxonomy	<p>Ye is a Gram –ve, facultative anaerobic, non-sporeforming rod-shaped bacterium that produces oval or coccoid cells in young cultures at 25 °C.</p>	<p>Bc is a Gram +ve, motile, sporeforming rod with a sporangium that is not swollen by the spore. Cell diameter is 0.9 µm. Growth occurs aerobically and anaerobically</p>	<p>C is a Gram –ve, microaerophilic, small, vibrioid, or spiral-shaped cell that moves rapidly, darting with a reciprocating motility</p>
Distribution and Importance	<p>Ye is widely distributed in nature and found worldwide in animals, food, and water; however, only certain bioserotypes associated with pigs have caused disease among consumers, especially young children in countries where eating raw pork is traditionally practiced</p>	<p>Bc is widely distributed in nature. The ability to form spores ensures survival through all stages of food processing except, for example, retorting. All documented cases of Bc intoxication have involved time/temperature abuse of food that allowed germination and multiplication. The majority of outbreaks involve heat-treated foods prepared in restaurants or for use in catering. Normally, the food vehicles are rice or starch-based (e.g., pasta, pudding, custard) foods. Current risk assessments should be considered when interpreting the public health significance of high numbers of Bc in pasteurized milk</p>	<p>C occurs in the intestinal tract of wild and domesticated animals. Raw poultry is the most important food source and typically is associated with sporadic cases. Other important sources include raw or inadequately pasteurized milk, raw and undercooked meat, untreated drinking water, and contact with livestock. C is also very sensitive to drying and heat</p>
Pathogenicity	<p>Pathogenicity is limited to certain bioserotypes that have been found naturally in the tonsil area of pigs where it does no harm to the host. Four serotypes (0:3; 0:5, 2:7; 0:8; and 0:9) account for most cases of human disease. Virulence is associated with a plasmid that enhances the ability of Ye to survive and proliferate in the intestine. Elevated levels of iron can significantly increase the virulence of Ye</p>	<p>Two types of illness are caused by Bc, diarrhea, and vomiting. Both syndromes typically involve large numbers of cells (e.g., $\geq 10^5$) but lower numbers have been reported in some outbreaks. Diarrheal types of Bc produce an enterotoxin in the small intestine. Emetic types produce a cyclic peptide (emetic toxin) in the food before it is consumed. Emetic strains are presumably</p>	<p>Campylobacteriosis is primarily due to <i>C. jejuni</i> and less commonly <i>C. coli</i>. Illness is a gastrointestinal infection. The minimum infectious dose is probably fewer than 500 CFU. Babies, young children, and the immune-compromised are the most susceptible. <i>C. jejuni</i> and <i>C. coli</i> produce a heat-labile enterotoxin. Over 70 % of C strains produce a cytotoxin which could be responsible for</p>

Symptoms	Gastroenteritis consisting of abdominal pain, fever, diarrhea, and many other symptoms. Diarrhea may last for several weeks. A pseudoappendicular syndrome has been observed in older children and younger adults. The combination of fever, abdominal pain, and tenderness in the lower right quadrant in these cases has led to surgery. Sequelae can develop among some patients that subsequently cause additional, very significant health problems			Symptoms reflect the type of <i>Bc</i> . The diarrheal syndrome involves abdominal pain, watery diarrhea, and occasionally nausea usually 8–16 h after eating the food. Symptoms usually last 12–24 h. The emetic syndrome involves nausea, vomiting, and malaise 0.5–5 h after eating the food. Symptoms usually last 6–24 h. Occasionally, diarrhea may occur due to the production of enterotoxin in the intestine			unable to multiply and produce toxin below 10 °C or in the absence of oxygen			bloody diarrhea. Penetration of the intestinal mucosal layer may be helped by the rapid motility and shape of <i>C</i>			Symptoms vary from mild to severe diarrhea (which may be bloody), fever, nausea, abdominal cramps, and pain. Vomiting seldom occurs. Dehydration may be severe, especially in the young and elderly. Incubation time is 2–7 days with illness lasting a similar time. Minor relapses may occur in up to 25 % of cases. <i>C</i> can be excreted for 2–7 weeks except when treated with antibiotics. The disease is normally self-limiting, however, septicemia, reactive arthritis, and Guillian–Barre’ syndrome are possible sequelae		
Limits for growth															
Temperature (°C)															
pH															
<i>a_w</i>															
Atmosphere															
Salt (%)															
Control															

(continued)

