FOOD SAFETY
FOR THE 21ST CENTURY

Managing HACCP and Food Safety Throughout the Global Supply Chain

CAROL A. WALLACE • WILLIAM H. SPERBER • SARA E. MORTIMORE

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Food Safety for the 21st Century

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Managing HACCP and Food Safety Throughout the Global Supply Chain

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To Christopher, Renate, and Lawrence for their encouragement to further develop this book and for their steadfast support of our careers and families.

and

To all participants in the global food supply chain, from farm to table, whose combined efforts are essential to provide a safe supply of food for all consumers.

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About the Authors

Professor Carol A. Wallace is Co-Director of the International Institute of Nutritional Sciences & Applied Food Safety Studies and Professor of Food Safety Management Systems at the University of Central Lancashire, UK, where she leads research themes in food safety effectiveness. Having entered the food industry as a microbiology graduate, she soon became involved in the early days of HACCP and food safety management systems in the UK and went on to gain 20 years of practical experience in the UK and international food industry before joining academia in 2004. She earned a PhD for her study of factors impacting HACCP effectiveness and has authored numerous books and research articles on HACCP, food safety management systems, and food safety culture. Carol continues to work closely with international food companies and organisations for the ongoing improvement of food safety standards and currently chairs *Salus, the Food Safety Culture Science Group*, an international research group investigating the role of food safety culture in the provision of safe food.

William H. Sperber studied biological and chemical sciences at the University of Wisconsin, Madison, culminating in a PhD degree in microbiology. This 'Friendly Microbiologist' has worked in research and management positions with major global food companies for 50 years, the majority with the Pillsbury Company where the HACCP system of food safety management originated. In his current retirement career, Bill is president of the Friendly Microbiologist, LLC, in which capacity he is an advocate of the broader use of Good Consumer Practices as an additional Prerequisite Programme to support the HACCP system.

Sara E. Mortimore has more than 30 years of food-manufacturing experience in food safety and quality management. Since 2008, she has been the Vice President of Product Safety, Quality and Regulatory Affairs at Land O'Lakes Inc., one of America's premier farmer-owned cooperatives operating in both the food and agricultural sector, including dairy-based products, animal feed, seed, and crop protection. Previously she worked in various international roles covering quality, food safety, and global sourcing for Pillsbury and General Mills. During this time, she gained a deep cultural understanding of the attitudes and behaviours of people towards food safety in manufacturing around the globe. As a result of this she has developed a major interest in the development of integrated food safety and quality management using the HACCP approach and in the impact of the operating environment.

Foreword

The effective development and management of food safety programmes is essential to minimise the occurrence of foodborne illnesses and outbreaks. However, that responsibility continues to be difficult to fulfil because of the growing human population and the rapidly growing global food trade. With our diverse professional experiences, we three authors have a combined experience of more than 100 years in food research, management, and education focused on food safety and quality practices. We have undertaken to write *Food Safety for the 21st Century* in an effort to assist all participants in the global food supply chain from farm to table to fulfil their individual responsibilities for food safety assurance. This book should be an excellent textbook in academic food safety courses and an excellent reference book for food safety researchers, managers, and regulators worldwide. We wrote this book to be comprehensive and forward looking, with sufficient technical detail to support the complete range of food safety activities from hazard analyses and training programmes to regulation and policy development. In updating it as a second edition, we were struck by the astonishing number of changes occurring in the supply chain, and in particular, the pace of change.

Future demands on the global food supply will challenge our ability to provide a sufficient supply of food that is reliably safe for consumption. The human population, projected to increase by 3 billion people by 2050, and the improving economic status in developing countries mean that we will need to double food production over the next 40 years. And all of this in the context of climate change, the diminishing availability of fresh water, fossil fuels and arable land, and the emergence and spread of new foodborne pathogens. The emergence and mismanagement of the bovine spongiform encephalopathy (BSE) epidemic 25 years ago, and the increasing awareness of food fraud, vividly demonstrate the necessity of improving food safety management practices, for defending the food supply from farm to table, and for effective communication throughout the global supply chain.

The HACCP system of food safety management began as a voluntary food industry effort nearly 50 years ago. Assisted by the Codex recommended code of practice for good hygienic practices and HACCP, first published in 1993, global food corporations have implemented HACCP wherever possible in their parts of the supply chain. Yet, our industry efforts to maximise the benefits of effective food safety management programmes have been hampered by fragmented governmental regulatory responsibilities and practices in many countries. It has been encouraging these last several years to see governments working together, not only through the formal auspices of the Codex process, but also in using international food safety meetings such as those organised by the

Global Food Safety Initiative and the International Association for Food Protection for discussion around challenges and the sharing of best practice. We look forward to seeing increased collaboration in the coming years.

Achieving effective food safety assurance in the global supply chain will likely require intergovernmental harmonisation of food safety regulations and practices and a more cohesive approach to ensuring global food protection.

The challenges facing all of us in our quest to maintain and improve food safety practices may seem daunting, but they are not insurmountable. There are large reservoirs of available food safety talent in the industry, academia, public health organisations, and regulatory bodies and a lot of momentum to do better. We need to generate the collective political will to collaborate and provide competent management and effective food safety management practices, effective educational programmes, and practical regulations. Working together, we will meet our challenges.

Bon appétit!

Carol A. Wallace
William H. Sperber
Sara E. Mortimore

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Glossary of Terms and Acronyms

aerobe A microorganism that can grow in the presence of oxygen. Obligate aerobes (e.g. moulds) 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 (International Organisation of Standards [ISO] 2011)

audit criteria A set of policies, procedures, or requirements. Audit criteria are used as a reference against which the actual situation is compared. (ISO 2011)

audit evidence Records, statements of fact, or other information that are relevant to the audit criteria and verifiable (ISO 2011)

audit findings Results of the evaluation of the collected audit evidence against audit criteria (ISO 2011)

auditee Organisation being audited (ISO 2011)

auditor Person with the competence to conduct an audit (ISO 2011)

BRC British Retail Consortium; based in London, United Kingdom, 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; accompanies a product or raw material and indicates compliance to specification

Codex Codex Alimentarius Commission (CAC), a United Nations organisation that supports Food and Agriculture Organisation (FAO) and World Health Organisation (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 (Codex, 2009)

corrective action Any action to be taken when the results of monitoring at the critical control point indicate a loss of control (Codex, 2009)

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, 2009)

critical limit A criterion that separates acceptability from unacceptability (Codex, 2009)

Crohn's disease A chronic inflammatory bowel disease of humans, thought to be caused by *Mycobacterium paratuberculosis*

D-value The process time required to reduce a microbial population by 90%, or one $\log_{10}$ unit

Dutch HACCP Code An auditable standard based on the principles of HACCP, prerequisite programmes, and management procedures

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

enterotoxin A toxic molecule produced by a microorganism that causes gastrointestinal illness symptoms such as vomiting and diarrhoea

essential management practices (for food safety) Management practices and procedures that support effective application of safe product/process design, prerequisite programmes, and HACCP systems and assure their ongoing capability to protect the consumer

extremophile A microorganism that can survive and grow under extreme conditions, such as high temperature or pressure, and extreme acidity

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

FAO Food and Agriculture Organisation; part of the United Nations and primarily responsible for food security

food crime Dishonesty relating to the production or supply of food, that is either complex or likely to be seriously detrimental to consumers, businesses or the overall public interest (NFCU no date)

food defence A set of countermeasures directed towards intentional contamination of the food supply chain. Several definitions exist - see Chapter 13, p267

food fraud 'a collective term used to encompass the deliberate and intentional substitution, addition, tampering or misrepresentation of food, food ingredients or food packaging; or false or misleading statements made about a product for economic gain (Spink and Moyer 2011). Several alternative definitions exist - see Chapter 13, p266

food protection All measures and programmes in place to protect the safety of the food supply (including food safety and food defence)

Food safety culture 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 (Griffith, Livesey, and Clayton, 2010)

food security The state existing when all people at all times have access to sufficient, safe, and nutritious food to maintain a healthy and active life (WHO 2010)

Gantt chart A diagrammatic representation of a project plan, including actions and timetable

GFSI Global Food Safety Initiative; organised through CIES, the Consumer Goods Forum

GIFSL Global Initiative for Food Systems Leadership; run by the University of Minnesota

GMPs Good manufacturing practices

Guillain-Barré syndrome A syndrome involving neurological complications that are often induced as a sequel to microbial infections, often attributed to *Campylobacter*

HACCP Hazard Analysis and Critical Control Point, a preventative system of food safety management based on product design, hazard analysis, and process control

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, 2009)

HACCP team A specific group of individuals with multidisciplinary expertise and experience who work together to apply the HACCP principles

halophile A microorganism that can grow at high sodium chloride concentrations (e.g. *Halobacterium* spp.)

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

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, 2009)

hydrophilic The tendency of a polar compound to be soluble in water

ICD Industry Council for Development

IFST Institute of Food Science & Technology (UK)

ILSI International Life Sciences Institute

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 A property that is an inherent characteristic of a food, such as pH or water activity

intoxication An illness or condition caused by the ingestion of a toxin

ISO International Organisation for Standardisation

Johne's Disease A chronic disease of cattle characterised by diarrhoea and emaciation, caused by *Mycobacterium paratuberculosis*

lipophilic The tendency of a nonpolar compound to be soluble in fats or oils

mesophile A microorganism that grows optimally at intermediate temperatures (e.g. 20° to 45° C)

monitoring The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a critical control point is under control (Codex, 2009)

NACMCF National Advisory Committee on Microbiological Criteria for Foods (USA)

OIE World Organisation for Animal Health

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 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 2015a)

opportunistic pathogen A relatively harmless microorganism that can more easily cause an infection in a person who is immunocompromised, or if it is accidentally inserted into a sterile host site

osmophile A microorganism, particularly a yeast, that can grow under conditions of high osmotic pressure, typically created by concentrated sugar solutions

osmotolerant A microorganism that can survive high osmotic pressure

PAS Publicly Available Specification

PMO Pasteurized Milk Ordinance (USA)

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 of the process identifying all processing activities, which is used as the basis for hazard analysis

PRP Prerequisite programmes, such as good agricultural, manufacturing, and hygienic practices, that create the foundation for a HACCP system

psychrophile A microorganism that grows optimally at low temperatures (e.g. 0-20°C)

psychrotroph A microorganism capable of growing at low temperatures but which has a maximum growth temperature above 20°C

sanitary operating practices A term describing certain hygienic practices that form part of prerequisite programmes

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)

SQA Supplier quality assurance; the programmes used to manage suppliers of raw materials, packaging, and contract manufacturing

SQF Safe Quality Food; one of the GFSI-benchmarked food safety certification schemes, originated in Australia but now based in the United States

thermophile A microorganism that grows optimally at high temperatures (e.g. 45° to 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 Obtaining evidence that the elements of the HACCP plan are effective (Codex, 2009)

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

verify To confirm the continuing effectiveness of a control measure through process or records observations, or analytical testing

WHO World Health Organisation; part of the United Nations and primarily responsible for public health

world-class food safety programme A programme based on the principles of safe product/process design, prerequisite programmes and HACCP that is supported by essential management practices, thus controlling the operational, environmental, and process conditions necessary for consumer health protection through the consistent production of safe food

WTO World Trade Organisation; an organisation closely linked to the United Nations where Codex guidelines and codes have the force of law among signatory members

xerotroph A microorganism, typically a mould, that can grow under very dry conditions

z-value The change in temperature (° C) required to change the D-value by 90% or one $\log_{10}$ unit

zoonotic A pathogenic organism that can infect humans and animals

How to Use This Book

Food Safety for the 21st Century is split into four main sections:

Part 1: Food Safety Challenges in the 21st Century
Part 2: Foodborne Hazards and Their Control
Part 3: Systematic Food Safety Management
Part 4: Food Safety Management in Practice: Current Issues and Challenges in the Global Food Supply Chain

In addition, there are two appendices providing a HACCP case study to supplement Chapter 12 and a Resources section to help the reader find information and help in applying food safety.

This book is intended to be a compendium of up-to-date thinking and best practice approaches to the development, implementation, and maintenance of world-class food safety programmes. 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 food safety management systems for the first time and for those who need to update, refresh, and strengthen their existing systems. The following paragraphs provide an outline of the content of each section and ideas of how they may be used.

Part 1, *Food Safety Challenges in the 21st Century*, sets the scene by providing a discussion of the key considerations for food safety in our modern world. Starting with considerations of where we have come from and how contemporary food safety programmes have evolved (Chapter 1), this section continues by considering lessons learned from food safety successes and failures (Chapter 2) and looks at challenges in the global food supply chain (Chapter 3). This section finishes with consideration of the future of food safety and HACCP in our changing world (Chapter 4), allowing us to look forward and predict some of the actions that need to be taken to continually improve and strengthen our food safety programmes and approaches in the global supply chain.

This section will provide the reader with a detailed understanding of the context within which food safety management must operate. It will outline the key food safety considerations for individuals, businesses, and organisations involved in the global food supply chains of the 21st century.

Part 2, *Foodborne Hazards and Their Control*, consists of three chapters that together form a database of information enabling the reader to recognise food safety hazards and design safe products and processes. This will be useful at the product development

stage to provide an understanding of some of the key hazards and control mechanisms available to the food business and will also be invaluable to HACCP team members who need to understand the likely hazards in their operations.

Part 3, *Systematic Food Safety Management*, outlines how to develop, implement, and maintain world-class food safety programmes based on safe product/process design, prerequisite programmes, and HACCP, and how to protect and defend the food supply chain from threats. The increasingly important role of people factors, training, and culture is embedded, and the eight chapters of this section provide a detailed understanding of current thinking on food safety management, drawing on the experiences and learnings of the last 45 years to offer best practice approaches for developing or strengthening an effective food safety programme.

Part 4, *Food Safety Management in Practice: Current Issues and Challenges in the Global Food Supply Chain*, introduces both theoretical and practical discussions on issues impacting sections of the food supply chain. The four chapters of this section use case studies to illustrate current thinking and challenges and provide guidance that can be used in making improvements to systems and practices.

Part I

Food Safety Challenges in the 21st Century

1

Origin and Evolution of the Modern System of Food Safety Management: HACCP and Prerequisite Programmes

1.1 Historical Perspectives

Food safety management practices have been evolving continually in the food industries of developed nations, particularly since the end of World War II (WWII) in 1945. Nevertheless, despite more than 70 years of progress in the assurance of food safety, failures sometimes occur. The intent of this introduction is to summarise the principal events in the origin and evolution of modern food safety practices so that readers can better understand how to improve practices and to provide even greater food safety assurance in the future.

The beginning of WWII coincided with the end of the Great Depression that had hindered economic progress throughout the entire world during the decade of the 1930s. Western nations mobilised their economic resources during the early 1940s to manufacture the weapons of war. Upon the war's end, the energised economic and manufacturing bases were converted to the building of infrastructure and the production of consumer goods rather than war materials. Several of the principal innovations that impacted food safety were the development and widespread use of mechanical refrigeration and the construction of national transportation systems, such as the interstate highway system in the United States.

Before the widespread use of mechanical refrigeration, many perishable foodstuffs were stored in iceboxes that required frequent replenishment of the ice supply. Iceboxes could not provide uniform or steady cold temperatures. As a result, perishable foods often became unfit for consumption; consumers were forced to shop frequently for perishable goods. Mechanical refrigeration units were able to provide relatively uniform and steady cold temperatures, about 4° to 7° C, thereby substantially reducing the amount of food spoilage and potential food safety incidents. The application of mechanical refrigeration was quickly extended to most homes and commercial establishments and to road and rail vehicles for the transportation of refrigerated or frozen foods and food ingredients.

The ability to use refrigerated transportation was greatly facilitated by the construction of modern rail and highway systems. Eventually, the production of refrigerated ocean liners and aeroplanes permitted the shipment of perishable foodstuffs across the oceans. These developments mean that the system of local food production and consumption that was widely used several generations ago has now been largely replaced by a massive global food supply chain in which foods and food ingredients are shipped amongst most nations of the world.

Food Safety for the 21st Century: Managing HACCP and Food Safety Throughout the Global Supply Chain, Second Edition. Carol A. Wallace, William H. Sperber, and Sara E. Mortimore.

Mechanical refrigeration and lengthened supply chains have enabled the concentration of food production operations into relatively few large facilities that can ship food products to very large geographical areas. This phenomenon has occasionally been responsible for large foodborne illness outbreaks that would have been less likely when food production occurred in multiple smaller facilities, each of which supplied smaller geographical areas. However, it has also given us the opportunity to improve standards in hygiene and safety through specially designed modern food facilities.

A trend towards more convenient foods accompanied these developments. In products such as dried cake mixes, for example, dried eggs and dried milk were added at the point of manufacture so that the consumer would not need to use shell eggs or fresh milk during the preparation of the cake batter. The use of dried ingredients in the place of fresh raw materials was quickly applied to the production of many manufactured foods. This practice brought with it an unanticipated problem – an increase both in the incidence of *Salmonella* contamination and in the number of outbreaks and cases of human salmonellosis.

The reasons for these increases proved to be analogous to the reasons for larger outbreaks of foodborne illnesses being associated with large, centralised food production facilities. In home kitchens, the use of *Salmonella*-contaminated fresh milk or shell eggs in family-sized food portions could, at most, be responsible for a few cases of salmonellosis. However, when *Salmonella*-contaminated dried eggs or dried milk were used in food manufacturing facilities in the production of massive quantities of food, many cases of salmonellosis could result.

The increased levels of pathogen contaminated foods and foodborne illnesses caused great concern in the rapidly evolving and growing global food industry of the 1950s and 1960s. Government regulators and consumers demanded safer foods. These demands were followed by intensified efforts to manage food production in order to reduce the food safety risks. Early efforts to assure food safety attempted to use quality control procedures that had been implemented with the modernisation of the food industry after WWII.

Manufacturers of many types of products, including foods and many household appliances, used similar procedures in their efforts to control quality. These procedures typically included the collection of a predetermined number of samples from a production shift, followed by the testing or analysis of the samples in a laboratory. Statistically based sampling plans were used to determine the acceptability of each production lot. If the number of defective samples exceeded the specification for a particular product, the entire production lot would be rejected. If the number of defective samples did not exceed the specified limit, the production lot would be accepted. The management of quality control was based on product specifications, lot acceptance criteria, and finished product testing.

Despite the applications of contemporary quality control procedures, foodborne illnesses caused by the new food ingredients and products continued to occur. It was discovered that food safety incidents, including foodborne illness outbreaks, were sometimes caused even when the implicated production lot of food was determined to be in compliance with all of its specifications. Repeated incidents revealed a fundamental flaw in quality control procedures that prevented the detection and prevention of such incidents. That fundamental flaw was the inability of quality control procedures to detect defects that occurred at low incidences.

Table 1.1 Probability of rejecting a lot containing a known proportion of defective units.

	Percentage of defective units in lot		
Number of samples tested	**0.1**	**0.5**	**1.0**
300	0.26	0.78	0.95
500	0.39	0.92	0.99
1000	0.63	0.99	—
2000	0.86	—	—
3000	0.95	—	—
5000	0.99	—	—

Adapted from International Commission on Microbiological Specifications for Foods (ICMSF) 2002.

Upon extensive investigations of production lots of food that were implicated in foodborne illnesses, it was determined that the foods were typically contaminated with a particular pathogen at a very low incidence. In many cases the defect rate was about 0.1%, i.e. about 1 unit of 1000 analytical units was found to be contaminated. Of course, when many millions of analytical units are produced during a single shift, it is easy to understand how numerous illnesses could be caused by a lot of food that was contaminated at the seemingly trivial rate of 0.1%.

Subsequent statistical analyses revealed that 3000 analytical units would need to be tested and found to be negative in order to provide assurance at the 95% confidence limit that a particular lot of food was free of a particular pathogen or similar foodborne hazard (International Commission on Microbiological Specifications for Foods [ICMSF] 2002; Table 1.1). Testing thousands of samples from each production lot of food was obviously impractical.

Additional factors were found to contribute to the inability of product testing to detect food safety defects. These included the uneven, or non-random, distribution of microorganisms in food materials, the variability between different testing procedures, and the competence of the laboratory personnel. In those days, it was not uncommon for plant production personnel to be promoted without training into laboratory positions.

For the reasons described above, reliance on product specifications and finished product testing were clearly inadequate to assure food safety.

1.2 Origin and Evolution of HACCP

During this same time period of the 1960s, several entities were collaborating on the production of foods for US military personnel and for the manned space programmes. These were The Pillsbury Company, the US Army Laboratories at Natick, MA, and the National Aeronautics and Space Administration (NASA). In an effort to guarantee that astronauts would not become seriously ill during a space mission, NASA had enacted very strict specifications on the foods that it used. All parties soon realised that a food safety guarantee could not be provided without 100% destructive testing of a given lot of food (Ross-Nazzal 2007). Several engineers recognised that the failure modes and effects

Figure 1.1 Space Food Sticks, designed for astronauts and later marketed to the public.

analysis (FMEA) used by the military to test the reliability of electrical components could be adapted to assess hazards and control measures in food production. The early seeds of the hazard analysis and critical control points (HACCP) of food safety were planted. One of the astronaut foods developed at this time, Space Food Sticks, was briefly produced as a consumer product (Figure 1.1). Its development included elements of both the FMEA and HACCP systems. The sticks were designed to be non-crumbling so that they could not contaminate and impair vital instruments in the space capsules. Additionally, they were produced under controlled conditions that provided a high degree of food safety assurance, both for astronauts and, later, for consumers.