Organism	<i>Yersinia enterocolitica</i> (Ye)	<i>Bacillus cereus</i> (Bc)	<i>Campylobacter</i> spp. (C)
	Processes used to produce fermented meat products (e.g., salami) containing raw pork as an ingredient should be validated to inactivate <i>Ye</i>	major concern. The food should either be cooled rapidly to <10 °C or kept >60 °C	underway in certain countries to reduce the presence of <i>C</i> in/on live poultry at the farm and on carcasses after processing. Preventing cross-contamination from raw poultry and meat to ready-to-eat foods is very important. Raw or under-pasteurized milk should be avoided. Drinking and processing water should be chlorinated

Organism	<i>Clostridium botulinum</i> (<i>Cb</i>)	<i>Clostridium perfringens</i> (<i>Cp</i>)	<i>Listeria monocytogenes</i> (<i>Lm</i>)
Taxonomy	<i>Cb</i> is a Gram +ve, sporeforming anaerobic rod. Cell size 0.3–0.7 µm by 3.4–7.5 µm, motile with peritrichous flagella. <i>Cb</i> produces oval spores which are subterminal and swell the sporangium. Eight serologically distinct neurotoxins have been identified and are used to differentiate <i>Cb</i> strains. <i>Cb</i> also can be divided into two groups, <i>I</i> = proteolytic and <i>II</i> = non-proteolytic	<i>Cp</i> is a Gram +ve non-motile, square-ended anaerobic (microaerophilic) rod. <i>Cp</i> is non-motile, ferments lactose, nitrate is reduced and is capable of forming oval central spores. Lecithinase activity can be observed on egg yolk medium	<i>Lm</i> is a Gram +ve, short, non-sporeforming rod that is catalase +ve and facultatively anaerobic. <i>Lm</i> is motile at 25 °C but not at 35 °C. <i>Lm</i> produces bluish-gray colonies
Distribution and Importance	<i>Cb</i> is ubiquitous in nature and can be isolated from soil, the shores, and sediment of lakes and coastal waters and from the intestinal tracts of fish and animals. Although widely distributed, <i>Cb</i> in food is very low in prevalence and numbers and is difficult to detect. Canned shelf stable foods, especially when home-canned, have a long history as a source of botulism. The occasional case or outbreak of foodborne botulism from a wide variety of foods is a continuing reminder that botulism is a hazard that must be considered. Honey can be a source of <i>Cb</i> spores that can lead to botulism in infants under 1 year of age	<i>Cp</i> is found in soil, dust, vegetation, raw, dehydrated, and cooked food. It is among the natural flora of the intestinal tract of humans and animals. Spores of the different types vary in their resistance to heat which influences survival during cooking. Outbreaks most frequently occur in food service establishments when a large volume of food is cooked for large groups of people and then chilled slowly or held at temperatures permitting growth. This can result in the large number of vegetative cells (e.g., $\geq 10^5$ /g) necessary to cause illness. Heat treatment commonly provides the shock that facilitates rapid germination followed by multiplication	<i>Lm</i> is found in soil, silage, sewage, food processing environments, raw meat, and the feces of healthy humans and animals. Infections in cattle can lead to the occurrence of <i>Lm</i> in milk. In-plant contamination of ready-to-eat foods during processing and packaging has been a major source of outbreaks. Harborage sites within equipment (e.g., slicers, diceers, conveyors) that comes into contact with exposed RTE food are significant sources of <i>Lm</i> contamination. <i>Lm</i> can multiply at the low environmental temperatures used in facilities for processing refrigerated foods
Pathogenicity	Botulin toxin is among the most toxic of all naturally occurring substances. Human foodborne botulism results from ingesting preformed toxin in food that has been	Enterotoxins are produced during spore formation in the intestine. Preformed enterotoxin in the food generally does not occur but, if present, the enterotoxin may	Listeriosis can manifest itself in two forms, invasive and noninvasive. Invasive listeriosis occurs in consumers with compromised immune systems (e.g., pregnant women,

(continued)

Organism	<i>Clostridium botulinum</i> (Cb)	<i>Clostridium perfringens</i> (Cp)	<i>Listeria monocytogenes</i> (Lm)
	<p>inadequately preserved or processed and then held at temperatures that permit outgrowth of the spores and production of a neurotoxin. Seven serologically distinct neurotoxins (i.e., A through G) have been identified. Infant botulism results from ingesting botulinal spores from either an environmental source or honey followed by subsequent multiplication within the intestine and toxin production</p>	<p>play a role in early onset of symptoms in some cases. Five types of <i>Cp</i> exist (A–E), enterotoxins of A and C cause acute diarrhea in humans. A and C produced in the intestine cause fluid loss due to the altered permeability of the cell membrane</p>	<p>elderly, cancer, and organ transplant patients). Noninvasive can occur in any population if sufficiently high numbers of cells are consumed due to growth of <i>Lm</i> in the food. For invasive listeriosis, three serovars account for the majority of cases. The infectious dose is influenced, for example, by virulence of the strain, health status (i.e., susceptibility) of the consumer, and number cells consumed. Initial infection occurs via the intestine. The death rate for <60 years old is 25 % while for >60 and in immunocompromised individuals it is 41 %. Infection in pregnant women can lead to death of the fetus and spontaneous abortion. All pathogenic strains are hemolytic</p>
Symptoms	<p>Symptoms may appear in a few hours or take several days to appear. Symptoms include weakness, fatigue, vertigo followed by blurred vision, and progressive difficulty in swallowing and speaking. Weakening of the diaphragm and respiratory muscles is also observed and death is usually due to respiratory failure. Prompt administration of antitoxin and artificial respiration decrease the mortality rate</p>	<p>Abdominal pain, nausea, and acute diarrhea 8–24 h after ingestion of large numbers of <i>Cp</i> cells. The illness is of short duration and full recovery can occur in 24–48 h</p>	<p>A third of cases involve pregnant women and the other two-thirds affect those with an impaired immune system. Pregnant women exhibit a mild fever with slight gastroenteritis and flu-like symptoms with major or fatal results for the fetus. The other cases involve bacteremia and/or meningitis with a small percentage having focal lesions</p>

	Intestinally pathogenic <i>Escherichia coli</i>			
	Enterohaemorrhagic <i>E. coli</i> (E. coli O157:H7)	Enterotoxigenic <i>E. coli</i> (ETEC)	Enteroinvasive <i>E. coli</i> (EIEC)	Enteropathogenic <i>E. coli</i> (EPEC)
Organism	<i>Ec</i> are Gram –ve, catalase +ve, oxidase –ve, facultatively anaerobic short rods. <i>Ec</i> are subdivided into four pathogenic groups by the main mechanism causing the illness			
Distribution and Importance	There are few outbreaks of <i>EPEC</i> , <i>ETEC</i> , or <i>EIEC</i> in developed countries; however, <i>E. coli</i> O157:H7 has seen major outbreaks in the USA, UK, Asia, Canada, and Argentina. These outbreaks have been linked to undercooked ground beef, raw milk, raw produce and fruit juice, water, and contact with farm animals. <i>ETEC</i> is more common in developing countries and has been linked to contaminated water and salads with raw vegetables			
Pathogenicity	<i>E. coli</i> O157:H7 has two major virulence factors. These are two verotoxins which invade a cell and cause cell death. Colonization occurs principally in the small intestine	<i>ETEC</i> only colonizes the small intestine and attach via antigens. Two major enterotoxins are produced which affect the microvilli of the intestine	<i>EIEC</i> attacks the colonic mucosa and invades the epithelial cells, eventually causing ulceration of the bowel	<i>EPEC</i> destroys the microvilli in the intestine via attachment of an outer protein membrane. Pathogenicity is also due to some other virulence factors
Symptoms	Hemorrhagic colitis: grossly bloody diarrhea, severe abdominal pain, vomiting, no fever. Hemolytic uremic syndrome (HUS): prodrome of bloody diarrhea, acute nephropathy, seizures, coma, death. Thrombotic thrombocytopenic purpura: similar to HUS but also fever and central nervous system disorder	Watery diarrhea, low-grade fever, abdominal cramps, malaise, and nausea. The most severe form resembles cholera, with severe rice/water-like diarrhea that leads to dehydration	Profuse diarrhea or dysentery, chills, fever, headache, myalgia, abdominal cramps; stools often contain mucus and streaks of blood	Diarrhea, nausea, abdominal pain, chills; diarrhea is watery with prominent amounts of mucus but no blood