Two coincidental events in 1971 hastened the development of HACCP and its use in the food industry. Americans learned of the first event when a national radio broadcaster intoned, 'Good morning, America, there's glass in your baby food'. Farina produced by The Pillsbury Company had been contaminated with shattered glass in its production facility (*The New York Times* 1971). Pillsbury's Director of Research, Dr. Howard Bauman, who led Pillsbury's production of space foods for NASA, decided to apply this new system of food safety management to all of Pillsbury's consumer food production. In the following month, Dr. Bauman delivered a presentation at the second coincidental event, the 1971 National Conference on Food Protection, sponsored by the American Public Health Association (APHA 1972). His remarks, and those of his fellow panel members, were limited to descriptions of critical control points (CCPs) and good manufacturing practices (GMPs). The term *HACCP* had not yet entered the professional lexicon, but this was to become one of the key events in the global spread and acceptance of the HACCP system (Table 1.2).

Table 1.2 Events that fostered HACCP development and evolution through the 20th century.

Year	Event
1923	US Pasteurized Milk Ordinance first published
1960s	Pillsbury, NASA, and US Army collaborations
1969	Current good manufacturing practices first published
1971	Pillsbury cereal recall National Conference on Food Protection Multiple canned foods recalls, *Clostridium botulinum* contamination
1972	Pillsbury trains US Food and Drug Administration inspectors to apply HACCP to canned foods Pillsbury begins application of HACCP to its consumer products
1973	Canned foods regulations first published
1975	Pillsbury internal HACCP system complete
1985	National Research Council recommends HACCP
1988	National Advisory Committee on Microbiological Criteria for Foods (NACMCF) formed ICMSF Book 4, the first entire book on HACCP, published
1992	NACMCF and Codex adopt seven HACCP principles
1994	*HACCP: A practical approach* published
1997	NACMCF and Codex HACCP documents harmonised

During the early 1970s, the US canning industry experienced a rapid succession of 12 or more incidents of contamination of canned foods by *Clostridium botulinum.* All were accompanied by product recalls and disposals, including one that cost approximately $100 million (Howard 1971). Although few illnesses and one death were associated with these incidents, the US Food and Drug Administration (FDA) recognised that better controls needed to be developed and required for the production of canned foods. Having participated in the 1971 National Conference for Food Protection, the FDA, intrigued by the concept of CCPs, contracted with The Pillsbury Company to conduct a training programme for its personnel responsible for the safety of canned foods.

Pillsbury presented a training programme for 10 FDA inspectors in September 1972. Lasting 3 weeks, the programme was almost evenly split between classroom activities and in-plant orientation and inspections at four canning companies. The accompanying instructional materials seem to represent the first substantial use of the term *HACCP* (The Pillsbury Company 1973). The newly-trained inspectors returned to Washington, D.C., and published the canned foods regulations in 1973 (Code of Federal Regulations [CFR] 2002). Based in significant extent upon time and temperature controls, the canned foods regulations bear striking resemblance to the Pasteurized Milk Ordinance (PMO) first published in 1923 (FDA 1997). It seems to the authors that the concepts of food safety based on prevention by adequate controls had long been present, perhaps subconsciously, in the minds of food processors and regulators. It is somewhat daunting to consider that our modern system of food safety management is so young.

Upon completion of the FDA training programme, Pillsbury began in earnest to apply the HACCP system to the production of its consumer products, a goal that was achieved

in 1975. Increasing awareness of Pillsbury's new system of food safety management and the obvious effectiveness of the canned food regulations in curtailing further incidents of *C. botulinum* contamination led to a steady adoption of HACCP by other US food processors. A fertile environment for food safety enhancement existed in the United States at this time because of these regulations and because of the 1969 promulgation by the FDA of current GMPs (CFR 1969).

The adoption of HACCP beyond the US food industry received a major impetus by the 1985 publication of a National Research Council report, 'An evaluation of the role of microbiological criteria for foods and food ingredients (NRC 1985).' Completely masked by its title, the report included several highly influential recommendations that propelled HACCP forward. The first of these recommended that food regulatory agencies should use proactive procedures to audit food safety compliance by records verification rather than the customary procedures of plant inspections and product testing.

The HACCP system fitted perfectly the description of a 'proactive procedure'. The report further recommended that the responsible agencies form an ad-hoc Commission on Microbiological Criteria for Foods. Sponsored by four US federal government departments – Agriculture, Health & Human Services, Commerce, and Defence – this commission emerged in 1988 as the National Advisory Committee on Microbiological Criteria for Foods (NACMCF). One of its first charges was to develop a report to guide industry and regulators on the structure and implementation of the HACCP system. At about the same time, the Codex Alimentarius Commission Committee on Food Hygiene (Codex) began working on a similar report and further focussed attention on HACCP came from the International Commission on Microbiological Specifications for Foods (ICMSF), a group established in 1962 whose objectives included, amongst other aims on microbiological criteria, sampling and testing, to assemble, correlate, and evaluate evidence about the microbiological safety and quality of foods (www.icmsf.org). The ICMSF published the first complete book devoted solely to the development and implementation of HACCP in 1988 (ICMSF 1988).

Following an abortive NACMCF HACCP report in 1989, both NACMCF and Codex published definitive HACCP reports in 1992 and 1993 respectively (NACMCF 1992; Codex 1993). Because the United States serves as the permanent chair of the Codex CFH, there was some overlap of personnel between NACMCF and Codex CFH. Accordingly, the two reports were quite similar. They were almost completely harmonised and republished in 1997 (NACMCF 1998; Codex 1997).

As originally developed by Pillsbury in the 1970s, HACCP was based on three principles:

1) Conduct a hazard analysis.
2) Determine critical control points.
3) Establish monitoring procedures.

Several food safety failures with this system after 1972 led to the gradual development and use of additional principles to facilitate better management practices. The 1992 and 1997 reports cited previously describe the seven current HACCP principles:

1) Conduct a hazard analysis.
2) Determine the critical control points.
3) Establish critical limit(s).

4) Establish a system to monitor control of the CCP.
5) Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.
6) Establish procedures for verification to confirm that the HACCP system is working effectively.
7) Establish documentation concerning all procedures and records appropriate to these principles and their application.

The global spread of HACCP as the preeminent system of food safety management was greatly facilitated by the Codex report of 1997. Jointly chartered by the Food and Agriculture Organisation and the World Health Organisation of the United Nations, the Codex Alimentarius Commission's reports have the effect of law between United Nations' (UN) trading partners who are signatories to the World Trade Organisation. Thus, the humble beginnings of HACCP as a voluntary programme within the US food industry in 1972 evolved into an effective global system. Prominent international publications also facilitated the understanding and acceptance of the HACCP system of food safety (ICMSF 1988; Mortimore and Wallace 1994, 1998, 2013). There is now a global understanding and implementation of a food safety management system that is the same in almost every country. This is a remarkable achievement that can serve as a model for international cooperation and improvement in additional areas such as animal, plant, human, and environmental health – areas that interface with our efforts to assure food safety.

Despite this promising history, HACCP has sometimes been misused as it was incorporated into regulations. Three prominent examples illustrate this unfortunate situation in the United States (Sperber 2005a).

The first of these was a final rule published by the US Department of Agriculture (USDA): Pathogen reduction; Hazard analysis and critical control point (HACCP) systems (CFR 1996). Commonly known as the 'megareg', this very lengthy document required no CCPs to enhance the safety of raw meat and poultry products. Rather, it required conformance to a number of statistical sampling plans that permitted the presence of salmonellae and certain levels of indicator microorganisms. The *Salmonella* performance standards best exemplify this point (Table 1.3). The performance standards were developed from baseline surveys that were conducted in the early 1990s. In the case of ground beef, for example, the performance standard was determined to be 7.5% *Salmonella* positives. To monitor compliance with this standard, a single 325-g sample (tested as 5 × 65g subsamples) of ground beef is analysed for the presence of salmonellae each day for 53 consecutive production days. If five or fewer samples are found to be positive for the presence of salmonellae during this period, the production facility is judged to be in compliance with its HACCP plan and no regulatory action is taken. If more than five samples are found to be positive, a second 53-day round of sampling is initiated. If a plant fails three consecutive rounds of such surveillance, regulatory action is considered. One or more years could pass before enforcement action was initiated. Clearly such standards, sampling procedures, and delayed or non-existent enforcement actions are unrelated to HACCP. As most readers already know, HACCP is a real-time food safety management programme in which immediate corrective actions are taken when deviations occur at a CCP. Regrettably, the 'megareg' also institutionalised a major misuse of resources, as a great deal of money and labour is necessary to conduct such a programme. While statistically-based sampling plans that

Table 1.3 *Salmonella* performance standards in the US Department of Agriculture 'megareg'.

Species	Performance standard[a] (%)	*n*[b]	*c*[c]
Broilers	20.0	51	12
Cows and bulls	2.7	58	2
Steers and heifers	1.0	82	1
Market hogs	8.7	55	6
Ground beef	7.5	53	5
Ground chicken	44.5	53	26
Ground turkey	49.9	53	29

[a]Percentage positive for *Salmonella*
[b]Number of daily samples tested
[c]Maximum acceptable number of positive samples
(Code of Federal Regulations 1996)

monitor the effectiveness of sanitation programmes (which is a better characterisation of the "megareg") are meritorious, they are more practically conducted with the use of far smaller samples and less expensive analytical methods for indicator microorganisms and tests, such as the aerobic plate count. Moreover, the results of such a sanitation monitoring programme would be closely linked in time to the in-plant cleaning and sanitation procedures.

Similar criticisms can be made of the FDA HACCP rules for the production of seafood (CFR 1997) and juice (CFR 2001). No CCPs were identified and required for the production of raw molluscan shellfish, the seafood category most identified with human illnesses. Unlike the PMO developed in 1923 for dairy products, no mandatory pasteurisation was required for juice products. Furthermore, exemptions were granted to small producers and retail operations, permitting the replacement of several recommended control measures to enhance juice safety with the weekly testing of a 20 ml sample of juice for the presence of generic *Escherichia coli.*

These three regulations bear no resemblance to the HACCP principles promulgated by NACMCF and Codex. Their promulgation as 'HACCP' regulations served to create confusion and undermine the well-deserved and excellent reputation of legitimate HACCP applications.

Despite these several regulatory missteps, numerous effective HACCP rules and regulations have been promulgated by regulators worldwide. Some of these will be highlighted throughout this book. As one example, the USDA (creator of the notorious "megareg") issued an effective rule to enhance control of *Listeria monocytogenes* in refrigerated ready-to-eat meat and poultry products. This rule recommends science-based alternatives that can be put into place as CCPs, for example, the use of post-lethality surface heat treatments or combinations of food preservatives to inhibit listerial growth (CFR 2003). In addition, the FDA formulated two effective rules: the Pasteurized Milk Ordinance (1923) and the Canned Foods Regulations (1973). Containing multiple CCPs, each of these rules remains effective today.

1.3 The Necessity of Prerequisite Programmes

The global adoption of HACCP did not proceed smoothly without the recognition of the need for additional measures to enhance food safety protection. As a preface to some of our discussion in later chapters, it was learned that HACCP cannot operate successfully in a vacuum. Even with HACCP plans in place, food safety failures sometimes occurred because of inadequate cleaning and sanitation procedures, for example. To be successful, HACCP must be supported by a number of prerequisite programmes (PRPs) (Sperber et al. 1998). We learned that food safety cannot be assured by HACCP alone. Rather, food safety can be much more effectively assured by the combined implementation of HACCP and PRPs (Wallace and Williams 2001). Originally formed to develop and implement HACCP plans, HACCP teams evolved into Food Safety Teams that must consider and manage both HACCP and PRP responsibilities and activities. PRPs are discussed in detail in Chapter 10.

It was also learned that HACCP does not usually work from 'farm-to-table', as many had hoped (Sperber 2005b). The types of CCPs that are available in the food processing industry, where HACCP originated, are usually not available at the 'farm' and 'table' ends of the farm-to-table spectrum. Rather than thinking about farm-to-table HACCP, we should be thinking about farm-to-table food safety. A hazard analysis can be conducted at every step of the farm-to-table supply chain. When no CCPs are available to control a significant hazard at the 'farm' end (e.g. pathogen colonisation of live animals), PRPs could be put into place to reduce the pathogen burden in the following links of the chain.

1.4 Recent Regulatory Developments in the United States

It has been obvious for more than four decades that, when it has been properly implemented, HACCP works well to assure the safety of processed foods, such as meat, dairy, and vegetable products where CCPs such as freezing, retorting, or cooking are easily applied and controlled. This success, however, contributed to false expectations on the part of many consumers and others unfamiliar with the food industry that ***all*** foods could be produced and marketed without being contaminated with pathogenic microbes. For the many foods that are consumed raw or undercooked, such as produce and raw meats, it is both unrealistic and unscientific to assume that these can be free of pathogens when no CCPs are available (Sperber 2005b). Simultaneously, consumers and their advocacy groups unwittingly blocked the use of treatments, such as electronic-beam radiation, that would improve the safety profile of such products with unscientific claims such as 'irradiated poop is still poop'.

Beginning about a decade ago, the FDA undertook a major effort to improve food safety outcomes by developing the Food Safety Modernization Act (FSMA) to be applied to some of the foods it regulates. This may have been a reaction stimulated by several major incidents during 2006–2008 (historically the game-changing improvements to food safety and regulation have been driven by failure [Acheson 2014]), but it was long overdue. The FDA likely was reacting to an outbreak of *E. coli* O157:H7 in fresh spinach, the deliberate contamination of imported wheat gluten with melamine, and the widespread cover-up of *Salmonella* in peanut paste, which was used in hundreds of food products.

Today, there are a few who think that FSMA will be not only unproductive, but might also impose extreme and counterproductive measures on the facilities it regulates. There are many others however, who are keen advocates and supporters of the FSMA and in particular, the preventive approach, as it so well marries HACCP and PRPs. One of the reasons for food safety failure (despite having a HACCP plan) is the disconnect between the two when undertaking a hazard analysis and establishing control measures. The gap has demonstrated lack of real understanding in many company HACCP plans and food safety programmes. Some operators are optimistic that the FSMA approach will help bridge that gap.

A review of the FSMA content shows that it is based largely on what has been covered very effectively by the food industry's HACCP plans and PRPs for the past 40 years; however, the benefit of having FSMA has been to bring these best practices very much to the fore and to require them for all the many food industries in the United States who, surprisingly, were not using the approach because it was not mandated. There are a number of regulations (rules) that have been published under the FSMA. We will not have the space to go through the US and other countries' food safety regulations in detail here, and there are many other sources of that information (FDA 2011b; Neale et al. 2016). What is relevant to note, however, is that two of the rules under FSMA, the Preventive Controls rules for Human and Animal Feed (2015), have the goal of identifying hazards (known or reasonably foreseeable), which may exist other than at CCPs and require a preventive control. Experienced supporters of HACCP know that in some company HACCP programmes there has long been provision for preventive control points (PCPs) or control points (CPs); (Mortimore and Wallace 2013), but that was voluntary and the company's own choice to do (i.e. not standardised). The FSMA makes it an approach that any manufacturer or importer into the United States is *required* to take.

Despite its lengthy time and cost of development, FSMA unfortunately has a relatively small involvement in the US food supply. While the FDA regulates about 80% of the US food supply, these foods account for a very low percentage of foodborne illnesses. Spread by food handlers in foodservice and institutional operations, norovirus is responsible for 58% of all foodborne illnesses in the United States. However, the FDA does not regulate food preparation and handling in these operations. The FDA also does not regulate meat and poultry products. These are regulated by the USDA, which account for 22% of the US food supply. The United States, perhaps along with other countries in the same food-regulatory quandary, could benefit from the formation of a single federal food safety agency that would bring a unified and scientific approach.

1.5 The Future of HACCP

The evolution of HACCP principles in developed countries from 1972 to 1997, a period of 25 years, seems quite rapid in the flow of global political events. However, we are optimistic that the continued globalisation of HACCP throughout the developing countries will proceed much more quickly. A major reason for the more rapid implementation of HACCP in developing countries is the quickly increasing globalisation of food trade. Global trading partners benefit by the uniform application of the most effective food safety procedures. In particular, aided by the inherent authority of the

Codex HACCP document, global food corporations have been largely responsible for the globalisation of HACCP.

The HACCP system was expanded from three principles in 1972 to seven principles in 1992. Whilst it may be reasonable to anticipate that additional principles will be developed and added in the future – as will be discussed in Chapter 4 – at the time of writing, it seems unlikely. The Codex Alimentarius Committee (CAC) agreed to open up the principles of food hygiene and HACCP for revision in 2015. The seven principles are so well incorporated into global regulations and private standards that it seems likely to remain at the same seven at this stage. However, there will be changes aimed at clarifying a number of the more difficult areas, including hazard analysis. It will take time for all stakeholders to agree on what the changes are.

Looking into the future, it is quite likely and appropriate that the HACCP system will continue to evolve. There is already an emerging recognition that even the broad matter of food safety cannot be managed in isolation from other health systems. Rather, food safety systems of the future will likely interface more directly with animal, human, and environmental health, and food security programmes. At the end of the 20th century, HACCP systems were positioned as the 'crown jewels' of a food safety programme, supported by PRPs. This particular arrangement should persist for a very long time, but it will likely become integrated into a much larger network that includes public health, animal health, food security, and agricultural sustainability.

1.6 Conclusions

The reader should remain aware that almost all of the progress in the development of HACCP as an effective food safety management programme and its global acceptance and use has been accomplished by the voluntary efforts of global food companies, beginning with The Pillsbury Company in the 1970s and continuing today with the efforts of many dozens of responsible and progressive food companies. Except for the 1997 Codex document that gave guidance for the use of HACCP and hygienic practices, and ongoing participation in Codex committees, there has been very little contribution to this effort by federal and intergovernmental public health and food agencies until recently. We will propose bold recommendations for the future effective involvement of federal and intergovernmental organisations in food safety matters in Chapter 4. Such involvement will be essential in order to maintain food safety in the rapidly changing global food supply chain.

2

Lessons Learned from Food Safety Successes and Failures

2.1 Introduction

If HACCP works so well then why do we still have so many cases of foodborne illness? This chapter will attempt to answer this question, drawing upon our own experiences together with observations made by others in the industry. Someone once said that a sign of madness is to do the same thing over and over and expect to get a different result. It feels a little like this in the food industry. Only by learning from other people's mistakes, by understanding root causes, and by doing things differently will we really start to see improved food safety.

2.2 Benefits of Using HACCP: Lessons Learned from a Successful Implementation

There are real benefits when HACCP is effectively designed, implemented, and maintained. This is not just from HACCP alone; the benefits really come through having a well-designed, broad-reaching food safety programme that has HACCP at the core. Key benefits include:

- *Public Health Protection*: This has to be the number one priority for anyone in the food industry. All consumers have a right to safe food that will nourish and sustain them. Any business will want to ensure public trust and confidence in its products. Costs of foodborne illness are significant. Monetary estimates may vary (see Table 2.1), but the human costs related to illness and death impact hugely on the individuals concerned, their families and friends. The World Health Organisation (WHO) recognises HACCP, when properly used, as the most effective way to ensure food safety and to protect public health (WHO 2007b).
- *Science based*: HACCP and the broader food safety programme must be based on sound science. This takes time and knowledge to do properly and can therefore be a challenge for small and less developed businesses where limited technical resources are available. Understanding of hazards and how they manifest themselves, validation of the various effective means for control, and techniques that look at likely failure modes are all essential for development of a robust programme, but this depth of understanding is what it takes for a company to be justifiably confident in their food safety strategy.

Food Safety for the 21st Century: Managing HACCP and Food Safety Throughout the Global Supply Chain, Second Edition. Carol A. Wallace, William H. Sperber, and Sara E. Mortimore.

- *Brand Protection*: Coming high up on this list not just because it is important to senior managers and business owners but because brand protection is essential for the continuation of the business or product line. Some brands and companies are never able to fully recover from an adverse food safety event. Later, we will examine some of the recent cases of foodborne illness and the reasons why they occurred. Many of them involved global brands and many of them are or were household names.
- *Cost Benefits*: So many publications list cost as a barrier to implementation, but in reality HACCP and a strong food safety programme can actually save a significant amount of money through prevention of failure. Any reader who is sceptical should examine whether their business truly understands the costs and implications of failure. Figure 2.1 illustrates how the cost of prevention is typically and significantly less than the costs associated with failure. The cost of prevention includes having an appropriate number of technically qualified staff, programmes such as HACCP, effective good manufacturing practices (GMPs) and hygienic operating environment, training and research. Costs of appraisal will include multiple inspection and testing activities such as audit (both internal and external third party), supplier audit, environmental microbiological monitoring programmes, product testing, and process control monitoring. Internal costs of failure are often underestimated but can be startling. This will include costs associated with holding product, testing product, destruction or downgrade of product that did not meet specification, consumer complaints resolution, claims, and staff time involved in these activities. External cost of failure obviously depends on the size of the company, but recall costs if the product has national distribution can quickly rise to tens of millions of dollars. Brand equity damage is another loss, but of course, as mentioned, the most important cost of all is the cost to human life in the event of severe food safety failure. The cost of implementation really depends on how the company was being run prior to implementing HACCP (McAloon 2001).

- *Increased Confidence through Reduced Reliance on Ingredient and End Product Quality Control (QC) Testing*: Food safety cannot be instilled by testing, and the likelihood

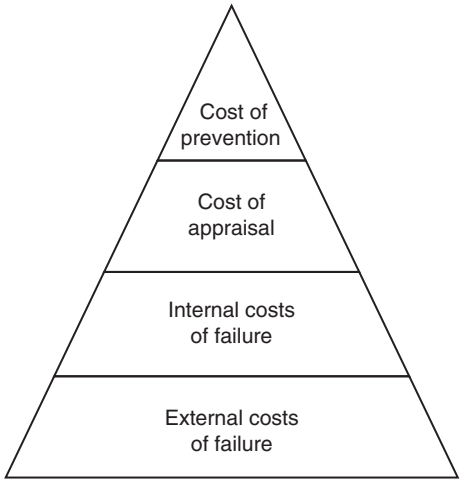

Figure 2.1 The cost of quality.

of finding a food safety hazard is much lower than many food business operators might realise. As discussed in Chapter 1, reliance on end product testing for food safety assurance is not only impractical, given the number of samples needed, but it is ineffective at low levels of contamination. Use of HACCP will move a company away from this retrospective quality control approach to a way of working that is much more proactive. Companies not only increase confidence in food safety assurance through knowledge that controls are in place throughout the process, but also reduce the costs of ineffective end product testing, and unnecessary waste generated by batch rejection.