Limits for growth									
Temperature (°C)	Optimum	Range	Optimum	Range	Optimum	Range	Optimum	Range	
pH	35–40	7–46	35–40	7–46	35–40	7–46	35–40	7–46	
<i>a_w</i>	6–7	4.4–9.0	6–7	4.4–9.0	6–7	4.4–9.0	6–7	4.4–9.0	
Atmosphere	0.995	0.950	0.995	0.950	0.995	0.950	0.995	0.950	
Salt (%)	Aerobic	Aerobic/Anaerobic	Aerobic	Aerobic/Anaerobic	Aerobic	Aerobic/Anaerobic	Aerobic	Aerobic/Anaerobic	
Control	–	<9.0	–	<9.0	–	<9.0	–	<9.0	
<p><i>E. coli</i> O157:H7 is found in the intestinal tract of cattle and to a lesser extent in other ruminants. Contamination of food can therefore occur via fecal matter during slaughter or milking. Control is based on pasteurization or proper cooking of foods likely to contain the pathogen and preventing cross-contamination of other ready-to-eat foods. Processes used to produce fermented meat products (e.g., salami) containing raw beef as an ingredient should be validated to inactivate <i>E. coli</i> O157:H7</p>									

Humans are thought to be the principal reservoir and carriers for *EPEC*, *EIEC*, and *ETEC* strains in human illness. They are carried in the intestinal tract and, therefore, infected food handlers can contaminate foods if they lack personal hygiene. Important controls include education and training of food handlers in personal hygiene and proper food handling including heating and holding foods under appropriate conditions. Untreated human sewage should not be used to fertilize vegetables and unchlorinated water should not be used to clean food processing facilities

Organism	Salmonellae (<i>Sa</i>)	Shigellae (<i>Sh</i>)	<i>Staphylococcus aureus</i> (<i>Sau</i>)
Taxonomy	<i>Sa</i> are Gram -ve, facultatively anaerobic, non-spore forming rod-shaped bacteria. Most are motile. Subspecies I of <i>S. enteric</i> accounts for about 99 % of human infections	<i>Sh</i> are non-motile, Gram -ve, facultatively anaerobic rods. There are four main subgroups which are differentiated by biological and serological characteristics	<i>Sau</i> is a Gram +ve, catalase +ve, facultatively anaerobic coccus occurring in pairs, short chains, or grape-like clusters. Certain strains produce enterotoxin
Distribution and Importance	Since <i>Sa</i> reside in the intestinal tract of humans and animals, foods subjected to fecal contamination become vectors. Foods commonly implicated in outbreaks include raw meat and poultry, eggs, raw milk, leafy greens, sprouts, untreated juices, and shellfish harvested from contaminated waters. When conditions permit, <i>Sa</i> can become established and multiply in processing plants, including where low moisture foods are processed (e.g., peanut butter, infant formula, chocolate)	<i>Sh</i> are not natural inhabitants of the environment. <i>Sh</i> originate from humans and higher primates and spread during the later phases of the illness via hands soiled with feces. Flies and contaminated water also can be vectors for transmission of <i>Sh</i> . A wide variety of contaminated ready-to-eat foods has led to shigellosis among consumers	<i>Sau</i> is ubiquitous and found in the nasopharynx and on the skin of warm-blooded animals and up to 50 % of humans. <i>Sau</i> is resistant to drying and can colonize hard-to-clean areas of processing equipment, if temperature permits. <i>Sau</i> is often found in the dust of ventilation and cyclone equipment. <i>Sau</i> competes poorly with other bacteria in raw food products (e.g., raw meat, poultry, and milk) and, thus, rarely attains the high numbers necessary for enterotoxin production. Poisoning normally occurs after cooked foods are contaminated by a food handler and then held at 20–40 °C for several hours. <i>Sau</i> can produce enterotoxin in certain foods with a relatively low a_w
Pathogenicity	<i>Sa</i> invades the lumen of the small intestine and multiplies. The dose required for human illness is influenced by many factors (e.g., strain virulence, concentration, quantity of food consumed, type of food and the age, and health status of the consumer)	<i>Sh</i> are invasive and penetrate the epithelial tissue of the intestine. The infective dose is low (10–100 CFU). <i>Sh</i> toxin is cytotoxic, enterotoxic, and neurotoxic. The toxin destroys the epithelial cells and promotes fluid loss. The virulence of the strain influences the severity of the illness	Certain <i>Sau</i> strains produce an enterotoxin during multiplication to >100,000 CFU/g in the food. Thus, preventing multiplication is an important control measure for preventing staphylococcal food poisoning (i.e., intoxication). Enterotoxins have low molecular weight and are very heat stable. As little as 1 µg of toxin can cause illness
Symptoms	Gastroenteritis usually occurs 12–36 h after ingestion of the food. Symptoms are diarrhea, nausea, abdominal pain, mild , and chills. Vomiting and headaches also can occur. Duration of illness is 2–5 days	Sudden abdominal cramps, diarrhea within 1–4 days of infection. Only when the disease progresses to the colonic phase after 3 days can <i>Sh</i> be diagnosed. These symptoms are waves of intense cramping and frequent bowel movements producing small amounts of blood, mucus, and acute pain	Illness normally occurs 2–4 h after ingestion of a food containing enterotoxin. Symptoms include nausea, vomiting, abdominal cramps, and diarrhea. Recovery is usually in 2 days