- *Real-Time Monitoring*: This allows for timely *corrective* (sometimes *preventative*) *action* to be taken, thereby reducing losses later in the process. In identifying controls that require monitoring throughout the production process, corrective action is able to be taken before finished products are made, thereby preventing waste. Once a product is made, it is usually too late to correct - other than by reworking. In Chapter 12 we will see how identifying operational limits in addition to critical limits can be an aid to making timely corrections, that is, in having the ability to adjust the process before it goes out of control.
- *Meets Regulatory Obligations and Customer Expectations*: Whether a formal regulatory requirement or not, implementation of HACCP enables a company to meet regulatory obligations and customer expectations for safe food. Effective food safety management will *keep company executives out of jail*. Senior management has the ultimate responsibility for food safety, and there have been a number of well-publicised failures where the management team was held accountable. In terms of regulation, countries vary in their requirements. Where HACCP is not regulated but is voluntary, the fact that it is recognised by WHO as being the best way to ensure food safety is a good reason to use it. HACCP is also recognised in global trade agreements through the World Trade Organization (WTO). Some countries and customers require third-party certification as a means of demonstrating that the HACCP programme has been independently assessed.
- *Global Food Safety System*: As established through Codex, HACCP was one of the first truly global food safety systems. This gave a common language and expectation amongst customers, suppliers, and regulatory enforcement authorities around the world and has become the basis for more recent global standards developments such as ISO 22000 (2005) and the Global Food Safety Initiative (2017).
- *Focused Use of Resources*: Use of HACCP enables a focused use of resources. HACCP is risk-based and therefore helps a company shift mentality from a 'one size fits all' approach to a 'what is the risk and how do we reduce it through introduction of focused control measures' mindset. When we come to look at barriers and misconceptions, it will be clear that the understanding of HACCP, and what it can do for a company that is committed to food safety, is often lacking.
- *Unanticipated Benefits*: Such benefits of using HACCP for food safety include a number of elements. There is usually a significant improvement in product quality as the preventative approach becomes the new culture of the organisation. The workforce can become highly motivated and empowered through greater involvement and team engagement. This has to be orchestrated as it rarely happens by accident. More discussion on this will take place in Chapter 9 when we review preparation activities. The same economic benefits can be seen for quality improvement as were seen for food safety. There will also be increased regulatory compliance - any food that is

adulterated (leading to a food safety issue or not) will likely be withdrawn from the marketplace before it becomes a regulatory matter (see also Chapter 13). Finally, there is a real competitive advantage that comes through having strong food safety programmes, with multiple functions (not just Quality Assurance personnel) who can really talk confidently about their company's food safety programmes.

2.3 Misconceptions or 'Failure to Understand HACCP'

Controversial issues exist 50 years after the concept was first conceived. HACCP is a tool that was designed to *enhance*, not hinder, food safety management programmes. It was revolutionary in moving companies away from reliance on end product testing to a systematic preventative approach. Whilst it is frustrating to see that many companies have yet to truly grasp the concept and how many misconceptions remain, this also means that the opportunity to implement a really good HACCP programme remains available to many in the industry. Others have also documented this (Motarjemi and Käferstein 1999; Motarjemi et al. 2014). Listed here are a number of often heard misconceptions:

- '*HACCP has been 'done' already*'. This view is most commonly held by large food manufacturers in the developed countries and even by some regulatory agencies. For example, when a HACCP-based programme for small businesses was launched in the United Kingdom by the Food Standards Agency, it was reported by an official that larger manufacturers had 'done' HACCP and were not of concern. It is interesting to consider some of the recent outbreaks of foodborne illness which originated in large companies in developed countries (see Section 2.5.1; Table 2.1). These case studies serve as a constant reminder to never be complacent and take food safety for granted. Food safety management is a continuum; it is never 'done'. Complacency is the enemy.
- *'Having a HACCP 'plan' = HACCP'*. A HACCP plan is a document. The document must capture knowledge and activities that are implemented, maintained, and supported by strong prerequisite programmes (PRPs), including having a hygienic operating environment and an educated and trained workforce. HACCP plans need to be owned by the business which generally means that they should not have been written by an external consultant. They must be based on a hazard analysis which considers all aspects of the product and the manufacturing process at all times. A consultant will not normally have that depth of knowledge unless working very closely with the company over a prolonged period of time. The HACCP plan needs to be current, which means being regularly reviewed and always updated when anything changes either in the product formulation, the process, or the operating environment. HACCP is not a paper exercise.
- *'HACCP Costs Too Much'*. How can any business afford *not* to use HACCP? (See earlier discussion on cost benefits). This issue needs more discussion in the public domain. Smaller businesses may need help to understand their true cost base. Public health professionals need to support education of consumers as well as their own teams to ensure both a well-informed customer base and enforcement authority. If evidence is needed that HACCP can save money, McAloon (2001) describes savings of $150 000 per year at Cargill through originally unintended cost savings that resulted from just one critical control point (CCP) improvement in process control. Costs

associated with the perceived need to add human resources are a genuine concern, however. Often, large companies find that they already have sufficient personnel in place to develop HACCP programmes and can usually reallocate people to more productive activities related to HACCP development. The cost of implementing HACCP is often confused with the cost of needing to upgrade PRPs in order to comply with sanitary design requirements, and this is often a real challenge in both large and small companies (see Chapter 10).

- *'HACCP is complicated and requires a huge amount of documentation'*. Whenever this is stated, it is often a result of poor understanding of what is needed. Where HACCP is highly focused on food safety critical controls, often the record keeping is minimal and, in many instances, can actually be reduced on a day-to-day basis when compared with previous systems. As a new approach, it can feel different - new practices and new terms will be introduced. It is really important to invest the time in both educating and training everyone in the business, particularly where increased documentation is a concern. Care should be taken to avoid jargon when starting to implement HACCP as this can overly concern employees. The mystique surrounding HACCP should be removed and the concept presented in simple terms to ensure that it is seen as a practical straight-forward approach. Records do need to be maintained both as evidence that the company has done the right thing and for peace of mind that products were made safely and according to specifications. Records are required for government and customer inspection as evidence the process was under control. In these ways, records can be presented in a positive light rather than being seen as a burden.
- *'HACCP requires too many resources'*. This can be a real concern for small companies, but many large companies also operate lean organisations. Certainly, when starting to implement a programme, the resources required will be more than are needed for running an established programme. There will be a need for training of the HACCP team and team leader, and for the wider workforce. Access to additional technical expertise might be needed if it doesn't exist in-house, and temporary administrative help will probably be a benefit. However, the benefits once implemented (e.g. reduced waste, fewer consumer complaints, improved quality, reduced testing) should offset many of the resource concerns.
- *'HACCP by itself will control food safety'*. HACCP is at the core of the food safety programme but is part of many other, often interrelated, activities. When HACCP was first being discussed more widely, some companies mistakenly believed that it replaced the need for solid PRPs (Wallace and Williams 2001). WHO (1998) defines PRPs as 'Practices and conditions needed prior to and during the implementation of HACCP and which are essential for food safety'. Most food safety failures are not failures of the HACCP system. Rather, they are usually caused by a lack of management commitment to provide adequate resources or a failure to properly manage PRPs, both of which indicate a poor food safety culture.
- *'HACCP is a one-time activity'*. HACCP is anything but a task that is done only once; however, after the major effort of conducting the HACCP study, many companies breathe a huge sigh of relief, mistakenly believing that the job is done. This is far from true. HACCP needs to be alive within the organisation, constantly at the forefront of people's minds regarding any change to the product (including its ingredients), the process, or the environment. External prompts such as emerging information on

hazards, other industry food safety issues, and availability of new technology need to be considered. Companies that fail often haven't recently reviewed and updated their HACCP plans.

- *'HACCP is not suitable for small companies'*. The consumer has a right to safe food whoever produces it. All food should be safe. It is perfectly possible to undertake a HACCP study and to implement a programme in a small business. However, there are often resource constraints, not least of which is the human resource in the form of technical knowledge. If the technical knowledge is available in a small business, then HACCP can be implemented. Some enterprising small companies have called upon their suppliers, customers, or trade and professional organisations to help them (Route 2001). Others have used consultants; however, it is important to ensure that they have the required competency (i.e. knowledge in both HACCP and the industry sector). Generic HACCP plans can also be a useful starting point (WHO 1999), but need to be customised for the businesses' products and operating environment.
- *'Zero risk is possible'*. This is an interesting and ideal statement. Although zero risk is unattainable, HACCP and PRPs in combination with a supportive food safety culture provide the most effective means of delivering safe food to the consumer (Mayes and Mortimore 2001). Generally, too little attention is given to the fact that use of HACCP can only minimise risk by reducing the likelihood that a food safety hazard will occur (Cormier et al. 2007). With microbiological hazards we have fairly common agreement and we are able to estimate risk in quantitative terms (e.g. log reduction during processing or estimation of microbial growth under certain conditions). With chemical hazards this becomes more difficult as technology advances (DeVries 2006). For example, when we are unable to detect the presence of an adulterant, we can say that the food is acceptable. However, technological advances might mean that smaller levels of the adulterant are now detectable than previously, and whilst this doesn't necessarily mean that the food is any less safe than before, there is now a regulatory and consumer concern that the food is adulterated with chemicals that should not be there. This technology advancement also, of course, has impact on increasing food waste and food insecurity (see Chapter 3).
- *'Farm-to-table HACCP is not possible'*. The reported successes of HACCP systems in food processing facilities led to interest in applying it to all segments of the food supply chain, from farm to table. As discussed in Chapter 1, whilst hazard analysis can be used and the process of conducting a HACCP study will provide a structured approach, the definitive control measures that are available to food processors in the centre of the supply chain are not often available at the 'farm' and 'table' ends of the supply chain, as well as at intermediate points. We cannot emphasise strongly enough that food safety is best assured by the simultaneous use of HACCP and PRPs. The latter must be used to the maximum possible extent in segments of the supply chain in which definitive HACCP controls cannot easily be used.

2.4 Barriers to Effective HACCP Use

Barriers to use of HACCP fall into two main categories:

- Those related to misconceptions, many of which have already been outlined.
- Those that are genuinely a hindrance to moving forward.

We need to articulate what the real and perceived barriers are in order to find solutions. If we are unable to do this, then the food supply chain remains at risk. Many of these barriers listed below stem from a lack of real understanding (and belief) of hazards and their required preventive controls.

- *Lack of Foundational Food Safety Knowledge*. This is a real barrier and includes not just technical knowledge within the team, which we'll discuss later, but broader managerial food safety ignorance leading to lack of support, as well as basic operator level knowledge that can lead to short cuts being taken and procedures not being followed.
- *Lack of Human Resources*. For small and medium-size businesses, this is frequently stated as a barrier. Even when support was provided through universities (Taylor 2002), the perception of HACCP as not being crucial to their business was voiced by a sample of small companies in the United Kingdom.
- *Local Language Materials Not Being Readily Available*. This is a genuine problem in developing countries such as those in Asia, but also in developed countries where increasing proportions of the food industry workforce may be made up of foreign born workers (Rienzo 2016; Rienzo and Vargas Silva 2017). Books are often translated, but for many people a book on its own will be insufficient for learning. There is a need for local language trainers and practitioners who have experience and competence in HACCP and food safety management, as well as local language training materials and, where appropriate, examinations.
- *Lack of Competent Third-Party Consultants*. A consultant who has limited actual experience of working in a HACCP team can be detrimental to the HACCP process in a number of ways. Firstly, if they don't have a good understanding themselves, weaknesses will be built into the HACCP system, and secondly, they may be unable to transfer ownership to the business team. This latter point will mean that the HACCP study will have been a one-time activity and not a live 24/7 beneficial element of the food safety programme.
- *Insufficient Expertise*. Lack of expertise for biological, chemical, and physical hazard analysis (HACCP Principle 1) within food companies, particularly at manufacturing sites, is a concern. This has been compounded by insufficient guidance on the application of HACCP Principle 1 (Wallace 2009). If the hazard analysis is inadequate, then the food safety programme is not going to be complete or of real value. Those charged with implementing a HACCP programme *must* become the experts in their organisations. They need to *really* know their products and plants at all times, under any and all operating conditions, and in great depth. They need to cross refer to known or potential hazards in the ingredient and product categories, understand implications if the products are cross-contaminated, and have a thorough knowledge of effective control measures.
- *Validation and Verification Difficulties*. Generally, verification is not too difficult once properly understood. Validation, however, needs to confirm that the elements of the HACCP plan are complete and that it will be effective in controlling the hazards of concern. It includes a review of scientific literature as well as possible microbiological challenge studies and in-plant process validation. Small companies certainly need help with this and may not be able to do much more than the literature review and some basic process confirmation unless they have some expertise on their staff. Large companies can also find this difficult given that much of the work happens at the plants.

- *Lack of Equipment and Poor Infrastructure*. This includes lack of control devices such as sifters, sieves, magnets, metal detectors, and bar code scanners, or lack of monitoring equipment such as thermometers, pH meters, or chart recorders. Incorrect plant layout is often a major challenge (Panisello and Quantick 2001). Plants must be designed to allow appropriate flow through the process with prevention of cross-contamination as a key objective. If this isn't the case, then HACCP implementation is a much more challenging (and costly) task due to the need to control and upgrade hygienic layout through risk assessment.
- *Misleading HACCP Publications*. Unfortunately, whilst there are many excellent publications on HACCP, there are also quite a few that contain misleading information. Some of these may be a result of knowledge having developed since they were written, but there are a number that indicate poor knowledge and understanding by the authors. This makes it very difficult for those newer to the concept to differentiate between what is a reputable source and what might be misleading when looking for good sources of information.

2.5 Reasons for Failure

2.5.1 Lessons Learned from Major Food Safety Events

With increasing expectations from consumers, the ever-improving ability to detect hazards and the real root cause of foodborne illness, together with advancing food safety knowledge, the bar is continually being raised in terms of food safety management. We should be seeing a fall in the incidence of foodborne illness, and yet this is far from being the case in many countries. In 2016, one article (Maberry 2017) cited 764 food recalls in the United States, which is a 22 percent surge compared to 2015. Two of the main culprits were undeclared allergens, along with *Listeria* contamination. A staggering number of the *Listeria*-related ones – over 50 – were due to sunflower seeds and products containing sunflower kernels. Various recalls were issued by Kashi, General Mills, Hershey, Atkins, Quaker, Publix, Kroger, and dozens of other companies. Recalled products included trail mixes, protein, energy and granola bars, nut butters, and salad toppings. These are all low water activity type products which might not have been considered a *Listeria* risk previously. Whilst part of this may be due to the regulatory position in the United States, it is important to remember that, whilst *Listeria* may be unable to proliferate in these types of products, its presence in any products at certain levels could be a concern and that the addition of low water activity products as ingredients to other products may result in conditions where *Listeria* could grow and cause a risk to consumer health.

It is important that as food safety professionals we remain alert to and continue to review foodborne illness outbreaks that have occurred previously and whose means of prevention are well understood (Table 2.1). Nonetheless, repetitions of such outbreaks continue. The 2015 outbreak of listeriosis caused by contaminated ice cream and implicating user practices could be traced back multiple years (FDA 2015b). In 2015, a prominent US national restaurant chain endured multiple illness outbreaks caused by a variety of enteric pathogens through prolonged product and environmental contamination (Zuraw 2015). The repetitive nature of these outbreaks in different restaurants

Table 2.1 Some examples of major food incidents.

Year	Country	Food	Contamination	Known/Suspected Cause	Effect	Cost	Reference
1989	United Kingdom	Hazelnut yogurt	*Botulinum* toxin	Formulation change to reduced sugar version. Thermal process insufficient for new formula hazelnut puree **Design**	27 ill 1 death	$ millions across entire UK yogurt market	Shapton (1989)
1990	Worldwide	Bottled water	Benzene	Filter not checked in 18 months **Preventative Maintenance**	Worldwide recall; 160 million bottles destroyed	$79 million	Reuter (1990)
1993	Germany	Potato chips	*Salmonella* (90 serotypes isolated)	Contaminated spice mix applied post cook step **Supplier Control**	1000 cases, mainly children	Unknown	Lehmacher et al. (1995)
1994	United States	Ice cream	*Salmonella* Enteritidis	Ice cream mix ingredients were transported in a truck previously used to transport raw liquid eggs **Cross-Contamination**	Over 200 000 ill	Unreported	Hennessy et al. (1996)
1998	United States	Toasted breakfast cereal	*Salmonella* Agona	Cross-contamination from ingredients or environment. Not proven. Plant cited for poor GMPs **Cross-Contamination**	Over 400 cases	Unknown	Breuer (1999)
2000	Japan	Milk products including yogurt	*Staphylococcus aureus* toxin	Lack of temperature control in raw milk during a power outage. Inadequate communication during a crisis **Lack of knowledge regarding risk**	Circa 10 000 ill	Unknown	Wrigley et al. (2006)

(Continued)

Table 2.1 (Continued)

Year	Country	Food	Contamination	Known/Suspected Cause	Effect	Cost	Reference
2006	United Kingdom	Chocolate	*Salmonella* Montevideo	Leaking waste water pipe dripping into production area (*S.* Montevideo found in drain, drain water) where chocolate crumb was manufactured and a seal breach in the crumb system may have contributed. Regulators criticised the manufacturer for their risk assessment, inadequacy of their HACCP plan, and inappropriate use of *Salmonella* testing methodology (most probable number method) and limits in their positive release procedure	Circa 60 cases	Over £21 million; company was prosecuted by regulators and pleaded guilty	Wallace and Lowe (2013)
				Cross-Contamination **Lack of knowledge regarding risk**			
2006	United States	Carrot juice	*Botulinum* toxin	Inadequate pH control to prevent. Product was refrigerated but temperature abuse suspected	4 cases in 2 states (3; 1)	Unknown	Kaye (2006)
				Design			
2006	Worldwide	Spices	Sudan red	Economic adulteration when spices were artificially coloured to look fresher and fetch a higher price	National recalls across many countries, mainly affecting Europe	Over £100 million estimated	Davies et al. (2006)
2008	Canada	Cooked sliced deli meats	*Listeria monocytogenes*	Inadequate sanitation of slicing machines. Insufficient verification testing	22 deaths	Over $20 million	Weatherill (2009)
				Sanitary Design			
2008	United States	Fresh jalapeño peppers	*Salmonella* St. Paul	Not determined- may have occurred on the farm, during processing or distribution	1442 ill; 286 hospitalised; may have contributed to 2 deaths	Unknown	US Centers for Disease Control and Prevention (CDC 2008)

2008	Australia	Frozen meal	Undeclared fish allergen	Company inadvertently packed a tuna meal in a package that did not declare allergen **Mislabelling**	National recall. No known ill effects	Unknown	Current recalls published on FZANZ website (http://www.foodstandards.gov.au/industry/foodrecalls)
2008	China	Dried milk powder	Melamine	Economic adulteration	Estimated 54 000 children ill; 13 000 hospitalised and 4 deaths	$ Many millions	Congressional Research Service (2008)
2009	United States	Peanut butter	*Salmonella* Typhimurium	Leaking roof; unsanitary process conditions; inadequate segregation between raw and roasted peanuts **Cross-Contamination**	700 ill, 9 deaths	100s of $ millions; company filed for bankruptcy	CDC (2009a)
2009	United States	Alfalfa sprouts	*Salmonella* St. Paul	–	228 cases in 13 states	Unknown	CDC (2009b)
2009	United Kingdom	Cooked meats provided to school catering services	*Escherichia coli* O157:H7	Many serious food hygiene deficiencies: staff were poorly trained; single machines were being used for both raw and cooked meats; inadequate cleaning; inadequate HACCP plan which was not implemented; falsified monitoring records; removing spoiled parts of a meat or redirecting them to processed product where the smell would be hidden by spices. These issues were compounded by poor inspections and contract follow-up through school purchasing channels **Cross-Contamination**	157 cases (118 confirmed microbiologically and 39 probable), 1 child died	Full costs not reported; public enquiry costs reported as £2.3 million	Pennington (2014)

(Continued)

Table 2.1 (Continued)

Year	Country	Food	Contamination	Known/Suspected Cause	Effect	Cost	Reference
2011	United States	Cantaloupe	*Listeria monocytogenes*	Environmental contamination **Cross-Contamination**	147 illnesses, 33 deaths	Not reported	Centers for Disease Control and Prevention (CDC 2012a)
2011	Germany	Sprouted seeds	*E. coli* O104:H4	Fenugreek seeds from Egypt found to be contaminated with the organism. No controls in sprouting process **Cross-Contamination** **Lack of knowledge regarding risk** **Design**	3816 cases, 54 deaths	Cost estimate for farmers and industry $1.3 billion; emergency aid to 22 European states $236 million	Frank et al. (2011); Food Safety Magazine News Desk (2015)
2015	United States	Ice cream	*Listeria monocytogenes*	Contaminated ingredients and environmental contamination in factory. Product used to make milk shakes. Traced back multiple years **Cross-Contamination and likely user usage**	10 illnesses, 3 deaths	Likely $ millions	FDA (2015b)
2014 and 2015	United States	Caramel-coated apples	*Listeria monocytogenes*	Insertion of wooden sticks into apple cores **Cross-Contamination**	35 illnesses, 7 deaths	Likely $ millions	FDA (2015a)
2015	United States	Multiple outbreaks/ pathogens in national restaurant chain	*E. coli* O157:H7, *E. coli* 026; *Salmonella* Newport, and Norovirus	Prolonged product and environmental contamination **Cross-Contamination**	491 illnesses, no reported deaths	Likely many $ millions	Flynn (2015)

of the same chain highlight concerns about practices in general but also about learning lessons. Similarly, in the report into the 2009 UK *Escherichia coli* O157:H7 outbreak (Pennington 2009), Professor Hugh Pennington clearly highlighted issues of lessons not being learned since the earlier 1996 outbreak in Scotland (Pennington 1997) in which 21 people had died – 17 directly of infection with the outbreak strain, and 4 associated deaths (Pennington 2014):

> I had hoped that the lessons from the shocking events in 1996 would stay in people's minds. But comparison of the failures that led to this Outbreak in South Wales with those in the outbreak in Scotland shows that this has not been the case (Pennington 2009).

It is more difficult, even for experienced food safety personnel, to understand and control unexpected illness outbreaks that are rare and not easily explained. In the 2011 cantaloupe *Listeria* outbreak (Table 2.1), the cause was attributed to environmental contamination of cantaloupes during harvesting and washing. Outer contamination of cantaloupe skins during agriculture may previously have been perceived to be a risk area; however, the significance of the poor design choice and management of washing equipment may not have been fully understood. Even more difficult to explain, an outbreak of listeriosis was attributed to caramel-coated apples on a stick. Researchers found that the insertion of wooden sticks into the apple core created an environment favourable for the growth of *Listeria monocytogenes* (Table 2.1; FDA 2015a).

In summarising the examples given in Table 2.1 (which is a very small sample of many), a number of conclusions can be drawn:

- There is a worldwide need to improve our food safety programmes. No single country is exempt.
- Food safety failure occurs in large well-known companies as well as smaller enterprises.
- All hazard categories – biological, chemical and physical – are involved.
- Various reasons for failure indicate the need for robust PRPs for assurance of:
  - Cross-contamination prevention
  - improved supplier control
  - hygienic design of equipment
  - adequate cleaning and sanitation practices, and
  - preventative maintenance programmes.
- Knowledge of intrinsic product safety is essential when modifying the design.
- Economically motivated and deliberate adulteration (food fraud) can be a food safety issue but that isn't always the case.
- There are high direct and indirect costs.
- There are sometimes positive (as well as negative) consequences to a failure, particularly a major one.
- **That we have not always learned from past mistakes**.

Most of these examples could have been prevented through safe product design and by avoidance of cross-contamination. Knowledge of the HACCP principles and how to use them effectively is a valuable tool in meeting food safety obligations. However, there are many companies that, despite having learned the basic theory, fail to make the conceptual leap in terms of using it to develop and maintain a food safety culture.

2.5.2 Commonly Observed Mistakes in the *Implementation* of HACCP and Management of Food Safety Programmes

In a company that has a good hygienic operating environment together with a positive culture aimed at doing things right, most of the requirements for HACCP will already be present; they simply need to be identified and brought into the HACCP framework. But even under these circumstances, it is possible to develop a less than adequate HACCP programme without the right advice and guidance. Listed below are some observations to consider and learn from:

- *Overcomplicated and, therefore, difficult to maintain programme.* Time needs to be spent in planning what the system will look like and thinking ahead about the ease of updating to keep the system current. Many companies find that a modular approach works best because it divides the plant and/or process up into manageable units. It is essential to check that there is a proper link between each unit and that all process activities are included.
- *Inaccurate process flow diagrams.* Many companies like to simplify process flow diagrams (PFDs), but in doing so the hazard analysis will be incomplete. Our recommendation is to create a simple outline PFD that can be shared externally along with a very detailed PFD that can be used internally for the hazard analysis. Other reasons why they are inaccurate are that there may have been changes since the PFD was originally drawn up and 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.
- *Lack of understanding of the products' intrinsic safety factors.* It is important to understand what is making your product safe. Is it low water activity (a_w), 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.
- *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 one where technical knowledge is needed. Some experts (Gaze 2009) recommend early consideration of whether the identified hazard is controlled by a PRP. If so, then it is usually not a CCP. Another mistake, but 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, Listeria monocytogenes,* or *Staphylococcus aureus.* By making a specific identification of a hazard, it is much easier 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.
- *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.

- *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 their responsibilities. There are some practical activities that can help:
  - Ensure the monitoring frequency is appropriate
  - Keep the documentation simple and easy to use
  - Train designated CCP monitors well – be sure to verify their understanding and their ongoing behavioural competency on a periodic basis
  - Involve the CCP monitors in the design of any forms
  - Use verification activities to follow up with them with regards to performance and
  - 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 only action required.
- *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. However, research (Wallace 2009) indicates a wide range of weaknesses in HACCP verification systems at production sites of a multinational manufacturer. Although all these sites had a range of verification procedures in place, including internal and external audit, the audits conducted had failed to pick up the weaknesses identified during the research project, and this underlines the need for agreed standard audit approaches and effective training of HACCP auditors (Wallace 2009). It is, therefore, recommended both that food companies question the competency and experience of external HACCP auditors before their engagement, and that standard setters establish effective qualifications, training, and experience standards for HACCP auditors. Recent developments in HACCP-based standards and auditor competency requirements may help to address this issue (e.g. the GFSI Auditor Competence Scheme, www.mygfsi.com). Problems can also arise from misunderstanding that the requirements for HACCP also apply to PRPs which also need validating and verifying. 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 programme and a contributing factor in the business food safety culture. 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
  - Willingness to hold people accountable in the event of failure
  - Provision of resources for food safety activities – seeing it as a priority
  - Frequent and visible confirmation of commitment through 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.
- *Lack of employee commitment*. This is just as important as management commitment and also contributes to the prevailing food safety culture. 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, of course, an essential starting point.

- *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 programme takes a lot of effort to bring to life. Again, education and genuine commitment are key, as is making it a team effort and everyone's responsibility.

The British Retail Consortium (BRC) published its global audit data from both 2013 and 2014, indicating that HACCP was the most frequently identified issue across over 17 000 manufacturing sites in multiple countries. Interestingly, the 2015 data shows that certain PRPs such as having a documented cleaning programme, and prevention of cross-contamination are now leading (BRC 2013, 2014, 2015).

2.6 Difficulties with Applying HACCP through the Entire Food Supply Chain

HACCP is a tool used to systematically identify significant hazards and preventative control measures which eliminate or reduce them to an acceptable level. A fundamental problem with doing this from farm to fork or in the case of animal feed – from field to trough – is that each link in the chain has no control over the next link and only limited control over the previous link.

In considering the supply chain (Figure 2.2), it is clear that even in this simplified diagram there are many stakeholders. In reality, there will be hundreds of them per product – adding up the farmers, the raw material suppliers, the distributors, and the numerous transport and storage stages. Communication from one to the next is often poor, with many opportunities for failure. In some countries, traceability is also weak and very few products use only local ingredients. However, each element does have a degree of control over the one that comes before it through supplier quality assurance (SQA) programme implementation, including having agreed specifications, conducting on-site

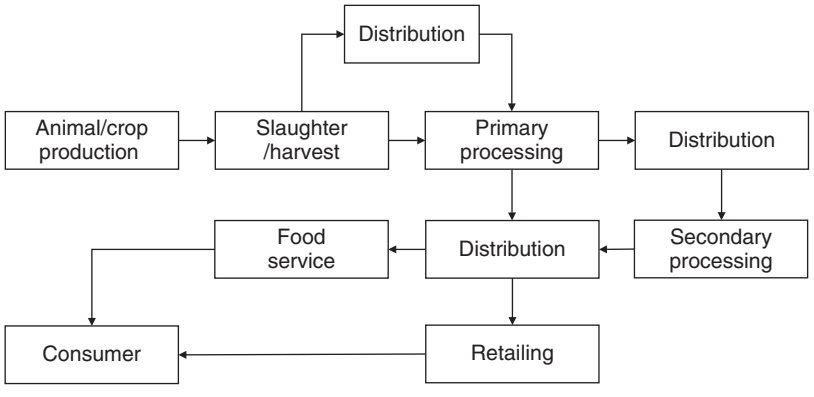

Figure 2.2 The supply chain model. *Source*: Adapted from Sperber (2005).

audits and inspections, and Certificates of Analysis (COA). These are PRP elements, but HACCP and, in particular, the hazard analysis that is done can be used to focus efforts towards ensuring that vendors back up the chain have knowledge and control over the elements of their programmes that are critical to food safety. Again, it is HACCP and PRPs that are being used to assure food safety – not just HACCP alone. There can be liability issues with SQA programmes and, for that reason, it is not recommended that any formal approval is given of a vendor HACCP plan, but using the HACCP tool to audit their programme is a valuable exercise. Problems have occasionally arisen where a customer does this but then tells their vendor where the CCPs should be. Both parties should refer to the science and get independent expert advice if needed. Another option (if the vendor and customer disagree) may be to highlight the control as a preventative control point (CP), or as part of a PRP.

A greater challenge comes in considering whether control can be applied *forward* through the chain. Arguably not, other than with clear communication of requirements using specifications and labelling. Some companies do go as far as to 'audit' who they do business with and, in the United States, making sure that your customer is aware when hazards are expected to be controlled through their part of the supply chain is now coming into the regulatory arena. In our experience, there can be a real benefit in ensuring that your distributors and customers have the capability to understand and handle your product correctly.

It is no surprise that the HACCP approach to food safety management originated at the centre of the food supply chain with the food processors. Their success in applying definitive control measures such as pasteurisation, sterilisation, acidification, and water activity reduction to processed foods led to the global acceptance and use of the approach. This in turn led to a move to apply HACCP from farm to table. At the farm end, hazard analysis is extremely useful in identifying hazards that need to be controlled. Consider the situations with fresh produce and raw meat and poultry products, which are responsible for a significant proportion of current foodborne illness outbreaks when they are contaminated with salmonellae, *E. coli* O157:H7, and *Campylobacter* spp. It is well established that cooking raw meat and poultry to a minimum centre temperature of 70°C will kill the above pathogens. Whilst raw meat and poultry producers cannot eliminate pathogens at the farm, many animal husbandry practices such as providing clean drinking water and using vaccination, competitive exclusion, and hide cleaning before slaughter can reduce, but not eliminate, pathogens (see also Chapter 16). At this stage, it is the PRPs that are used to great effect.

At the table end of the supply chain is the consumer. Consumers often have limited knowledge, and there is much evidence that poor practices abound in home kitchens (Griffith & Worsfold 1994). However, consumers can cook raw meat and poultry just as the processors can. Given the many millions of servings per day of cooked meat and poultry, it is not surprising that some consumers unintentionally or deliberately undercook meat or cross-contaminate from raw meats to other foods, such as salad ingredients, in the kitchen. In the matter of fresh produce that can be consumed raw, definitive control measures to eliminate pathogens are not yet available even to food processors. Whilst good agricultural and sanitation practices can reduce the numbers of pathogens on fresh produce, they cannot assure elimination of all pathogens. Cross-contamination and poor temperature control (cooling and storage) combined with their need to make choices (such as wanting meat rare) make this a challenge. As manufacturers, we must validate and clearly communicate preparation instructions.

As will be discussed later, consumers and all stakeholders in the supply chain will need more realistic views on the presence of pathogens in foods that are traditionally consumed fresh or raw.

HACCP can be extremely useful in understanding where the significant hazards and control measures are across the entire supply chain. It is systematic and provides an excellent framework for discussion, and we would highly recommend its use in this way despite the limitations. A key lesson learned over the years is that, as food manufacturers, we have the responsibility to do everything possible to assure the safety of the food we produce. Knowledge of how our raw materials are produced, likely hazards and controls at our suppliers, together with understanding the effect of likely abuse in distribution and sale is vitally important as we design our products and set process parameters.

Despite the difficulties, HACCP can be a useful tool in helping to assure food safety from farm to table. However, HACCP alone is not enough, PRPs must be in place throughout, plus the willingness to share the responsibility and have good science-based dialogue between all stakeholders.

2.7 Roles and Responsibilities: Lessons Learned

Everyone has a role both as individuals and as organisations. WHO defined this as the concept of a 'shared responsibility' (Figure 2.3). As we have just seen, the global

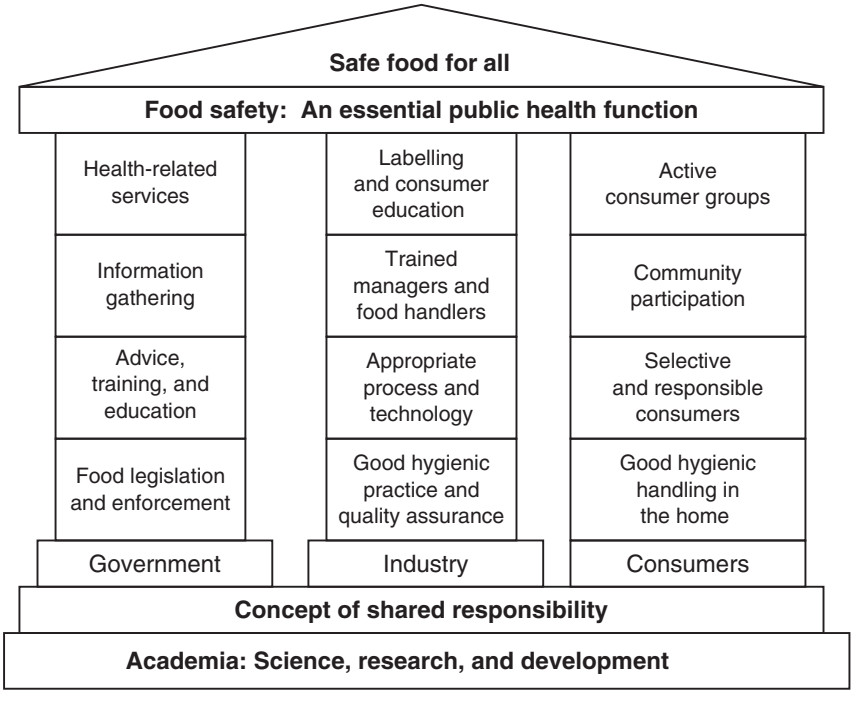

Figure 2.3 Temple of food safety.

supply chain is highly complex and will only become more so over time. The range of hazards is broad and the food safety challenges that the industry has to address are enormous. Ensuring food safety in today's world is a formidable challenge and we have to work collaboratively. Whilst everyone has a role, the responsibilities need to be defined (Mortimore and Motarjemi 2002) and, as nations, we should not be arrogant in thinking that our way is the only way.

2.7.1 Industry

We have a responsibility to do everything possible to prevent unsafe food being sold to the consumer. We have a long way to go with regards to proper implementation of tools such as HACCP. We need to do a better job with training and educating our workforce, and we have a responsibility to communicate issues quickly and accurately in the event of a problem.

We have to carefully consider the science and do the right thing in designing products (ensure intrinsic safety), in operations (follow defined procedures), and in knowing when and how to take corrective action when needed. We need to be open to new and different approaches to food safety management. A key lesson learned is that there are best practices in industry in all parts of the world. We have a responsibility to share our knowledge and be open to finding new solutions to old problems. Food safety should not be a competitive advantage.

2.7.2 Government

Government's primary responsibility is for *setting policy and regulations* and taking care to be transparent in the process. This role includes establishing initiatives for the regular evaluation of existing regulations through gap analysis, assessment of impact, and review of likely effectiveness across the supply chain. Governments need to ensure focus is maintained with regards to food safety policy as opposed to food policy. Enforcement of regulations is a key task, but arguably this can be done in a supportive as opposed to policing manner. Government is also responsible for considering consumer opinion (perception) in the risk analysis process and for risk communication.

Governments/public health agencies have a *hazard guidance role and responsibility*. They should be unified in establishing guidance on potential hazards by food category. They conduct risk assessments as significant new hazards emerge, for example, *L. monocytogenes* in soft cheeses and deli meats in the 1980s, and more recently, Acrylamide. They are also responsible for monitoring environmental contaminants.

Consumer information and education is essential and government often plays a role here too, for example in the home, in the school education system, in the workplace for food handlers, for health professionals, and the media. Increasingly important is the need for the various national governments to liaise and agree key messages given the rapid developments in global communications.

Crisis management and communication in the event of major outbreaks or incidents (see Table 2.1) is essential to ensure information flow and to maintain control as much as possible. Consumers as well as manufacturers and distributors need information in order to make informed decisions and to conduct investigations. Governments also have a responsibility to ensure resources are available for rapid investigation, to share key learning, and to give advice on preventative actions.

2.7.3 Retailers/Foodservice Establishments

Increasingly recognised as being a highly impactful element of the supply chain. Food retailing and food service covers such a wide range of operators that to discuss them under one heading is almost inappropriate. However, there are some general themes that are noteworthy.

The large global retailers and foodservice chains have the ability and therefore the responsibility to influence manufacturers, support services, distribution, operations and consumers. The Global Food Safety Initiative (GFSI), whilst not perfect, has provided a forum for the global and national operators to come together to take a more coordinated approach (e.g. to required expectations, third-party audits, specification format, COAs, and testing). It is very inefficient to be operating to virtually the same standards but in many different formats.

With the desire to sell locally produced foods as well as to distribute internationally, these organisations have the purchasing power to raise standards worldwide by sharing knowledge and influencing providers of consultancy, verification activities, training, and equipment.

Retailers and foodservice companies have a responsibility to have frequent dialogue with manufacturers in the event of a food safety market recall. Sometimes, these events can have a global as well as local impact. The horsemeat scandal in the United Kingdom fuelled frequent dialogue both nationally and internationally with suppliers, manufacturers, retailers, foodservice operators, and testing laboratories, working in unison to manage through that very challenging issue.

Retailers and foodservice providers can talk directly to consumers. This can be done reactively, where there is a real or perceived public health concern as in the case of the horsemeat crisis mentioned earlier, or proactively. In the latter case, we often see the public looking to the retailers as a source of advice and guidance on topics such as the safe handling of foods, healthy eating, and nutrition. They have the ability to educate and many do this well.

2.7.4 Trade and Professional Associations

Trade organisations have several roles. They can be extremely helpful in providing a forum for companies to come together to discuss pending legislation, which enables the trade association to lobby on behalf of the industry. They are also an excellent forum for information sharing across their membership. Whilst often largely financed by the larger companies, both large and small companies can share knowledge in a neutral setting, recognising that just one incident in a category can have a catastrophic effect across the whole sector.

There are many good examples of their work, so we will just highlight a few by way of illustration. In the United States, the Innovation Center for US Dairy has been running food safety workshops since 2011. These are facilitated by subject matter experts from the member companies and delegates include those member company employees, but they also come from smaller enterprises with limited resources. The same organisation also funds research and publishes guidance documents, including a recent one on control of *L. monocytogenes* (Innovation Center for US Dairy 2015). Also in the United States, the Grocery Manufacturers Association has published many excellent reference

documents, runs frequent training courses, and has experts on staff who are available to its members. It has long been associated with thermal process training but more recently has published on wide ranging and very relevant topics such as *Salmonella Control in Low Moisture Foods* (Grocery Manufacturers Association 2009) and the *Industry Handbook for the Safe Shelling of Peanuts* (Grocery Manufacturers Association 2016). In the United Kingdom, the Chilled Foods Association is another good example. Its *Best Practices Guidelines for the Production of Chilled Foods* (Chilled Foods Association 2006), is now in its fourth edition, and that will not be the last. There are trade associations in most countries and they are of great value to the membership. Trade associations and professional associations such as the International Association of Food Protection (IAFP) and the Institute of Food Technologists (IFT) enable easy exchange of food safety knowledge across industry (often competing companies), academia, and government – all for the common good.

2.7.5 Academia

Academia has the dual responsibility of educating professionals to a higher level of knowledge, both at entry level to industry and for career development, and of challenging the status quo by implementing research programmes which provide evidence to enable improvements in food safety and HACCP programme effectiveness. Many of the developments in knowledge around behaviour of hazards in foods and mechanisms for their control have come from academic research, and this information is important both for the good of the supply chain and for public health protection. Funding for academic research can come from a variety of sources, including governments, research funding associations, charity funds, food companies, and other supply chain stakeholders. It is important that funders allow research findings to be shared and academics have a role to play, both in publishing their findings via peer review and translating them into information that can be used by industry, governments, and consumers. Academia also has a role in providing a neutral discussion forum between educators, industry and government, and promoting the necessary discussions between stakeholders in this way can only help to improve food safety standards throughout the global supply chain.

2.7.6 Consumers

Often overlooked as a link in the supply chain, their primary responsibility is to recognise their role in food safety. Consumers have so many food choices these days, some of them not always good choices from a food safety perspective, for example, choosing to drink raw milk when so many outbreaks continue to occur in both raw milk and raw milk cheeses. Consumers need access to reliable information in order to make informed choices for healthy eating. Clearly, they have a major role in being able to handle food in a hygienic manner and follow manufacturers' instructions for preparation and storage. The role of the consumer is an area ripe for further development and discussion. It has been proposed that good consumer practices Good Consumer Practices (GCPs) be developed for use in all venues where consumers purchase and/or consume foods (Leighton and Sperber 2015). GCPs would parallel Good Agricultural Practices, Good Manufacturing Practices, and Good Distribution Practices as necessary prerequisite

programmes to support the HACCP approach to food safety. A complete explanation of this topic is provided in Chapter 18.

Governments often resort to treating all consumers as though they won't read anything and will not follow directions (i.e. we must reduce potential hazards as much as possible as the consumer can't be trusted to manage any required control measures). This indeed will be true for some but certainly not all. Many are driven to search for information and, in fact, the volume of traffic going through search engines to search for symptoms of foodborne illness and likely foods at fault is one of the mechanisms for early indication of an outbreak.