Limits for growth					
Temperature (°C)	Optimum	Range	Optimum	Range	Optimum
pH	35–43	5.2–46.2	35–43	6.1–47.1	37
<i>a_w</i>	7.0–7.5	4.1–9.5	5.5–7.5	4.9–9.34	6.0–7.0
Atmosphere	0.99	0.94 to >0.99	–	–	0.98
Salt (%)	Aerobic	Aerobic/Anaerobic	Aerobic	Aerobic/Anaerobic	Aerobic/Anaerobic
Control	–	<9.4	–	<5.18	<21.59
<p>As low numbers can cause illness, it is important to ensure the absence of <i>Sa</i> from foods by:</p> <p>1. Applying a kill step (e.g., heat, irradiation, acidification, or a combination of these factors), especially when using raw agricultural foods of animal origin as an ingredient</p> <p>2. Preventing contamination of ready-to-eat foods</p> <p>3. Storing foods outside the temperature range for growth</p> <p>Personal hygiene of individuals handling ready-to-eat foods is the main point of control. This can be prevented by using utensils and instead of hands and/or disposable gloves. Applying Good Agricultural Practices on the farm can minimize contamination of leafy greens and other crops</p> <p>Protect food from contamination and avoid conditions that favor growth of <i>Sau</i>. The conditions influencing growth and enterotoxin production include, for example, temperature, type of acidulant, <i>a_w</i>, type of packaging (aerobic/anaerobic), competing flora, and interactions among the factors. The conditions for growth are generally less restrictive than for enterotoxin production.</p> <p>Foods held for extended times at temperatures that permit growth during their production (e.g., fermented foods such as cheeses and meats) must develop sufficient acid at a predictable, inhibitory rate.</p> <p>Commercial starter cultures are typically used as a control measure. Lots that are slow or do not develop an inhibitory level of acid within the time expected for the conditions of fermentation should be investigated. Direct acidulation is another possibility for certain foods. Organic acids are more inhibitory than inorganic acids (e.g., HCl)</p>					

Pathogen Profiles—Part 2: Toxicogenic Fungi

Toxicogenic Fungi		
Organism	<i>Aspergillus</i> (<i>As</i>)	<i>Penicillium</i> (<i>Pe</i>)
Taxonomy	Many foodborne <i>Fusarium</i> species produce toxins which are hazardous to human health	
Distribution and Importance	Xerophilic will spoil foods that only slightly exceed safe moisture limits. <i>A. flavus</i> and <i>A. parasiticus</i> produce aflatoxins, <i>A. carbonarius</i> and <i>A. niger</i> form ochratoxins	50 common species. These are classed by morphological features into four subgenera with subgenus <i>Penicillium</i> spp. being most important toxigenic and food spoilage species
	<i>A. flavus</i> is found extensively in the environment, unlike <i>A. parasiticus</i> which is less widespread. Both are commonly found on nuts and oilseeds. In developed countries strict sorting reduces the risk of aflatoxins to low levels in foods. Developing countries do not have these systems in place and therefore are at risk from the aflatoxins. <i>A. carbonarius</i> and <i>A. niger</i> are found on grapes. Ochratoxins may contaminate wine, grape juice, dried vine fruit	<i>Pe</i> with <i>Aspergillus</i> are the dominant fungi on decaying vegetation. <i>Pe</i> can grow at lower temperatures than <i>Aspergillus</i> and are found in the environment in temperate climates and in cool stores worldwide. Some are xerophilic but less so at low a_w than <i>Aspergilli</i>
Toxins and toxicity	The aflatoxins have four effects; acute liver damage, liver cirrhosis, tumor induction, and teratogenesis. Ochratoxins are nephrotoxic and may be carcinogenic	Many diverse types of toxin with a variety of molecular structures. Patulin is an example of one of the toxins produced. Two effects are produced by the toxins. Either they affect liver/kidney function or they are neurotoxins (e.g., penitrem A)

(continued)