Ready-to-eat (RTE) foods versus non-RTE is a conundrum for many manufacturers who acknowledge that consumers can and will use the foods differently to the design intent – eating raw pizza and cookie dough and using dry soup mix to make a savoury dip are a couple of well-known examples. Education can assist in some cases but it isn't the only solution.

One role and responsibility that is relatively easy for consumers to follow through on is to quickly report any deficiencies to manufacturers or retailers where the product was purchased. Consumers also have a responsibility to be open to new technologies that are valuable for food safety (and food security) such as irradiation and genetically engineered foods.

2.7.7 The Media

With the still rapidly developing social media, it is difficult to know who the media is anymore. Not so long ago we would have been referring to print media such as newspapers and magazines, together with television news. Nowadays, with the advent of technology, we have to include bloggers, Twitter, newsfeeds, and a plethora of Internet sites. Anyone can become part of the global news scene and be an influencer.

Whatever the source, the official media (if we can call it that) has a responsibility to report accurately and be fact-based. They are usually the voice to the consumer in the event of a food safety issue. Social media is often associated with over-communication and scaremongering that will only confuse or make consumers numb to the information provided. Many are already weary of the amount of food safety information relating to what is safe to eat. Industry and the media must collaborate and build a more trusting relationship. There are countless examples of the social media creating a perception of a food safety concern when the public had no real cause for alarm. The pink slime scenario in the United States is a good illustration. Pink slime (which is lean, finely-textured beef) has been used as a filler in meat products such as burgers for many years. Through the media, a very well-known celebrity chef highlighted the issue, which was then amplified by the media and caused a very well-known global fast-food restaurant chain to remove it from their products. Although there will be a range of views on the ethics of this practice, it was not a food safety issue. Rather than put a reference here, the reader can 'Google it' if interested to learn more!

2.7.8 Advocacy and Pressure Groups

Like the media, organised pressure groups have a responsibility to report accurately and be fact-based. They have an important role in promoting change where change may be

needed and often tackle difficult topics. However, they should be the voice of reason and avoid sensationalism. Having said this, we should think about who the advocacy and pressure groups are in today's society. Like the media, the situation has evolved in recent years. Individuals can use social media and become an advocate for change by getting large numbers of followers to their cause. Unfortunately, they don't always have the resources or the will to do the fact checking.

2.7.9 Influencers and Experts

These come from a number of fields, some of which have already been described. They can be academics, industry subject matter experts, people in government positions of authority, celebrity chefs, bloggers, or just celebrities. The best ones are those that see the responsibility that they carry and collaborate with others rather than being on a single-minded mission for change.

We started this section by saying that everyone has a role. In summing up, we can say that everyone has a responsibility to *do things right* (as defined by documented HACCP programmes and PRPs in case of industry) and to *do the right thing* (from the consumer's perspective).

2.8 Conclusions

In reading this chapter, there should be a few key conclusions drawn:

We can always do better

HACCP has been around for so many years that many think it has been 'done'. This is far from the truth – so much so that perhaps we need to start over with a new name in order to galvanise the industry into action. HACCP is not a book or a document. It is an incredibly valuable tool (in the right hands), and we need to get back to basics in some ways. Get back to the science, the systematic approach, and develop some *real* and sustainable food safety programmes with HACCP at the core.

We can learn from others' experiences and should be open to doing so

We must not ever think we are better than anyone else, otherwise we will lose the opportunity to learn.

People matter – enormously!

Every single person from the CEO and chairman of the board to the very lowest operator, and from the farmer to the consumer. Each has a key role and responsibility and what each does matters. *Everyone* has to be committed to food safety and anyone can come up with a new idea for improvement or can identify a potential hazard.

Food Safety = HACCP + PRPs + People
Doing Things Right
and
Doing the Right Thing
… Always

We cannot take short cuts

Decisions must be based on a hazard analysis and a careful evaluation of risk. If we do accept that a different way of working is safe, then it should be capable of becoming the new norm and not just a one-off time saver.

Hazard analysis and risk evaluation, risk communication, and risk management needs to be our modus operandi – everyday – 24/7.

We need to understand intrinsic product safety

What is making our product safe? What would make it unsafe? What are the consequences if it became contaminated? Are we concerned about presence of microorganisms, cross-contamination, or growth? How can we be more specific during the hazard analysis unless we really know our products?

We cannot rely on others to fix our problems

Regulators, third-party auditors, and customers are only in the plant for a short while and will not see everything. We have to take ownership for food safety and work together with others to find opportunities to improve.

We sometimes make our own problems

Sometimes through not really understanding what happens in the plants, sometimes by missing the indicators of impending failure, and sometimes by accepting misplaced guidance and advice from those who don't have sufficient expertise to give it we make our own problems.

Many misconceptions remain

Many misconceptions remain about HACCP and, for many, there are barriers (sometimes real, other times perceived) to its implementation. But these can be overcome by understanding what it takes to be successful.

Many food safety incidents were preventable

If only those companies involved had had the right knowledge and resources, were committed to food safety and to doing the right thing it is possible these incidents could have been avoided. It is astonishing to see examples where other companies had had similar issues yet still no action appeared to have been taken. We do not learn from others' experiences.

There are real benefits

However, these will not be widely realised until we do a better job of implementing HACCP and PRPs. Many companies have yet to do this fully, which means that there is an opportunity to reduce foodborne illness by use of improved understanding.

3

Food Safety Challenges in the Global Supply Chain

3.1 Introduction

Global trading in food is not new, but it is continually changing and evolving to meet consumer demand. Sir Walter Raleigh took potatoes from America to England in about 1590 and the Eastern spice trade has long been established. The reasons for us to continue trading with the world are expanding, but the basic driving forces of availability and innovation remain. Global sourcing today extends far beyond food, which probably lags behind industries such as apparel, appliances, consumer electronics, and many others. Consumer-led demand for increased variety via year-round produce, ethnic foods, and innovative and organic foods, combined with industry's desire for improved productivity through low cost sourcing (and the consumer desire for safe and affordable foods), has led to increased momentum to source food around the world. Add to this, the continuing growth in population and improved economies in some of the developing countries and resulting food safety challenges start to emerge.

Where does our 'global food' come from? The single ingredient and commodity foods mostly still come from the parts of the world that have traditionally grown them – spices from the orient, fruits from the tropics, grains from the great plains of North America, Asia, etc. Historically, there have been few problems with global food commodity trading. Increased demand, however, may lead to an intensification of commercial agricultural practices with both increased risk of crop contamination issues such as has been seen in the US produce industry in recent times and an increase in the likelihood of economically motivated adulteration, where there are numerous examples in many countries (see also Chapter 13). What has certainly changed is the amount of products that are being sourced and the diversity of companies and products that now use them. As an example, in the first 3 months of 2007, US imports of fresh fruit from China grew 279% to $7.4 million, fresh vegetable imports grew 66% to $32 million, and fruit and vegetable juice imports grew 98% to $109 million. Whilst these percentage increases sound high, the 'share' of the US food supply that comes from China is tiny, reportedly less than 1% (Gale and Buzby 2009). The volume of exports and imports of 9 principal food commodities traded among 17 nations in all regions of the world are presented in Table 3.1. The total amount of exports substantially exceeds the total imports because these larger nations also export to more than 100 smaller nations not included in this tabulation. The total volumes of each of those 9 food commodities traded by the 17 nations are presented in Table 3.2.

Food Safety for the 21st Century: Managing HACCP and Food Safety Throughout the Global Supply Chain, Second Edition. Carol A. Wallace, William H. Sperber, and Sara E. Mortimore.

Table 3.1 Food commodity trade among major nations, 2016 (in thousand metric tonnes).

Region	Country	Imports	Exports	Deficit/Surplus
Europe	European Union	47 703	37 397	−10,306
	Russia	6 449	37 734	+31,285
	Subtotal	**54 152**	**75 131**	**+20,979**
N. America	Canada	3 632	31 473	+27,841
	United States	13 616	151 612	+137,996
	Mexico	26 865	2 894	−23,971
	Subtotal	**44 113**	**185 979**	**+141,866**
S. America	Brazil	9 291	98 194	+88,904
	Argentina	1 058	50 261	+49,202
	Subtotal	**10 349**	**148 455**	**+138,106**
Asia/Pacific	Japan	28 549	407	−28,142
	Australia	893	26 687	+25,794
	China	109 800	4 198	−105,602
	India	20 200	13 191	−7,009
	Indonesia	13 552	28 421	+14,869
	Korea, South	18 826	263	−18,563
	Subtotal	**191 820**	**73 168**	**−118,653**
Africa	South Africa	4 923	3 306	−1,617
	Algeria	13 858	18	−13,840
	Kenya	3 745	60	−3,685
	Subtotal	**22 526**	**3 384**	**−19,142**

Source: USDA, FAS, PS&D data (2016).

Table 3.2 Volume of food commodities traded among major nations, 2016 (in thousand metric tonnes).

Commodity	Imports	Exports
Wheat	60 667	140 530
Corn	64 852	120 633
Rice	13 411	15 980
Soybeans	115 776	129 602
Vegetable oils	46 088	46 084
Red meat	11 794	15 830
Poultry	4 033	9 296
Fruits	6 339	8 161
Grand Total	**322 960**	**486 116**

Source: USDA, FAS, PS&D data (2016).

Within this framework, there are pockets of intense trade. For example, China produces over half the world's pork, most of the world's vitamins, and a third of the world's horticultural output. Meat and dairy products continue to be a growing segment of US–China agricultural trade, but exporters are facing more stringent requirements, which may be discouraging. Chinese officials have appropriately been overhauling food safety regulations and strengthening oversight for both domestic and imported products. Many exporters to China are now required to register with various government agencies, and China is starting to require the US regulatory agencies to certify that exporters meet Chinese laws and standards (Gale 2009).

It is a similar story for many other countries. In European history, global sourcing was enabled by trading with former colonies, existing overseas territories and Commonwealth nations. Due to the advent of refrigeration, it was not just dry spices that were traded. The first cargo of frozen meat was reportedly shipped from Buenos Aires to France in 1877. In 1901, the first shipment of chilled bananas arrived in the United Kingdom. By 1910, the United Kingdom was importing 600 000 tons of frozen meat (James and James 2006). Global sourcing of food has rapidly expanded since then and given its role in ensuring global food security, the trend is set to continue. Contrast this with the rise in consumer demand for locally and transparently sourced, 'clean label', healthy foods, often from small entrepreneurial producers, that we see in many of the developed countries. Both approaches will likely expand and find a way to co-exist. In this chapter, we will focus on some of the challenges posed by the developing global food supply chain and then discuss strategies and tactics to promote food safety assurance.

3.2 Increased Complexity of the Global Supply Chain

The drivers of change in the global food supply chain include economic, environmental, and social factors. These each present certain challenges, which are discussed below.

3.2.1 Economic Factors

Land and Labour

Both are lower cost in less developed countries though this differential with developed countries continues to diminish. Cost reduction has driven many established Western companies to outsource from developing countries, resulting in a shift from trade being related primarily to commodity items, where climate played a key role in year-round sourcing, to the advent of finished, often highly processed, product manufacturing in developing countries, which now have the emerging technological base combined with a workforce to undertake the task at a lower cost. The total value of processed food trade with the United States has nearly tripled in the past 20 years, with the amount of US imports exceeding the amount of exports (Table 3.3). Lower labour rates as a driving force mean that higher cost savings are realised in those processes which are highly manual, such as the hand peeling of shrimp. This is demonstrated by the reports that shrimp have been exported from Scotland to Asia specifically for peeling and exported back to Europe. Figure 3.1 shows the staggering differences in labour costs from just a few years ago.

Table 3.3 US processed food trade (in billions of dollars).

Commodity	Exports	Imports
1992	10.6	14.9
1996	13.5	19.5
2000	15.0	26.8
2004	18.6	37.4
2008	31.2	53.6
2012	42.4	67.2
2016 est.	42.5	75.7

Source: USDA, FAS, and US Census Bureau Trade Data (2017).

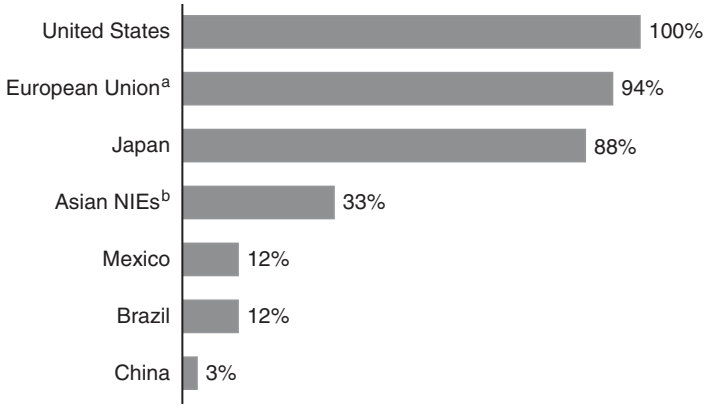

Figure 3.1 Labour cost comparison. Indexed against the United States at 100% (US$21.11). [a]European Union is the 15 member countries in 2002 prior to expansion in 2003. [b]Asian NIEs are the newly industrialised economies of Hong Kong, South Korea, Singapore, and Taiwan. Bureau of Labor Statistics (2005, p. 32).

Construction and land costs are also still relatively low in developing countries, enabling companies to build manufacturing facilities for less than a tenth of the cost in developed countries.

Emerging Economies

Large countries like China and India continue to have an impact on the globalisation of the supply chain. With rising incomes in emerging economies, however, combined with the global expansion of foodservice and retail companies, there appears to be a converging pattern in food consumption. Typically, this means that food spending increases through the purchase of more calories usually found in higher priced goods (Frazao et al. 2008). Low-income countries typically have a diet high in starchy vegetables and low in animal protein, since meat and dairy products are considered a luxury due to their expense. The increase in income combined with the fact that multinational retail and foodservice chains have grown rapidly has resulted in a convergence in consumption patterns. This change is happening at a much faster pace than in previous

centuries. For example, Latin America national retail sales in food, as a percentage of food consumption, before the 1980s were 15–30%. By 2001, it had grown to 50–70%. In just 20 years, the growth was equivalent to what had previously taken 50 years in the United States. Asian trends in food consumption patterns are similar. Economic growth is accompanied by increased urbanisation- about one million people are moving every week from rural to urban areas where the need for labour is greatest and intensive construction of housing and manufacturing facilities and civic infrastructure is occurring.

3.2.2 Environmental Factors

Expansion of Pathogen Range

About 50 years ago, there were only four major recognised foodborne pathogens – *Staphylococcus aureus, Salmonella* spp., *Clostridium botulinum,* and *Clostridium perfringens.* Today, there are nearly 30 recognised foodborne pathogens, including bacteria, viruses, protozoans, and prions (Sperber 2006). We can expect more. Epidemiologists have identified about 1400 human pathogens. About 800 are zoonotic, capable of infecting humans and animals, and 200 of these are considered to be emerging or re-emerging (Woolhouse and Gowtage-Sequeria 2005). The H1N1 and H5N1 influenza strains are examples of re-emerging pathogens. Many factors are involved in spreading pathogens and extending their traditional ranges (Osterholm 2006). These include:

- Modern transportation systems permit rapid worldwide movement of massive quantities of crops, animals, and people, thereby enabling the spread of plant, animal, human, and zoonotic diseases and invasive species of plants and animals.
- The well-known ability of microorganisms to mutate and adapt to changing environments is accelerated by their introduction into new environments.
- The changing climate and weather patterns are expanding the geographical range of pathogens and their vectors from tropical to temperate regions as the planet warms.
- Poverty, war, and famine place enormous stresses on human populations, increasing their susceptibility to infectious diseases.
- A lack of political will at the governmental and intergovernmental levels to take effective measures to better protect the public health and the environment.

Representative of the many diseases whose spread is widened by these factors are influenza, malaria, tuberculosis, Rift Valley fever, and West Nile virus.

Decreasing Arable Land

Changes in developing countries had been so gradual that the loss of crop land through increased urbanisation did not seem to have a major impact on agriculture. Labour-intensive farming was acceptable when work was needed for the large numbers of people in rural areas of those countries. However, today, the use of more efficient Western-style agricultural technologies will be necessary to offset the loss in land caused by urbanisation. Increased agricultural production efficiencies will displace even more farm workers, accelerating the urbanisation trend. Loss of arable land will also occur because of desertification and the increasing scarcity of water for crop irrigation. Advances in biotechnology to develop drought-resistant crops may help to ameliorate this issue. Sub-Saharan Africa and South America are the principal regions that have a surplus of arable land. Combined with their normally adequate rainfall,

these regions will be important to maintain an adequate global food supply; however, the potential impact of climate change may need to be considered.

Climate Change

Climate has always been important to agriculture and with change comes winners and losers. In 2007, the United States harvested record maize crops due to increased planting and favourable weather. That same year, Australia suffered a drought and saw a drop in output. Predictions are being made by scientists regarding the effect of global warming on climate. Regions currently well-suited for agriculture may become drier or may become deserts. Cooler regions may benefit from longer growing seasons should global warming continue. Rising sea levels will reduce crop land in coastal regions, a recent example being flooding such as that seen in Bangladesh. These changes will require greater knowledge, resources, and agility in the management of agricultural resources. Many traditional agricultural practices may have to be altered or abandoned. An example of a climate-induced crop change occurred in Panama. This country had a great climate for pineapple production, but did not grow it until they were taught by a global trader who saw the opportunity. We will certainly witness many changes of greater magnitude in the coming years.

Water Availability

The agricultural activities that support our civilisation are wholly dependent on an adequate supply of water, received either by rainfall or by irrigation. The amount of fresh water (blue water) contained in rivers, lakes, and groundwater is about 0.8% of the total water on the planet. Whilst most crops are fed by rainwater, irrigation is increasingly used to permit the production of crops in semi-arid regions to feed the growing population. During the past century, the human population has increased fourfold, whilst the use of blue water for human activities has increased ninefold (Falkenmark and Rockström 2005). More than two thirds of the blue water is used for irrigation (Table 3.4). Major aquifers (groundwater) are being depleted in agricultural areas. Already irrigation water is being used to grow rice and maize in semi-arid and desert regions, accelerating the groundwater depletion rate. Jägermeyr et al. (2015) report an estimate of global irrigation water withdrawal of 2469 km^3 (2004–2009 average), of which 608 km^3 are non-beneficially consumed (i.e. lost through evaporation, interception, and conveyance). Replacing surface irrigation systems by sprinkler or drip systems could reduce

Table 3.4 Global blue water withdrawals in the 20th and early 21st centuries.

	Percentage of volume		
Water used for	**1900**	**1995**	**2010**
Irrigation	88	69	75
Industrial	7	21	15
Municipal	5	10	10
Total	100	100	100

Source: Adapted from Falkenmark and Rockström (2005); Wada and Bierkens (2014).

Table 3.5 Regional and global population under green-blue water scarcity in the 'Enhanced Agronomic Practices' AGROPRAC* scenario.

	Population under green-blue water scarcity in millions (%)				
Region	**1905**	**1935**	**1965**	**1985**	**2005**
Australia and Pacific	––	––	––	––	––
Central America	––	––	2 (2%)	13 (10%)	19 (10%)
East Asia	170 (35%)	207 (34%)	342 (37%)	436 (34%)	546 (35%)
Eastern Europe and CA	––	3 (1%)	12 (4%)	24 (6%)	33 (9%)
Middle East	1 (2%)	3 (5%)	9 (9%)	88 (47%)	118 (42%)
North America	––	––	––	––	––
Northern Africa	1 (1%)	2 (3%)	4 (5%)	34 (26%)	74 (38%)
South America	––	––	2 (1%)	5 (2%)	17 (4%)
South Asia	158 (47%)	219 (56%)	505 (78%)	783 (76%)	1128 (75%)
Southeast Asia	––	1 (1%)	77 (30%)	4 (1%)	6 (1%)
Southern Africa	4 (4%)	8 (6%)	39 (16%)	100 (23%)	292 (39%)
Western Europe	28 (11%)	3 (1%)	––	––	––
WORLD	361 (21%)	447 (20%)	992 (29%)	1488 (30%)	2232 (34%)

*'Enhanced Agronomic Practices' scenario (AGROPRAC). This acknowledges the trends and variability of both green-blue water availability and requirements of the reference food supply.
Numbers are 5-year averages aggregated from FPU level results.
Source: Adapted from Porkka et al. (2016).

the non-beneficial consumption at river basin level by 54% (sprinkler) and 76% (drip), whilst maintaining the current level of crop yields.

It will be increasingly difficult to produce an adequate food supply as the human population increases and the long-accumulated natural stores of blue water are depleted. This is clearly illustrated by the growth in population over the last century and percentages of regional populations living under green-blue water scarcity (Porkka et al. 2016); (Table 3.5).

Limited Fossil Fuels

The general consensus among petroleum geologists is that sometime in the past several years the world reached 'peak oil' production, that is, the point at which half of the estimated global oil reserves had been extracted and used. We are faced with shrinking reserves of all fossil energy sources, including oil, coal, and natural gas. Modern agriculture is highly dependent on fossil fuels for cultivating the land, fertilising and harvesting crops, transportation, and storage. Shrinking fossil fuel reserves and the need for developing countries to modernise their agricultural capabilities will drive an upward spiral of increasing energy costs. This is occurring as much of the developing world is attempting to modernise production and provide more food and more food choices. These trends are certain to increase the cost of food. It is imperative that effective fuel conservation measures be enacted and that practical alternative and renewable energy sources be developed for widespread use.

Alternative Energy Sources

Much of the renewable energy used worldwide is produced from established sources and technologies – hydropower, geothermal, and the burning of municipal waste. Currently, 10.4% of the United States' energy consumption (Table 3.6a) and 13% of the European Union's energy consumption (Table 3.6b) is produced from renewable energy sources. Continued development may enable these sources to provide a larger share of the global energy need. Wind and solar technologies hold promise for electricity generation, but cost and the lack of distribution systems have limited them to less than 1% of all energy produced.

Biofuels are receiving a lot of attention and governmental support because of their ability to reduce the use of gasoline and diesel oil. The production of ethanol from sugar crops appears to be practical when sucrose is the substrate. However, when dextrose derived from maize starch is used as the substrate, the productivity of ethanol

Table 3.6a Energy consumption in the United States, 2016.

Energy source	Percent contribution (%)
Petroleum	36.9
Natural gas	29.2
Coal and coal coke	14.6
Nuclear	8.3
Biomass/waste	4.9
Hydropower	2.5
Wind	2.2
Solar	0.6
Geothermal	0.2
Total	100

Source: US Energy Information Administration (2017).

Table 3.6b Energy consumption in the European Union and the United Kingdom, 2014.

Energy source	Percent contribution EU (%)	Percent Contribution UK (%)
Petroleum	34	36
Natural gas	21	32
Coal and coal coke	17	16
Nuclear	14	9
Renewables	13	6
Others	––	1
Total	100	100

Source: Eurostat (2014).

production compared to sucrose is reduced by 95%. That is, the production of ethanol from corn starch is at best a break-even proposition, with no net energy gain based on the petroleum inputs. As shown in 2008, the diversion of food crops such as maize to ethanol production will decrease the global food and feed supply while driving up prices. In 2014–2016, 17% of total world maize output was used for ethanol. This compares to 58% for animal feed in the same period (OECD/FAO data, 2017). Ten years earlier, virtually no maize was converted to ethanol.

The production of biodiesel from food crops could create a similar dilemma. Therefore, a great deal of effort is being expended to develop technologies in which bioethanol can be produced from cellulose and biodiesel can be produced from non-food plant or algal oils. Methane, the same molecule as fossil natural gas, is readily produced by the anaerobic digestion of manure and waste vegetation. In the very long term, hydrogen produced by the electrolysis of water or by microbial fermentation may become a practical fuel supply.

3.2.3 Social Factors

Human Overpopulation

World population is now over 7 billion and is expected to surpass 11 billion by 2100. Many developing and developed countries will not be able to feed their own people. This will drive the need for increased global trade in food – out of real necessity as opposed to being related primarily to lower labour costs and the consumer demand for variety. Today, Brazil, sub-Saharan Africa, and some former Soviet bloc countries have adequate rainfall and large amounts of land available for cultivation. At present, some 11% (1.5 billion ha) of the globe's land surface (13.4 billion ha) is used in crop production (arable land and land under permanent crops). This area represents slightly more than one third (36%) of the land estimated to be, to some degree, suitable for crop production. The fact that there remain some 2.7 billion ha with crop production potential suggests that there is still scope for further expansion of agricultural land (FAO 2003b, p. 27).

Based on current agricultural practices, these largely untapped agricultural regions may be able to provide food security to the expected population increase. However, infrastructure to be able to move the food from the rural areas to ports is also essential and this may need further development. At this point in time, there has been limited political or social will to tackle the very difficult subject of establishing humane population control measures. China has recently abandoned its one child policy. As global consumers, we will have to embrace the technology that enables increased productivity on the farm, including genetically engineered crops.

Too Much Wasted Food

It is increasingly recognised that we have to look seriously at reducing food waste. As testing capability improves, we get closer and closer to chasing zero in terms of contaminants in food. It is accepted that food should not be adulterated, but when food is scarce, as an industry, we do need to agree on whether the contamination is harmful enough for us to have to throw it away. This is a risk assessment that is appropriate for governments and organisations such as Codex Alimentarius to take on.

Food is also wasted in the Western world by consumers who buy more than they need. In addition, the date labelling of food, which is generally perceived as a good thing, has probably not helped, particularly as no common approach is taken to the way we label across the globe. For nutritional purposes (notably baby formula), it can be vitally important to date code in order to ensure that nutrient levels match what is on the label, but for many having a 'best before', 'use by', 'enjoy by', 'sell by', or 'best if used by' date is confusing. Estimates suggest that 40% of food is wasted in the United States and yet 15% of US residents struggle to get enough to eat (NRDC and Harvard Food Law and Policy Clinic 2013). We have to find a better mechanism which meets the needs for both food safety and food security.

Increase in the Numbers of Immunocompromised People

In addition to the members of the population who are immunocompromised due to illness and through being a very young age, we will see an increase in the number of old people in many countries around the world. This means an increase in the percentage of the population that fall into this category, requiring an even greater emphasis on food safety assurance (see Section 5.2.2).

Year-Round Sourcing

Consumers in developed countries have come to expect a year-round supply of inexpensive fresh produce, as opposed to a seasonal supply. Environmental concerns are changing attitudes a little; for example, the European move to calculating the carbon footprint of products is raising consumer awareness and could drive a reduction in 'food miles'. However, this may be offset by the current trend for corporate social responsibility programmes. Reduction in global produce sourcing could negatively impact the lives of farmers in less developed countries who have come to rely on the income gained from Western retail customers. Moreover, long-distance transportation of foods by ocean ships or railroads are substantially more efficient than local transportation by small vehicles (Table 3.7).

Improved Living Standards

Developing countries' improved standards of living have already been mentioned. But it does mean an increase in the demand for more processed foods – sometimes through imports from the West, increasingly through establishing local production capability

Table 3.7 Comparative efficiencies of modes of transportation of food.

Transportation mode	Relative efficiency
Ocean shipping	100
Railroad	63
Highway trucking	19
Aeroplane	1
Automobile	0.03

Source: Derived from Bruhn (2009).

which can be a challenge as local raw materials have to be sourced and food safety managed back up through the supply chain (Chapter 17).

Changes in Retailing and Consumer Shopping Habits

This is evolving as online shopping continues to become mainstream and we see online retailers such as Amazon not only moving into food but also opening stores which have no cashiers and no checkout lines. According to Amazon (who made the announcement on their website on December 5th 2016), consumers will be tracked via an app which, with the aid of sensors, computer vision, and deep learning, will track their movements and purchases as they move about the store. Almost at the other end of the spectrum, we are seeing an increase in the desire to connect with where food comes from. Consumers enjoy the social experiences that they get by shopping in farmer's markets, by growing their own food, and by watching television and online cooking shows. What they do not usually appreciate is the increased food safety risk associated with these activities (Harrison 2014).

Food distribution is changing too, partly due to the shortage of truck drivers and rising costs, especially for smaller drops. Some companies have begun to test distribution efficiencies using private services such as Uber, using driverless vehicles and even drones. Similarly, local delivery services from foodservice providers such as restaurants continue to grow. These might be individual delivery services arranged by the restaurants themselves or central app-based services, normally operating in larger cities (e.g. Deliveroo in the United Kingdom and UberEats globally), where food is ordered via the app and picked up and delivered by the app-assigned courier by bicycle, motorcycle, or car.

All of these economic, environmental, and social factors mean increased pressure on the global food supply chain and therefore an increased need for a common approach to effective food safety management. The changing world will also require some new thinking in food safety management - what worked in the past may not be effective in the future. These are new and different challenges that we have to think carefully about and certainly cannot ignore.

3.3 Food Safety Issues in Global Trade

Let's consider recent issues. Microbial pathogens, presence of heavy metals, undeclared allergens, foreign material contamination, and economic adulteration require focused food safety management strategies to prevent product failure. Many will be aware that, at the consumer level, the list includes non-permitted additives, avian influenza, and the use of biotechnology, all of which present regulatory and genuine consumer concerns. Whilst also being a challenge to manage, these are not always the real food safety issues (Gibney 2012).

The rejection of imported foods because of food safety violations is an important economic consideration. A large number of food categories are affected by such regulatory actions in different countries and regions (Tables 3.8a and 3.8b).

The number of rejections is not surprising. Many food producers, particularly in developing countries, do not yet fully comply with the basic food manufacturing practices of operating in a hygienic environment and with equipment designed for sanitation (see more on this in Chapter 17). Temperature-controlled storage, pest control,

Table 3.8a FDA food import refusals by industry, 01/01/2002–31/12/2016.

Food	Number of violations	Percentage of violations (%)
Vegetables	24 681	19.34
Fruits	15 155	11.88
Seafood/fish	30 296	23.75
Bakery products/cereals*	9174	7.19
Additives/flavourings/spices	9975	7.82
Soft drinks/water	4642	3.64
Multi-food sauces/soup*	5842	4.58
Cheese	4447	3.49
Milk	1611	1.26
Chocolate/cocoa/coffee/tea*	5950	4.66
Seeds/nuts	2775	2.18
Vegetable oils	1087	0.85
Pasta	2517	1.97
Non-chocolate candy	9433	7.39
Totals	127 585	100.00

*Categories reported individually but have been combined for more meaningful comparison to EU categories.
Source: FDA database, www.accessdata.fda.gov/scripts/importrefusals/

Table 3.8b European food import refusals by industry, 01/01/2002–31/12/2016.

Food	Number of violations	Percentage of violations (%)
Vegetables/Fruit	2921	26.5
Seafood*	767	6.9
Fish/fish products	1214	11.0
Bakery products/cereals	406	3.7
Additives/flavourings/spices*	772	7.0
Soft drinks/water*	130	1.2
Multi-food sauces/soup	79	0.7
Milk/milk products	21	0.2
Chocolate/cocoa/coffee/tea	249	2.2
Seeds/nuts	3558	32.2
Fats/oils	88	0.8
Eggs	11	0.1
Meat/poultry meat*	725	6.6
Other	99	0.9
Totals	11 040	100.0

*Categories reported individually but have been combined for more meaningful comparison to US categories
Source: RASFF Database, https://ec.europa.eu/food/safety/rasff/portal_en/ (2016).

allergen management, cross-contamination control, and sanitation programmes are often inadequate. Neither do they understand the requirement or expectations of the supply chain once it leaves their shores. That combined with poor understanding of HACCP, microbiology, and allergen control leads to a high likelihood of failure. The media in countries such as China, for example, report a high number of foodborne illness outbreaks domestically, especially in institutions such as schools and hospitals, which is evidence of this knowledge gap. So, there is a real desire to improve not only in export but also for improvement in domestic food supply.

In many companies, there is often a willingness to learn and often an appreciation that their customers are prepared to help. The lack of knowledge, however, is significant. As an example, one potential supplier when learning about electric insect killers (EIKs) enthusiastically installed them not only inside the building but also on the outside! Another company when informed that it was a good practice to leave an 18-inch gap between storage racking and the walls of a warehouse for cleaning and inspection purposes responded with a comment that they had very tiny people in their country and would not need such a wide gap. It would be hard to disagree with such logic. Many good manufacturing practice (GMP) standards are based on Western manufacturing circumstances. Another great example of this is that few global pest control standards make mention of monkeys, lizards, snakes, and wombats, illustrating the differences that exist among company and country practices and expectations.

Among the many recorded failures are instances of filth, illegal pesticides, herbicides, and heavy metals. More recently, economic adulteration has started to come to the forefront in border rejections. The European Commission Rapid Alert System for Food and Feed (RASFF) Portal reports notifications of a wide range of food safety, contamination, and adulteration issues. Between 1980 and July 2016, adulteration/fraud notifications comprised only a small proportion (2%) of the 44 815 notifications in the RASFF database, but the rate of growth of these issues was particularly marked in the last 15 years (Figure 3.2).

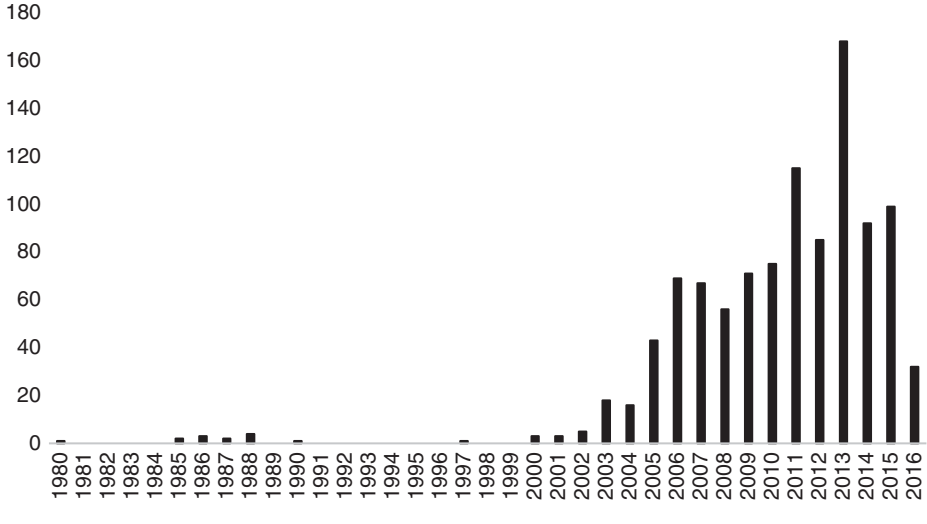

Figure 3.2 Total number of food/feed adulteration/fraud notifications per year 1980–July 2016 ($n = 1031$). *Source*: European Commission RASFF Portal (RASFF 2016).

Further examples of food fraud/economic adulteration have included the deliberate addition of melamine to wheat gluten used in US pet food in 2007, and only 1 year later, into milk products in China. Spices contaminated with Sudan Red and Para Red are another example; this has happened a number of times (that we know of), and typically, given the spice trade, with global impact, causing market recalls to happen in many countries including the United Kingdom, the countries of mainland Europe, South Africa, Australia, and China. Another global example of economic adulteration was the use of diethylene glycol (a low cost - but frequently deadly - substitute for glycerin) in the production of toothpaste and cough syrup in China, resulting in the deaths of 51 people in Panama (see also Chapter 13).

These instances serve only to underline the inadequacy of testing versus preventative approaches such as effective implementation of HACCP and prerequisite programmes (PRPs) across the industry, as well as the more recent efforts to develop know-how in conducting vulnerability assessments as a defence against economic adulteration. In the United States, the Food and Drug Administration (FDA) is struggling to keep up with testing the increasing number of US imports- they cannot sample everything, and many of the exporting countries are not testing before export. Even if all imports and exports could be sampled, we know very well that product testing does not work to assure food safety (Chapter 1). No amount of additional inspectors or product testing will better enable us to guarantee food safety, though it is possible to reduce risk through structured initiatives (e.g. in the case of the FDA, establishing regional offices around the world was seen as an improvement to the import testing protocols). Other countries have taken a similar approach with reciprocal agreements in terms of food safety standards equivalency and in country verification assessments.

A few additional specific considerations:

- Difficulty with traceability at the global level. A number of the global issues have highlighted this (e.g. Sudan Red, melamine, and dioxin contamination).
- Spread of disease as a result of global trade. Notable examples include those involving trade in live animals affected with bovine spongiform encephalopathy (BSE), avian influenza, and *Salmonella* DT104.
- Political and consumer reactions to global trade safety issues. Most frequently governments simply set up trade barriers. There is nearly always increased sampling and testing, and sometimes a change in standards and requirements, following an issue. At the consumer level, the reaction is usually fear and avoidance of the likely products associated with the issue, or sometimes any products from countries where the affected exports came from.

3.3.1 Lack of Uniformity in Regulations and Requirements

The success of HACCP as an industry food safety management programme has led some national governments to promulgate HACCP-based regulations. There are differing opinions as to the best approach here. In Europe, the broad requirement in European Commission (EC) Regulation 852/2004 on the Hygiene of Foodstuffs (EC 2004) to use HACCP principles for food safety management across all elements of the food industry has been fairly successful over the last several years, despite the absence of definitive controls by the industry sector. Recent focus from the European Commission has included guidance on PRPs and HACCP procedures, including

flexibility of implementation in certain food businesses, particularly small businesses (EC 2016). However, in other countries, views differ to the effect that regulations are sometimes described as having been incompletely developed. For example, as discussed in Chapter 1, the US HACCP regulations for raw meat and poultry products and juice products do not require definitive process controls that can be managed as critical control points (CCPs) to control identified microbiological hazards. Moreover, many small producers can be exempted from processing controls (Sperber 2005b). Such regulations can undermine support and understanding of legitimate preventative food safety management procedures typically expected in a HACCP system. However, there are recent examples of satisfactory and effective HACCP-based regulations such as the US rule for *Listeria monocytogenes* control in ready-to-eat meat and poultry products (CFR 2003) and the Food Safety Modernization Act (FSMA), where domestic and imported foods that come under the jurisdiction of the FDA are required to implement hazard analysis and risk-based preventive controls. This approach differs to many other countries, yet in many ways the United States is to be applauded for evaluating the effectiveness of HACCP and food safety regulation in other countries and determining whether a more effective approach could be taken. FSMA, as a result, however, has some distinct requirements.

Lack of uniformity in regulations around the world and the promulgation of poor regulations puts an unnecessary burden and leads to additional unnecessary costs for the food industry and ultimately to the consumers. A few additional examples are described below:

- ***Allergens.*** The differences in regulations lead to the need for multiple labelling and additional allergen control measures in companies that export around the world. It is not just about whether an ingredient is an allergen, and this does vary around the world, but also whether there is a recognised threshold level. Some countries have government guidance on the thresholds for action, whilst others may have zero tolerance. Differences regarding which allergens are regulated can be very confusing if you are a food exporter (Table 3.9).
- ***Mycotoxins.*** The regulatory expectations related to mycotoxins in cereal and food crops is somewhat clearer. Of the several thousands of mycotoxins that have been identified, five are of principal concern in the food and feed supply; regulatory limits have been established in many countries for one or more of these mycotoxins. However, there is significant variation among countries as to the types of mycotoxins, the types of food and feedstuffs affected, regulatory limits, and testing requirements that can complicate trade for both exporters and importers. The reader is referred to Chapter 5 for additional information on mycotoxins, as well as persistent organic pollutants and heavy metal contamination.
- ***Other Chemical Contaminants.*** Some of the emerging chemical contaminants such as cyanuric acid, an analogue of melamine, and melamine itself are fairly new as contaminants in food. Their example serves to indicate that any chemical which should not be there is an adulterant and that science is needed to help the industry figure out whether these adulterants pose real food safety hazards and how to deal with them. Some governments have published guidelines or regulations. However, differences exist in what is considered acceptable (nitrite levels in milk powders are a good example), and often more research and guidance is needed to help industry manage these hazards.

Table 3.9 Regulated food allergens.

Food allergen	United States	Europe	Australia and New Zealand
Celery		✓	
Cereals with gluten	✓	✓	✓
Crustacea/Shellfish	✓	✓	✓
Egg	✓	✓	✓
Fish	✓	✓	✓
Milk	✓	✓	✓
Mustard		✓	
Peanuts	✓	✓	✓
Sesame		✓	✓
Soya	✓	✓	✓
Sulphite		✓	>10 mg/kg
Tree nuts	✓	✓	✓
Others		Lupin Mollusc	Bee pollen Propolis Royal Jelly

Source: Adapted from Higgs and Fielding (2007).

- ***Counterfeiting.*** There are some real concerns arising from countries which are known for their ability to counterfeit consumer and industrial products. Clearly, the counterfeiters are interested in commercial gain rather than food safety. Companies should always buy from reputable companies and check for copycat labelling (see Chapter 13).
- ***Microbiological criteria.*** Differences exist in the use of microbiological criteria around the world. There are also differences of opinion at the public level, surrounding what these should be (e.g. zero tolerance for *L. monocytogenes* in the United States), and sometimes differences in required test protocols (e.g. Japan). It has been proposed that microbiological criteria or standards are not necessary for finished products that are produced in a supply chain in which HACCP and prerequisite programmes are applied. Rather, microbiological guidelines can be used to verify the safe and sanitary operating conditions of production environments (Sperber and NAMA 2007).

3.3.2 Lack of Uniformity in Standards and Audit Requirements

Differing requirements, particularly amongst multinationals, combined with the plethora of independent and national audit standards and auditors can make this very difficult if you are on the receiving end. A few years ago, this was how it was. We still have challenges, but the framework has moved forward through the work of the Global Food Safety Initiative (GFSI) and others (see Section 3.4.2 and Chapter 14).

3.4 Strategic Level Responses

At a high level, strategies are needed which are preventative. Failure can be a catalyst for change, but, predictably, what often emerges, particularly as an immediate response to failure, is a reactive strategy involving additional testing, more inspections and regulations. This does at least ensure that issues remain in the spotlight until more preventative work can be initiated but that is often harder to do.

3.4.1 Government Communications Systems

National governments that have food safety responsibilities spread among several departments or agencies may encounter communication difficulties. That difficulty may be expected in the United States, which currently has its food safety accountabilities spread among five departments (Agriculture, Health and Human Services, Commerce, Defense, and Homeland Security) and numerous agencies. Nonetheless, several excellent communications systems and databases were established in 1995 by the US Centers for Disease Control and Prevention (CDC), which are housed in the Department of Health and Human Services (http://www.cdc.gov). The Foodborne Diseases Active Surveillance Network (FoodNet) tracks foodborne illnesses to assist epidemiologists in the determination of foodborne illness outbreaks. Tracking 10 principal microbial pathogens, in 2014, FoodNet confirmed 19 507 individual cases of infection, of which 4476 required hospitalisation and 75 of the patients died. PulseNet is a network of laboratories that share information from standardised molecular subtyping procedures, such as pulsed field gel electrophoresis (PFGE), that very specifically identify foodborne pathogens (with a specificity analogous to that obtained by fingerprinting humans). FoodNet and PulseNet enable the detection of low-incidence, widely spread illness outbreaks that could not have been previously identified by conventional microbiological and epidemiological fieldwork. PulseNet is being implemented as a collaborative system that will soon link public health laboratories on all continents. The technology supporting PulseNet – PFGE – is based on the identification of genetic markers within the genome of pathogenic microbes. PFGE is rapidly being replaced by whole genome sequencing (WGS), in which the entire genome of the pathogen is copied, thereby creating a complete DNA library of each pathogen. The speed and accuracy of WGS testing will make it more feasible for government inspectors to conduct environmental testing in food plant operations. Whilst food product recalls have been based upon the detection of pathogens in a food, future recalls may also be based upon the WGS identification of pathogens anywhere in the processing facility (McEntire 2017). The National Antimicrobial Resistance Monitoring System (NARMS) for enteric bacteria assists in the identification and evaluation of the spread of antimicrobial-resistant pathogens in the food supply and human and animal populations.