Organism	<i>Toxigenic Fungi</i>		
	<i>Aspergillus (As)</i>	<i>Fusarium (Fu)</i>	<i>Penicillium (Pe)</i>
Symptoms	Exposure to acute aflatoxin poisoning produces jaundice, rapid development of ascites, and hypertension. Long-term exposure to low levels of aflatoxin produces liver cancer; has a very long induction period. Ochratoxin exposure causes kidney damage		
Limits for growth			
Temperature (°C)	Optimum 33	Optimum 22.5–27.5	Optimum 20–24
pH	Range 10–43	Range –2–35	Range <5–37
<i>a</i> _w	2 to >11	<2.5 to >10.6	<2.2 to >10
Salt (%)	0.65 to >0.99	0.88 to >0.99	0.78 to >0.99
Control	Control is focused on farm management as it has been shown that <i>As</i> invades the crops while in the field. Good storage practices and the final screening of crops are the final method of controlling the aflatoxin	A lack of information exists on the physiology of the fungus or the factors which influence toxin production. Therefore, no control measures can be suggested. Deoxynivalenol is controlled through legislation in some countries	Cereals/foods should be stored far from the optimum levels for growth and ideally out of the growth ranges

Pathogen Profiles—Part 3: Foodborne Viral Pathogens

Organism Taxonomy	Viruses		
	Hepatovirus (HAV) (Hepatitis A virus)	Enterovirus (EnV)	Norovirus (NoV)
Distribution and Importance	<p>HAV and EnV are members of the Picornaviridae. HAV is now classified in the genus <i>Hepatovirus</i>. HAV and EnV are non-enveloped single-stranded RNA virions (22–30 nm diameter). They are primarily enteric viruses which pass through the gastrointestinal tract intact and are transmitted by the fecal-oral route. Human HAV can infect all species of primates. The Enterovirus genus includes poliovirus, Coxsackie viruses, ECHOviruses, and enteroviruses. HAV and EnV are resistant to acid (pH 3), detergent, and lipid solvents. Hepatitis A virus is very stable showing high resistance to chemical and physical agents, including drying, heat, low pH, and solvents. Heat resistance is reported to be higher in shellfish and foods. HAV survived acid conditions in shellfish for >4 weeks</p>	<p>HAV causes hepatitis A, a severe liver disease formerly known as infectious hepatitis or jaundice. EnV cause a range of illnesses from meningitis and encephalitis to poliomyelitis. The main source of contamination for food is by direct or indirect fecal contamination. Bivalve molluscs are a major source of infection in growing waters contaminated by sewage, bivalve molluscs take up HAV and EnV via filter feeding and concentrate the viruses to higher concentrations than in the surrounding environment. The viruses remain infectious in the shellfish for several weeks or longer, presenting a risk to those who consume contaminated shellfish. Food contamination may occur pre-harvest (fresh produce, salads, soft fruits) or post-process (milk, food handling)</p>	<p>Transmitted by the same routes as HAV. Viral gastroenteritis is a problem for the bivalve shellfish industry. Passive transfer via food handling to salads, sandwiches, and bakery products is also a main transmission route. NoV can be detected in feces and vomitus in the acute phase of illness and for up to 14 days or longer in feces</p>
	<p>Incubation is 2–6 weeks so it is difficult to determine a specific food source. The maximum number of HAV are excreted in late incubation and the early clinical stages of illness. Therefore, infected food handlers still at work can be a hazard. Many HAV outbreaks are due to infected food handlers in food service establishments</p>	<p>EnV has been found in bivalve molluscs but they have not been proven to cause EnV infection by this route. EnV has been found in meat, vegetables, fruit, and milk. This is often due to contact with contaminated water. Contamination with an infected food handler is another common transmission route</p>	<p>NoV is very infectious, has a low infectious dose of ~10 particles, and secondary transmission by aerosols or via surface contamination is common. Can be transmitted after the symptoms have cleared and by asymptomatic cases. Environmentally stable and can persist on surfaces for weeks</p>

(continued)