Similarly, Codex Alimentarius Commission (CAC) procedures promote communications between intergovernmental organisations. CAC was created in 1963 by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) to develop food standards, guidelines, and recommended codes of practice under the Joint FAO/WHO Food Standards Programme. The purposes of this programme are to protect the health of consumers, ensure fair practices in food

trade, and to promote coordination of all food standards development undertaken by intergovernmental organisations (IGOs) and non-governmental organisations (NGOs) (http://www.codexalimentarius.net). The standards, codes, etc. have the force of law in trade among United Nations' member nations who are signatories to the World Trade Organization (WTO). Additionally, CAC coordinates several continuing expert consultations: the Joint FAO/WHO Expert Committee on Food Additives (JECFA), the Joint FAO/WHO Meetings on Pesticide Residues (JMPR), and the Joint FAO/WHO Meetings on Microbiological Risk Assessment (JEMRA). Whilst the Codex work can be painstakingly slow, it is often no slower than governments are in developing and publishing regulations, and to be fair, in being the global food code, inputs have to come from governments worldwide so it is a true collaboration.

3.4.2 Global Food Safety Private Audit Standards and Schemes

Great progress has been made in the last 15 years or so, and largely due to the Global Food Safety Initiative (GFSI) rather than government level activity. This is also a fairly recent development and one that is also driving auditor calibration and competency.

GFSI was established in May 2000 and was made up of representatives from international retailers coordinated by CIES (Comite International d'Enterprises a Succursales, established in 1953) - the Food Business forum. The objectives are firstly, to promote convergence of food safety standards through the maintenance of a benchmarking process for (existing or new) food safety management schemes. Secondly, to improve cost efficiency throughout the global supply chain through the common acceptance of GFSI standards by retailers from around the world. And thirdly, to provide a unique international stakeholder platform for networking, knowledge exchange, and sharing of best food safety practices and information. The GFSI Guidance Document was written and approved by the group, and the already existing British Retail Consortium (BRC) Global Standard for Food Safety (now in version 7; BRC 2015) was the first standard to be benchmarked and recognised. This was followed by the International Food Standard (IFS), Dutch HACCP, Safe Quality Food (SQF), and New Zealand GAP (Good Agricultural Practice). FSSC 22000, incorporating ISO 22000 with supplementary prerequisite GMP standards via PAS220 (now ISO/TS 22002-1:2009; International Organization for Standardization [ISO] 2009) was recognised in May 2010.

The GFSI benchmarked standards and schemes have been adopted by many retailers, foodservice establishments, and manufacturers. Notably, the top global retailers such as Wal-Mart, Carrefour, and Tesco, as well as the larger manufacturers, have been a driving force.

Currently, the GFSI mission is stated as 'Continuous improvement in food safety management systems to ensure confidence in the delivery of food to consumers'. Who could fail to support such a mission! All of the benchmarked schemes are certification schemes, which means that they require certification bodies, who are themselves accredited by national standards institutes, to audit and certify. This requires that they adhere to certain standards regarding protocols of operation including those related to auditor competency (see Section 3.4.3).

The GFSI has the potential to be a significant milestone though it has taken more than 10 years to gain global acceptance across the industry and it needs continued support to ensure its continued improvement.

3.4.3 Verification and Auditor Competency

It is not just harmonisation of third-party private audit standards with which we need be concerned. There must also be standards of competency for food safety auditors to give us confidence in their ability. If we can help support getting the certification bodies to a common standard for audit operations then that may truly help the industry. In Australia, a government initiative was set up in 2006 to develop auditor competency standards within a national food safety audit framework. This had some modest success. The GFSI has been working on this same topic for a number of years and are making good progress (GFSI 2014). The International Register of Certificated Auditors (IRCA, www.irca.org) has operated an international recognition scheme for auditor competence for some years. This covers a range of different auditing fields, including quality (ISO 9000:2015 (ISO 2015a)) and food safety (ISO 22000:2005 (ISO 2005)) auditors. Smaller national schemes have also developed, such as the UK Institute of Food Science and Technology's Register of Professional Food Auditors and Mentors (www.ifst.org). The challenge is to bring this together for global acceptance of auditor skills competency and practice standards.

3.4.4 Global Food Traceability Systems

The Global Food Traceability Centre (GFTC) was set up by the Institute of Food Technologists (IFT) together with international food industry and academic stakeholders following a series of summits on the topic in 2011 as a means to provide some leadership to the issue of global food traceability. IFT operates in 100 countries and in the absence of a global 'go-to' resource, agreed to take it on (Fisher 2014). The aim is to generate research to close knowledge gaps and foster better collaboration and awareness of the issue rather than provide a single solution.

3.4.5 Public-Private Partnerships

The formation of public-private partnerships (PPPs), such as the examples described above, is a recent trend that is enhancing our ability to assure food safety by fostering collaboration between different types of organisations that ordinarily had not worked together. The participants in PPPs can be from food companies, academia, and non-governmental, national, and intergovernmental organisations. Trade associations and professional associations (IFT as above, and others as described in Chapter 2) play a key role in facilitating such partnerships.

A further hallmark of PPPs is that they focus more broadly on issues that affect food safety, public health, and animal health, especially by focusing on the interfaces that might be overlooked by the individual disciplines.

The Safe Supply of Affordable Food Everywhere, Inc. (http://ssafe-food.org) was incorporated in 2006. Its initial projects focused on the interface of human and animal health by building veterinary capacity in developing countries and participating in the One World One Health project of the Wildlife Conservation Society (http://wcs.org) to better understand and control the threat of avian influenza. The Global Initiative for Food Systems Leadership (GIFSL, http://foodsystemsleadership.org) was organised in 2008 to build capacity in food safety leadership. Its initial projects to train national leaders

in China and India will help to strengthen food safety in these major parts of the global supply chain. The Global Food Safety Partnership (GFSP) is another potentially helpful example of another PPP, which is under the auspices of the World Bank. Recognising the difficulty associated with many separate organisations doing good work within the global food supply chain, their aim was to bring many of the various stakeholders together, such as private sector producers, processors and retailers, regulatory agencies, consumer advocates, and technical service providers, for effective collaboration on food safety. With a number of philanthropic efforts being funded by various private foundations (e.g. Gates), the GFSI developing markets programme, as well as government aid funded projects, the number of initiatives seems to be growing. There is a lot of potential in this idea of a more transparent and coordinated approach but what remains to be seen is whether the GFSP can deliver. At the time of writing, a new effort is being considered via this organisation, targeting China and ongoing improvement in food safety education. The Partnership for Food Safety Education (www.fightbac.org) was organised to assist consumers in applying safe food handling practices in the home. Its principal strategy is based upon Clean-Separate-Cook-Chill protocols (see Chapter 18).

3.4.6 Food Waste Reduction through Labelling Improvements

The US date labelling report issued by the National Resources Defense Council (NRDC) and Harvard Food Law and Policy Clinic (2013) was previously referred to (see Section 3.2.3). After analysing the problems associated with consumer confusion, which were highlighted in the report, they did publish recommendations which include:

- Making 'sell by' dates invisible to consumers, as they indicate business-to-business labelling information and are mistakenly interpreted as safety dates. These could still be used by commerce to manage inventory.
- Establishing a more uniform, easily understandable date label system that communicates clearly with consumers by (1) using consistent, unambiguous language; (2) clearly differentiating between safety- and quality-based dates; (3) predictably locating the date on the package; (4) employing more transparent methods for selecting dates; and other changes to improve coherency. What could be said, in addition, is that there should be more effort to harmonise the approach taken across the global supply chain – using Codex (which does already have recommendations) as the coordinator.
- Increasing the use of safe handling instructions and 'smart labels' that use technology to provide additional information on the product's safety. Smart labels do not work for everybody, but we likely need a number of mechanisms.

Labelling is, of course, influenced by national legislative requirements and so not all countries would have the same issues as the United States, but there are similarities that this guidance could help to address.

3.5 Tactical Level Responses

What can you do as a food business operator who is inevitably caught up in the global supply chain and perhaps feeling a little overwhelmed by some of the big problems and equally big solutions that are underway? A number of things can be done on a tactical level.

3.5.1 Supplier Audits and Approvals

Given everything described, to find and approve a good global supplier in these circumstances takes a lot longer than it does when working with someone locally, and at a tactical level different approaches are required. A single supplier 'audit' is insufficient in most cases, and the skills required to undertake this work are different to that which would be needed in a traditional local purchase setting. Having said that, given the number of issues that have arisen in the developed world recently, perhaps we need a different approach wherever the supplier is located.

In addition to having a deep food safety technical knowledge, enabling valid risk evaluation, supplier auditors need the softer skills to be able to educate, motivate, and negotiate. This is a different skill set requirement to that of a certification body auditor whose role is solely to assess compliance. With many supplier audits, problems cannot just be identified. Practical solutions (short and long term) will usually need to be discussed, and training and education of suppliers must often be delivered at all levels of their organisation. This starts with motivation of the senior team to want to make the changes needed, followed by education at the cross-functional manager level on food safety hazards and training within the manufacturing environment to effect behaviour change. Training and coaching is also essential during implementation of the HACCP process, which requires deep technical knowledge and judgement, not only during the initial study but ongoing. To support suppliers in development of a sustainable programme takes a lot of resources, but it is important to set a good example to the emerging global food supplier base. Auditors should not take the HACCP plan at face value but need to dig deeper on content (i.e. assess the scientific basis for decision making, validation data, and change management). To do this properly, it is not sufficient to visit once and then every 2 to 3 years. Building a relationship with the suppliers and having a frequent and ongoing presence is *critical* for success, and it is something which the private sector is able to do perhaps more effectively than government in its enforcement role.

Where language barriers exist, the process becomes more difficult, and there are also important differences in cultural understanding around the globe. For example, in some parts of the world, the culture is such that people are very polite and will usually wait to be told the requirements even if they already know them. In a company with the right attitude, once these are understood, corrective actions will be done almost immediately, and they will wait to be told the next thing on the list. Contrast this with some other cultures, where although there may be an excellent knowledge of the theory in terms of what is required, there may be less action orientation in terms of timely implementation.

Many companies have a risk-based approach in terms of the frequency of auditing their suppliers. Often only high food safety risk suppliers are audited, with third-party certification and desk top reviews being used for the lower risk ones. This risk assessment is usually based on microbiological risk, but with recent events, we have to reconsider supplier approval requirements. Sourcing strategies may have to change. Buying through brokers, even for minor ingredients, also requires careful consideration, which will no doubt involve a much more in depth investigation into their supply chain. A 'seeing for ourselves' mentality will increasingly apply back up through the supply chain. Focusing efforts on developing suppliers will almost certainly include a more thorough evaluation of their own ingredient supplier management programme than previously done.

This approach is clearly resource-intensive and probably not realistic given the resources that many of us have, so a risk-based strategy is a good approach, if not essential. Criteria should be considered, such as food safety history within the food product category and whether the supplier is already exporting and/or working with multinational companies who have similar requirements. Use of third-party audits and certifications as a screen and even approval mechanism for low food safety risk suppliers can be helpful, but at the other end of the scale, hiring and training local resources to oversee production on a continuous basis can sometimes be the best or only option if your supplier base justifies this.

There are increasingly some very good and enlightened suppliers in developing countries. A number of multinationals are setting up or acquiring overseas manufacturing plants. There is heavy investment by the local food industry and a hunger for knowledge within the regulatory enforcement arena as well as the industrial workplace. Developing countries often have plentiful natural food resources, inexpensive labour, and are catching up fast, aided by Western companies who are sharing their knowledge. But given the complexity of the supply chain, it is unlikely that we will be able to sit back and feel confident that all issues are covered – not for many years to come.

3.5.2 Business Continuity Planning

Challenges are many and varied, meaning that there is no one single risk mitigation strategy- flexibility is key.

To be flexible, you need to plan ahead. Use a risk evaluation to understand not only which are your high food safety risk ingredients, but also which ingredients pose a high risk due to:

- Sole supplier situation,
- Unique functional role,
- Characterising ingredient (e.g. pecans in pecan pie),
- Instability of the country – economically and politically,
- Variability in currency exchange rates, and
- Commodity items are vulnerable to weather or other factors that could affect crop yields.

Each of the criteria (including the food safety criteria) should be rated and assessed in terms of likelihood of occurrence and severity of effect (including impact to the business). Consider all raw materials, including those used by contract manufacturers and the contract manufacturers themselves. From a cost perspective, the trend some years ago was to go sole supplier. In a global market, it is preferable to understand your risks and have a dual supplier strategy to enable flexibility.

3.5.3 Sharing Technology

It is a natural instinct for global food companies to protect their brands and production and trade practices in order to gain and maintain a competitive advantage over their rivals. However, in the matter of food safety management, many progressive global food companies have adopted corporate policies, declaring that advances in food safety procedures and systems will not be used as a competitive advantage. Rather, the advances

will be shared with the industry, through publications, vendors, and trade associations. The Pillsbury Company perhaps established this trend in the 1970s by very openly sharing its early ideas about HACCP and in continuing to develop HACCP for another 25 years. Cargill Inc. openly shared its otherwise proprietary knowledge in 1996 in which steam pasteurisation of beef carcasses was used to reduce the hazard of *Escherichia coli* O157:H7 in raw ground beef. Similarly, Cargill was also an early developer and continuing participant in trade association training programmes to eliminate the hazard of *Listeria monocytogenes* in cooked, refrigerated, ready-to-eat meat and poultry products.

3.5.4 Shared Training and Education Resources

A recent (2016) and interesting development in the United States is the formation of a food industry learning alliance under the leadership of the Grocery Manufacturers Association. The idea is that member companies who subscribe to the alliance are able to share in training and education resources – either that they have contributed and are willing to make available, or that are jointly developed. Many topics are not proprietary-HACCP, metal detector operation, pest control, and many other GMP areas can be easily shared but customised if needed by the user company.

3.5.5 Increased Awareness of Emerging Issues

As food business operators, we all need to be proactive about keeping up to date with emerging issues. Joining news feeds, being a member of professional associations, participation in trade association share groups, and attending meetings can all be very helpful.

3.6 Conclusions

The world is changing quickly and the speed of change is accelerating. Technology, ease of travel and distribution, the low cost of labour in the developing countries, and environmental changes are just a few of the factors that were considered in this chapter. One thing is certain- that a world-class food safety programme needs the agility to anticipate and adapt to change. It is complicated. As the developing countries continue to develop their food safety programmes based on what worked in more developed countries, we need to be aware that what worked before and in a different environment may not be the best approach now. We have to be mindful of the basic concepts and open to new ideas from anywhere in the world.

Global food trading is no longer a choice. It is now a way of life. At a tactical level, we have to find approaches to manage the various challenges and risks. There are varying standards and a lack of knowledge which requires a different approach to not only approving a supplier but also supporting their development. Sourcing management strategies must be risk-based and flexible: use of third-party auditor schemes, consultants, and laboratories as well as going to see for yourself and carrying out detailed audits, training, and follow-ups are options, and, of course, these lead to a different cost structure for supplier approval.

Ironically, as we look at the recent major (real and perceived) food safety outbreaks, for example, *Salmonella* in chocolate and peanut butter; *E. coli* O157:H7 in salad crops;

horsemeat in processed meat products; and *Listeria* in ice cream, it is interesting to reflect that these occurred in the established food production arena of the West where we should have the knowledge to prevent this from happening. The lesson here is that we can never feel complacent that all issues are under control – anywhere in the world. New issues arise and we have to have the flexibility to respond and strengthen programmes as needed. As we have said already, some of these recent issues arguably could have been prevented with stronger implementation of prerequisite and HACCP programmes (chocolate and peanut butter), but some perhaps required new research into control mechanisms (salad crops).

Problems can be seen as opportunities. The US FDA developed HACCP-based regulations for canned foods in 1973 as a result of food safety failures. India set up the spice board as a result of Sudan and Para Red contamination. The United Kingdom now probably has one of the safest meat processing operations in the world as a result of BSE and they have set up a food crime unit in the aftermath of the horsemeat issue, and the Chinese government remains committed to working hard to rebuild the country's food safety systems and to deal with the economic adulteration issues that were all too visible to the Western world.

It should be easy to follow best practice standards and to act with integrity, always seeking to do better and learn from others. But it is not easy. Through the still remaining lack of robust global coordination (e.g. of standards, regulations, training and test protocols), we make it difficult.

4

The Future of Food Safety and HACCP in a Changing World

4.1 Introduction

Change is the new norm and change is all around us – in technological advances, in globalisation, in economic and environmental conditions, in the expectations of the new generation coming into the workforce, and in changing consumer values and demands. Many social changes have impacted the food industry across the globe, for example:

- Changing lifestyles – more people eating out than cooking at home, leading to an increase in foodservice establishments and a decrease in domestic cooking and in-home food preparation skills and knowledge.
- More women working outside the home and an increased reliance on convenience – producing a further decrease in food preparation skills.
- Decreasing number of people involved in agriculture and more urbanisation – very evident in rapidly developing countries such as Asia but also in the Western world where we have seen a dramatic shift in the last 50 years. This leads to increased demand for prepared foods or for out of home eating.
- Increased mass production of foods and globalisation of the supply chain means that more people can be affected if there is a food safety failure. Such failures are exacerbated when communications are hindered by difficulties in tracing products in distribution.
- Increased travel and tourism means that people are exposed to new food experiences, driving the desire for a more global food choice, which means a need for global supply chains. It also means that consumers are more exposed to foodborne hazards from multiple countries.
- Evolution of consumer eating patterns – the demand for shorter and 'cleaner' ingredients lists, foods that are 'free from', and fresher refrigerated foods with shorter shelf life.
- Consumer increased desire to know where their food is coming from (increased transparency), along with ethical decision making, often based on perceived social value such as environmental protection or animal welfare.
- Consumer emerging preference to supporting smaller local entrepreneurial producers, often by shopping at farmers' markets.
- The increase in functional foods or diets seen to have health benefits – such as fermented foods/probiotics, high fibre, and protein source.

Food Safety for the 21st Century: Managing HACCP and Food Safety Throughout the Global Supply Chain, Second Edition. Carol A. Wallace, William H. Sperber, and Sara E. Mortimore.

- Ageing populations in many countries, together with the increase in the types and numbers of foodborne pathogens, mean that a higher number of people are susceptible to foodborne illness.
- Attempts to improve public health, for example through reduction of salt, fats, and sugar in processed foods. In this space, consumers are often confused in terms of what they are supposed to do for a healthy diet. Research is sometimes published, debated in public as it is picked up by the media, and consumers are swayed back and forth. One such example is salt reduction targets where, based on recent research (Mente et al. 2016), the wisdom of this as a widespread practice is now being questioned. The research findings suggested that cardiovascular disease and death are increased with low sodium intake (compared with moderate intake) irrespective of hypertension status, whereas there is a higher risk of cardiovascular disease and death only in individuals with hypertension consuming more than 6 g of sodium per day (representing only 10% of the population studied). These data indicate that lowering sodium is best targeted at those individuals with hypertension who also consume high sodium. For food safety practitioners who know how valuable salt is as a preservative to prevent the growth of pathogenic microorganisms, this is potentially good news! No doubt further research will follow.

Against this complex and ever-changing backdrop and with continued high numbers of foodborne illnesses from both developed and developing countries, it is clear that something has to change. We cannot continue to operate as we have been and expect a better result – if anything the situation will get worse. And yet, we are asking the same questions now as we were 10 years ago. They were the right questions then, so *why has nothing changed*?

The European Commissioner for Health and Consumer Protection said in 2001 that consumers fundamentally expected safe food (Byrne 2001). This is a basic human right. The events leading up to his speech had included bovine spongiform encephalopathy (BSE), dioxin, contaminated olive oil, and then foot and mouth disease. Consumers were shocked, but the complexity of modern food production methods became more transparent to them as a result. In 2012, an ABC news story in the United States shocked US consumers as it revealed how 'pink slime' (a dysphemism for lean, finely-textured beef) is manufactured and used in the food industry. Whilst not permitted in all countries, in the United States, the product is allowed to be used in ground beef, and it can be used in other meat products such as beef-based processed meats. This was not a food safety issue but like the revelation regarding substitution of horsemeat as an economically motivated adulterant in the United Kingdom and Europe in 2012 and 2013, it rocked consumer confidence in the food industry, particularly larger scale.

This chapter will look at some possible ways forward but will begin by briefly cataloguing some additional changes in food safety and technology that need to be taken into account when thinking about future needs.

4.2 Food Safety Issues

4.2.1 Emerging Pathogens

Food safety professionals in the early 1960s were confronted with the need to control only four recognised foodborne pathogens – *Clostridium botulinum, Clostridium*

perfringens, Salmonella, and *Staphylococcus aureus*. Fifty years later, we can easily compile a list of about 20 microbial pathogens that includes bacteria such as *Escherichia coli* O157:H7, *Listeria monocytogenes*, and *Vibrio vulnificus*; parasites such as *Cryptosporidium* and *Cyclospora*; viruses such as hepatitis A; and even prions associated with BSE.