Organism	Viruses		
Pathogenicity	Hepatovirus (HAV) (Hepatitis A virus)	Enterovirus (EnV)	Norovirus (NoV)
	HAV replicates in the gastrointestinal tract and spreads via the blood. Damage to the liver occurs by an immunological reaction to the virus	EnV multiply mainly in the gastrointestinal tract but may also multiply in other areas of the body, especially the central nervous system (e.g., Poliovirus)	NoV infects cells in the small intestine but the mechanisms of infection are not well understood. Infection does not produce long-term immunity to the virus
Symptoms	HAV has an incubation period of 2–6 weeks with the onset characterized with fever, headache, malaise, fatigue, anorexia, nausea followed by vomiting, and abdominal pain. Jaundice and dark urine may appear later. Incapacitation can last for several months but recovery leads to life-long immunity	EnV infections have an incubation period of 3–7 days. Infections are most common in summer and early autumn, with many being asymptomatic. Some people develop viral meningitis but long-term complications rarely follow.	Nausea, vomiting, diarrhea, abdominal pain, cramps plus headaches, fever, and chills. An incubation period of 10–50 h is experienced with an acute phase of illness lasting 2–3 days. Patients may feel unwell for about 4 days
Control	Measures to prevent direct/indirect fecal contact are critical and rely on appropriate work practices from food handlers. Food handlers should not work when ill with gastroenteritis. Good hygiene practices are essential at all times, especially in the food industry. Proven effective handwashing regimes should be used. For critical operations, gloves should be worn as hand disinfectants are not effective against enteric viruses. Vaccines are available and should be considered for Hepatitis A virus. Waterborne viruses should be eliminated from food by ensuring that all water is of good microbiological quality. Shellfish-borne viral illness can be controlled by preventing harvesting from polluted waters. Post-harvest treatment such as depuration and relaying to clean waters over time have been shown to reduce but not eliminate viral contamination in shellfish		

Appendix C Glossary

This glossary has been compiled using Codex (2009b) as the reference document. Certain definitions have been adapted in order to aid understanding. Where there is a significant change, the actual Codex definition is also provided.

Aerobe A microorganism that can grow in the presence of oxygen. Obligate aerobes, e.g., molds, cannot grow in the absence of oxygen.

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

Anaerobe A microorganism that can grow in the absence of oxygen. Obligate anaerobes, e.g., *Clostridium* spp., cannot grow in the presence of oxygen.

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).

Audit Criteria A set of policies, procedures, or requirements. Audit criteria are used as a reference against which the actual situation is compared (ISO, 2002).

Audit Evidence Records, statements, of fact or other information, which are relevant to the audit criteria and verifiable (ISO, 2002).

Audit Findings Results of the evaluation of the collected audit evidence against audit criteria (ISO, 2002).

Auditee Organization being audited (ISO, 2002).

Auditor Person with the competence to conduct an audit (ISO, 2002).

Carver Plus Shock (FDA, 2007) Is a technique for assessing the likely public health impact in the event of an intentional intervention/attack.

C = Criticality (to public health and economic impact)

A = Accessibility (physical access to the target)

R = Recognizability (ease of identifying the target)

V = Vulnerability (ease of accomplishing the task)

E = Effect (amount of direct loss from an attack)

R = Recuperability (ability of the system to recover)

Shock = psychological effect of an attack

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.

Cleaning The removal of soil using appropriate cleaning chemicals and physical methods.

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

Codex Codex Alimentarius Commission (CAC), a United Nations organization that supports FAO and WHO by developing food standards, guidelines, and codes of practice.

Control Measure An action or activity that can be used to prevent, eliminate, or reduce a hazard to an acceptable level.

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).

Emerging Pathogen Typically an uncommon pathogen that becomes more prevalent because of changes in the host, the environment, or in food production and consumption practices.

Extrinsic A factor or process that is applied externally to a food, such as heating or modified atmosphere packaging.

Facultative A microorganism that can grow in the presence or absence of oxygen, a class that includes most foodborne microbes.

Disinfection The reduction of microorganisms (on equipment and in the environment) such that (food) safety is not compromised.

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

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

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 The document which defines the procedures to be followed to assure the control of product safety for a specific process. Codex (2009b) defines this as: 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.

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

HACCP Team The multidisciplinary 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 property or condition of food which may cause it to be unsafe for human consumption. Codex (2009b) defines this as: A biological, chemical, or physical agent in, or condition of, food with the potential to cause an adverse health effect.

Hazard Analysis Codex (2009b) defines this as: 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.

Hazard Analysis is described by NACMCF (1997) as “A biological, chemical, or physical agent that is reasonably likely to cause injury or illness in the absence of control.”

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.

Immunocompromised A condition in which the host’s immunity to infection is diminished by factors such as age (very young or very old), illness, or chemotherapy.

Infection An illness or condition caused by the growth of a microorganism in a host.

Infectious Dose The number of microorganisms required to cause an infection.

Intrinsic Factors Basic, a_w integral features of the product, due to its formulation, e.g., pH, a_w .

Monitoring 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 Limit A value that is more stringent than a specific critical limit that is used in process management by providing a buffer zone for safety.

Operational PRP 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 product(s) or in the processing environment (ISO, 2005).

Opportunistic Pathogen A relatively harmless microorganism that can more easily cause an infection in an immunocompromised person, or if it is accidentally inserted into a sterile host site.

Potable Water Wholesome, drinkable water.

Preventative Measure See **Control measures**.

Prion A misshapen cellular protein that causes the agglomeration of normal-shaped prion proteins which in turn can cause transmissible spongiform encephalopathies, fatal brain diseases, such as BSE (“mad cow disease”).

Process Flow Diagram A diagrammatic representation providing a detailed step-wise sequence of the operations in the process under study.

Prerequisite program (PRP) Prerequisite programs, such as good agricultural, manufacturing, and hygienic practices that create the foundation for a HACCP system.

Psychrotroph A microorganism that grows optimally at low temperatures, e.g., 0–20 °C.

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

Sanitary Operating Practices A term describing certain hygienic practices that form part of prerequisite programs.

Significant Hazard 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).

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

Target Level See Operational limit.

Thermophile A microorganism that grows optimally at high temperatures, e.g., 45–70 °C.

Toxic Dose The amount of toxin required to cause a food intoxication.

Toxin A chemical or microbial metabolite that can cause toxic effects when ingested.

Validate To investigate and prove the effectiveness of a control measure, such as the critical limits at a critical control point.

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

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

Verify To confirm the continuing effectiveness of a control measure through process or records observations, or analytical testing.

Zoonotic A pathogenic organism that can infect humans and animals.

Appendix D Abbreviations and Definitions

BRC	British Retail Consortium, based in London, UK, and one of the GFSI benchmarked food safety certification scheme standard owners
CFR	Code of Federal Regulations, a repository of US regulations
CFSA	Canadian Food Safety Agency
COA	Certificate of Analysis that would accompany a product or raw material and indicate compliance to specification
<i>c</i>	The maximum allowable number of defective sample units (two-class plan) or marginally acceptable units (three-class plan). When more than this number are found in the sample, the lot is rejected
CCP	Critical Control Point
CIP	Cleaning in Place
Codex	Codex Alimentarius Commission, an FAO/WHO Organization
EC	European Community
FAO	Food and Agriculture Organization of the United Nations
FDA	The US Food and Drug Administration
FIFO	First in, First out—principles of stock rotation
FMEA	Failure Mode and Effect Analysis
FSMA	Food Safety Modernization Act (US FDA, 2011)
GDP	Good Distribution Practice
GFSI	The Global Food Safety Initiative, organized through CIES, the Consumer Goods Forum
GLP	Good Laboratory Practice
GMA	Grocery Manufacturers of America
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis Critical Control Point
HAZOP	Hazard and Operability Study
HHA	High Hygiene Area
HMSO	Her Majesty's Stationary Office
HTST	High temperature, short time
IAFP	International Association for Food Protection

ICMSF	International Commission for Microbiological Specifications for Foods
IDF	International Dairy Federation
IFST	Institute of Food Science and Technology, London
IFT	Institute of Food Technology, USA
ISLI	International Life Sciences Institute
ISO	International Organization for Standardization
<i>m</i>	A microbiological limit which separates good quality from defective quality (two-class) or from marginally acceptable quality (three-class). Values $\leq m$ are acceptable values $> m$ are either marginally acceptable or unacceptable
<i>M</i>	A microbiological limit in a three-class sampling plan which separates marginally acceptable product from defective product. Values $> M$ are unacceptable
MAP	Modified Atmosphere Packaging
MRL	Maximum Residue Level
MSDS	Material Safety Data Sheet
<i>n</i>	The number of sample units examined from a lot to satisfy the requirements of a particular sampling plan
NACMCF	National Advisory Committee for Microbiological Criteria for Foods (USA)
NASA	National Aeronautics and Space Administration (USA)
NGFA	National Grain and Feed Association (USA)
OIE	World Organization for animal health
PAS	Publicly Available Specification
PDCA	Plan-Do-Check-Act
PPM	Planned Preventative Maintenance
QMS	Quality Management System
RDA	Recommended Daily Allowance
SPC	Statistical Process Control
SQA	Supplier Quality Assurance
SQF	Safe Quality Food, one of the GFSI benchmarked food safety certification schemes, originated in Australia but now based in the USA
SRSV	Small round structured virus
TVC	Total Viable Count
USDA	United States Department of Agriculture
WHO	World Health Organization
WTO	The United Nations World Trade Organization, where Codex guidelines and codes have the force of law among signatory members

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