One might think that this fourfold expansion of microbial foodborne hazards would signal that we have finally identified all of the pathogens that will require specific control measures. That is not likely. Epidemiologists suggest that we can expect many additional foodborne pathogens in the future (Woolhouse and Gowtage-Sequeria 2005). They have identified 1407 species of human pathogens, of which 816 are zoonotic. About 130 species are classified as emerging or re-emerging bacteria or viruses. The ability of microorganisms to rapidly mutate or adapt to changing conditions assures that some of these will inevitably enter the food supply chain. We will need to remain vigilant in order to establish effective control measures as new foodborne pathogens emerge.

4.2.2 Changes in Distribution of Pathogens

The ability of pathogens to move globally due to increased trade and travel has been proven. It is now possible for food materials, people, animals, and pathogens to move around the entire world in just one day (Osterholm 2006). The range of pathogens and vectors is expanding as a consequence of climate change and changing ecosystems. Many social factors contribute to the spread of pathogens and complicate our efforts to provide safe food and protect the public health. These include poverty, war, famine, social inequalities, inadequate political structures, and the threat of bioterrorism.

4.2.3 Additional Control Measures

Control measures that we have in place for pathogens that we are aware of today may not be effective against emerging pathogens. This may necessitate changes in food consumption habits if adequate control measures cannot be developed. For example, the global distribution of fresh produce provides many opportunities for pathogen contamination and human illnesses. It may be necessary for immunocompromised people, for example, to consume only cooked produce in order to avoid a serious potential illness.

4.2.4 Antibiotic-Resistant Pathogens

A consumer concern in milk and animal production is that the use of antibiotics as growth promoters in some countries or to treat animal illnesses may lead to a rise not only in foodborne illnesses but also in fatalities as a result of infection caused by antibiotic-resistant pathogens. Widespread and unnecessary use of antibiotics in the medical industry has also contributed to this, but overuse in the food industry is a concern.

4.2.5 Allergens

As discussed earlier, what is considered an allergen does vary slightly from country to country. There are eight allergens that are common through Codex recommendations,

but with several local variations (see Table 3.11 in Chapter 3). At the time of this writing, some countries have regulations on allergen labelling and some do not.

It is also anticipated that, in addition to any current local allergen patterns, similar allergen problems to those seen in the West may emerge in other parts of the world as Western diets become more prevalent. Overall, there needs to be greater awareness of allergen control measures. The good news may come from the research that is underway regarding treatments. These centre around desensitising therapies and appear to give grounds for hope for the parents of children who have nut allergies (see Chapter 18). There is also ongoing research to better understand threshold levels. Australia and New Zealand have published these, but many food processors are unaware of the work and how it may be utilised in the industry.

4.2.6 Other Chemical Hazards

Melamine and its analogues such as cyanuric acid were never included in a HACCP plan before 2008. Hopefully, there will be no repeat of that particular issue, but there will no doubt be other chemical hazards that emerge as a concern. Radiological hazards are referenced for consideration in FSMA (Food and Drug Administration [FDA] 2011b), and many consider this as part of their HACCP chemical hazard analysis. It is not possible to predict such hazards when they occur as the result of a catastrophe (most usual source of radiological contamination) or from deliberate economic adulteration; however, it is essential that processors remain up-to-date with knowledge on chemical hazards, emerging issues, and amend their control systems accordingly.

4.2.7 Physical Hazards

In the last 10 years, advances in technology have brought improvements in physical hazard control – improved metal detector capability and understanding of best practice for operation, X-ray detection, and vision systems. Improvements will continue and businesses should be on the alert for new improved equipment. It is hoped that there will also be advances in other areas such as sifter screens which do not break up – or have an alarm to alert the operator if they do.

4.2.8 Economically Motivated Contamination

This is a relatively new area of concern but rapidly developing (see Chapter 13). Not all contaminants that have been associated with food fraud are a food safety concern, but, as highlighted earlier, some are. In addition, consumers want increased transparency and trust in their food sources. The type of contaminant that is a concern is often difficult to detect unless looking for it (an example is cumin being diluted with ground up peanut shells in 2015), but we are advancing our capabilities by using big data technologies – able to connect data on imports, versus scarcity due to crop failure or weather, increases in pricing, and to gain insights on potentially higher vulnerability items.

With increased understanding of new or changing foodborne hazards, there may be opportunities to develop new control measures.

4.3 Technology Advancements: Processing and Laboratories

Technological advancements mean that there will be increased use of newer technologies for process control. For example, processing techniques such as pulsed electric fields and ultra-high pressure treatments have been discussed in the literature as new for some time but are starting to be used more widely. Further use of technologies such as eBeam, microwave, and dry pasteurisation treatments such as hot boxing of flour will become more commonplace.

Use of robotics has given us the opportunity to reduce one of our greatest hazards from food manufacturing plants (i.e. people and the manual handling of food). Whilst it is unlikely that robotics will ever completely replace human workers in the food industry, we may also see developments in robotics for sanitation, thus eliminating the risk that comes when someone is wielding a pressure hose! Further online control systems (e.g. electronic, real time, and continuous critical control point [CCP] monitoring) will help to remove potential for human error; however, the need for verification by human monitors is likely to remain important.

Another area where advances are being made all the time is in laboratory detection equipment for chemical analysis. This means that we will have choices to make regarding minimum detectable levels versus safe levels. Often, these decisions will be made on the basis of regulatory or legal, rather than technical or public health, considerations. The downside of this improving capability (as already highlighted in Chapter 3) is increased food waste as we increasingly detect contaminants that are not meant to be there at very low levels, which might not have potential for safety impact but will likely mean recall and destruction of offending food batches. There are implications here for food security as we recognise the need to feed a growing global population.

Rapid and improved methods for microbiological testing also offer major benefits, not least improvements in reducing detection time that will be a huge help to the industry and public health laboratories. Whole genome sequencing (WGS) for foodborne pathogen subtyping has emerged as a new technology that has potential to provide rapid detection of the cause of foodborne disease outbreaks. WGS characterises pathogen isolates based on genetic identity which allows scientists to rapidly distinguish between different isolates; however, data interpretation can and will still be challenging, particularly if one aims to establish whether two isolates that are genetically identical (or have only one or a few genetic differences) share a recent enough common ancestor to establish a cause-and-effect-type relationship (Wiedmann 2015). Using WGS, Orsi et al. (2008) were able to demonstrate that a 2000 human listeriosis outbreak was caused by a *L. monocytogenes* strain that had persisted in a food processing facility over 12 years.

The GenomeTrakr network (www.fda.gov) is the result of an international effort to build a network of laboratories that can sequence the genomes of foodborne pathogens and was established by the FDA in 2012. It comprises FDA, state, federal, and international food safety laboratories focused on sharing WGS data on a global scale. Use of the network is allowing major progress in outbreak investigations. For example, in determining which illnesses are part of an outbreak and which are not, and which ingredient in a multi-ingredient food is responsible for the outbreak. The technique also allows differentiation of sources of contamination, even within the same outbreak, and the linkage

of small numbers of illnesses, including geographically diverse illnesses that might not otherwise have been identified as a common outbreak (Food Safety Magazine 2016).

Communication systems have significantly improved over the last 20 years. Rapid communication capability exists today and is used during incidents to some effect. However, there must be opportunities to harness this for more proactive means such as best practice information sharing during normal circumstances and better coordination of information flow and consistency of messages when there is a crisis.

4.4 Food Safety Management

4.4.1 HACCP Preliminary Steps and Principles

As we saw in Chapter 1, there were only three HACCP principles when Pillsbury first started using the system, now there are seven. It is reasonable to think that there may be additional changes to come, either in the principles themselves, in the guidelines for their application, or by the addition of other food safety management tools. At time of writing, the Codex Alimentarius Committee on Food Hygiene has agreed to open up the documents for revision and draft amendments are being discussed. The following were our suggestions in the first edition of this book of where additional principles and guidelines could strengthen the HACCP system and maintain its consistent use throughout the world. It is interesting to note where Codex might be headed with these changes. It is early days, but from what has been published, we have indicated whether this might be a likely change.

- **The need for a HACCP principle on validation.** The way validation appears in the Codex document currently is in the guidelines on verification activities. Whilst validation could usefully be established as a principle in its own right in that it currently plays a role in Principle 3 in the validation of critical limits and in Principle 6 to verify the accuracy of the HACCP plan (Sperber 1999), this is unlikely to change despite recent Codex Committee discussions. Written in this way, it is somewhat confusing and almost certainly one of the reasons why validation sometimes gets missed as a requirement by those new to the concept. However, the seven HACCP principles have been promulgated into regulations worldwide, are well accepted and would be difficult to change or add to in number.
- **The need for a HACCP principle or further guidance on the need for maintenance of the HACCP system once established.** This would do more for ensuring that HACCP is kept up-to-date than any amount of training. History has shown the need to call this out as a basic rule of ensuring continued food safety. The need to *constantly* be on the alert for any change that could lead to a change to the HACCP plan is often lacking. Changes in plant layout, equipment, new ingredients, processes, emerging hazard data, and industry issues – anything that is different to the original basis on which the plan was built should trigger a maintenance activity. For the same reason as validation above, it is unlikely that this will become a further HACCP principle, but further guidance on maintenance requirements of HACCP systems will be important.
- **The need for additional guidance on HACCP Principle 1 - Hazard Analysis**. This is a really important element of HACCP and yet is the area that new (and many

existing) users struggle with the most. Practical guidance is needed not only on how to identify hazards but also in how to do a qualitative risk evaluation in terms of assessing the likelihood of occurrence and the severity of effect. Plant-based personnel, in both small and large companies, often lack access to the necessary information and competence to be able to do this properly (Wallace et al. 2014). A documented risk evaluation is now a requirement of many of the third-party audit schemes, including ISO 22000. Overall, this may be helpful as in the past many companies did not formally discuss and certainly did not document their decision-making processes.

- **The need for additional guidance on implementation activities.** Implementation of the results of the HACCP study as documented in the HACCP plan needs to be emphasised and guidance provided. Most companies do understand that once a CCP is identified, they have to manage it, but guidance on implementation would be helpful to drive a consistent approach. It could include the need for training, possible additional equipment, and documentation such as forms and record keeping.
- **The need for additional guidance on the need for prerequisite programmes (PRPs) and their relationship with HACCP.** Since food safety can only be assured by proper implementation of both HACCP and PRPs, it seems reasonable to include the latter as a formal part of the HACCP system. Guidance is needed not so much as to what PRPs are, since that is covered in Codex General Principles of Food Hygiene CAC/RCP 1-1969 (Codex 2009a), but clarification on how they enable the HACCP system to focus on the specific critical areas of control for food safety (i.e. those which manage significant hazards). A PRP decision tree such as that proposed by Campden BRI (Gaze 2009) or that published by Mortimore and Wallace (2013) (see Chapter 10, Figure 10.9) could be introduced into Codex guidelines. This is an area that is under discussion by the Codex Alimentarius Committee (CAC) on Food Hygiene (CCFH48 2016). In the proposed revisions (which can be found on the CAC website), it can be seen that the need for further discussion was highlighted regarding whether the concepts of GHP-based control measures and HACCP-based control measures (recently used in other Codex publications) would be appropriate for CAC/RCP 1-1969. A call for a definition of operational PRPs has also been proposed along with several other terms. As this is still very much at the discussion phase, we will refrain from further comment. Readers are advised to follow the latest proposals on the CAC website (http://www.fao.org/fao-who-codexalimentarius/meetings-reports/en/).
- **The need for additional guidance on training and education.** Training and education is such an essential component of all food safety programmes that it may well warrant inclusion as a HACCP principle in its own right in the future or at least as a strengthened requirement. Training is currently in the guidelines but in general terms. In the future, this could be enhanced to be more specific towards both training *and* education for the actual use of the principles, including education on hazards, how to carry out risk evaluation, and training and knowledge requirements for the HACCP team versus the CCP monitors and their supervisors as well as for implementation and ongoing maintenance of the system. The requirement for validation and verification of the training could also be included as a requirement. Guidance on knowledge needs by HACCP principle (i.e. a standard globally accepted and

recognised curriculum) could dramatically aid uniformity of application in the future. This by itself will not be enough, experience has shown that support and mentoring post training is also needed.

These are just a few ideas for consideration and there will no doubt be additional thoughts and comments from other experienced practitioners. Further discussion (at time of writing) is ongoing at the level of the Codex Committee on Food Hygiene in order to gain international consensus on required amendments. The development of a more cohesive approach to hazard analysis and the combined role of HACCP and PRPs in assuring food safety will strengthen future food safety management systems. More importantly, it will strengthen the fundamental understanding that food safety cannot be assured by HACCP alone.

4.4.2 Additions to Current Prerequisite Programmes (Codex Principles of Food Hygiene)

Understanding of the important role of PRPs came after the initial developments in HACCP and evolved to allow HACCP to focus on significant food safety hazards associated with food processes (Wallace and Williams 2001). Whilst some of these control systems had previously been in existence in industry under the titles of good manufacturing or good hygienic practices, the need for formalisation of support systems for HACCP brought PRPs to the fore. Development of the Codex International Principles of Food Hygiene (Codex 2009a) highlighted key areas where PRP controls were needed; however, like the HACCP document, the ongoing Codex review is likely to bring changes. The following are areas highlighted for consideration in the previous edition of this book, which remain issues today.

- *Allergens* are included in most industry PRP documents but do not get mentioned in Codex Hygiene Principles (2009a); instead, they are only inferred under consumer information. They should be included at the next revision.
- *Training* is included in the Codex document but could be strengthened, not least by adding that supervisors of food handlers should have more in-depth training to enable them to *reinforce* and *enforce* appropriate hygienic behaviours. HACCP training has already been mentioned, but adding emphasis to the requirement for HACCP training (HACCP team, CCP monitors, and HACCP auditors) within the Food Hygiene document would be an additional way of ensuring closer ties between HACCP and PRPs. Again, there is an opportunity emerging for the upcoming revision.

4.4.3 The Human Factor

In reviewing the numerous incidents that have occurred over the past few years, it appears that the future involves a *back to basics* approach. We have not yet mastered the basics of food safety. Despite calls for a new intergovernmental agency to coordinate on standards (see next section), we are putting people at the top of the list of basics that need to be addressed.

Food safety events occur at manufacturing or foodservice establishments, or in the home. They do not occur in:

- government offices (though failure root cause may include inadequate regulation and enforcement),
- corporate offices (though failure root cause may include inadequate policies, deployment and culture, or an unsafe product design), or
- customer offices (though failure root cause may include inadequate supplier requirements and specifications).

Every scenario, every decision cannot be anticipated and documented ahead of time. We need trained, educated people *close to the action* - people who understand concepts and can think on their own, people with the knowledge to do things right and the integrity to do the right thing, and people who are held accountable and who take responsibility.

Just because global standards exist, it does not mean they will be followed, so we have to think bigger. The 2009 peanut butter incident in the United States, where over 700 people were made ill and 9 people died, is a great example. The company is reported (*USA Today* 2009) to have cleaned up just prior to their third-party customer audit and reverted to their normal (dirty) state after. This is about both trust and culture. Trust does not exist if there is a 'they/them' versus 'us' mentality. It has to be about 'we'.

Despite depressing headlines, the calls for action seem to have stayed the same over the last couple of decades. What has changed, and what is perhaps the real hope, is the recognition that food safety is very much a human as well as microbiological or systems problem (Griffith 2009). Cross-contamination is still one of the major root causes of most food safety incidents. Getting consumers as well as food handlers to behave hygienically and implement food safety practices is crucially important. It needs to start in schools (which, for example, in the United Kingdom it does – see http://curriculum.qcda.gov.uk) and be a part of a global public education ongoing initiative (e.g. using the WHO '5 Keys to Safer Food' [WHO 2006b]), with the goal that food safety is one of the life skills that is just 'known' – like crossing the road safely. This places major emphasis on effective training if this type of behaviour change is to be successful, and it will not be the food scientists who lead the charge, or if they do then they will certainly not be on their own –the behavioural scientists and human resource professionals will be right beside them.

Training, Education, Leadership, and Culture

Most authors of HACCP texts, including ourselves, have highlighted the need for training and education (Mortimore and Wallace 1994, 1998, 2001; Scott and Stevenson 2006; Gaze 2015). For many other authors, however, training has historically been mentioned but in an almost 'check the box' manner. The tide started to turn in 2009 when several thinkers in this space started to gain traction. Motarjemi and Gorris (2009), Gorris and Motarjemi (2009), Griffith (2009), Pennington (2009), and Yiannas (2009) were amongst the first authors to raise the topic to another level in which the recognition of the critical role the human factor plays in food safety assurance gained recognition. Analysis of outbreaks of foodborne illness shows that food safety incidents can often be prevented. That is why we implement HACCP and PRPs. However, unless people have the knowledge enabling them to have the understanding necessary to want to work hygienically and operate in a culture where they believe that following procedures is the right thing to do and the normal way to do things, then there will always be a higher probability of failure.

Despite the recognition that this area is a critical element of a food safety programme, there are gaps that must be addressed. We will examine a few of these in the sections that follow.

The quality of training can be improved. Many industrial consultant trainers have limited knowledge of the theory of adult learning and even less concerning human psychology. Some may also have limited grasp of their food safety topic. Many trainers do have the facts but often fail to make the conceptual leap between presentation of factual information and being able to use that information for risk-based decision making (Mortimore and Smith 1998). There is also variable awareness that, like any PRP, training needs to be both validated and verified (Wallace and Williams 2001). In the United States with the FSMA Preventive Control rules becoming law in September 2016, there has been a mammoth effort focused on training. This comprehensive curriculum was developed by the Food Safety Preventive Controls Alliance and the materials are freely available via the FDA website (FSPCA 2016). There is, however, no oversight of the trainer's ongoing capability and no requirement for knowledge validation post training. This is a missed opportunity and one that will no doubt be regretted in the years to come.

There is a shortage of good quality global resources for both training and education. It is important to make the distinction between the two as both are needed:

Training: Aims to provide specific task-related skills and is often practical. Objectives are usually expressed in behavioural terms.

Education: Aims to provide theoretical and conceptual material which stimulates the learners' critical and analytical faculties.

Topics can cross over between the two, for example:

- HACCP training for operators as part of giving them the skills they need to monitor CCPs.
- HACCP training for HACCP team members as a way of thinking and working within the overall food safety hazard management programme. This would include an educational element.

We need a food safety human resource strategy for the industry that utilises both training and education and, as added value, strives to develop leadership across all levels. Figure 4.1 illustrates how the industry needs a mix of both in order to develop a trained and educated workforce. Higher education can fill the gap with up-to-date technical knowledge and thinking. Industry personnel at all levels in the organisation should be encouraged to take advantage of this and to continually improve skills and knowledge both through industrial experiences and academic input. The Global Initiative on Food Systems Leadership (GIFSL) has been mentioned already (see Chapter 3, Section 3.4.4) as one example.

There must be a coordinated approach with oversight across countries. The Industry Council for Development's (ICD; http://www.icd-online.org) mission has been to partner with intergovernmental organisations and to jointly contribute to public health through training, education, and building knowledge capacity in both food safety and nutrition. But it is not enough. Training and education need to be raised to a higher level, recognised as an integral part of food safety management and not a 'box that has to be checked'.

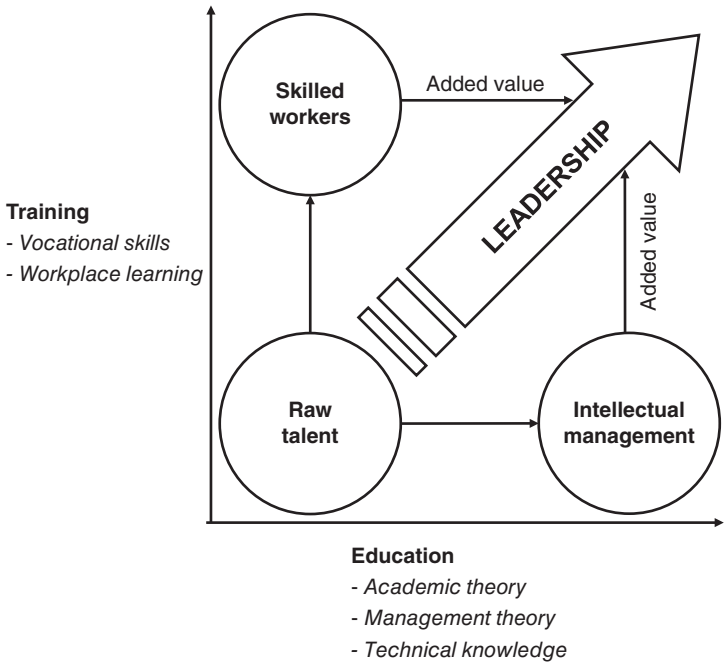

Figure 4.1 Trained and educated workforce.

Availability of Food Safety Professionals

The food industry is one of the biggest employers globally. For example, in the United Kingdom, there are an estimated 400 000 employees in 6620 businesses (Food and Drink Federation [FDF] 2016). Yet, there is a shortage of higher level skilled workers as well as blue-collar workers coming into the industry. Student interest in science-based subjects has decreased significantly and the food industry does not exactly have a glamorous image when compared with some of the newer and more fashionable professions, such as those related to the media, biotechnology, or environmental sustainability. This is a challenge for the future of the food industry and where, again, a coordinated effort across borders may be needed and new initiatives such as food safety education in schools are starting to play a part (e.g. [the 'Hands On'] Middle School programme in the United States; Hands On Classrooms 2013).

Knowledge Resources

Linked to above areas, there is a need now and in the future for a trustworthy knowledge base. Many books, internet sites, and academic papers exist, and many are excellent but some are not peer-reviewed or written by acknowledged experts. It is difficult for those still learning to differentiate between those that are good and those that may mislead and confuse. In addition to this, global food corporations are the major repositories of information about food safety hazards and their means of control but may treat it as proprietary knowledge. We need to consider how to make more of their knowledge available publicly.

Food Safety Culture

Emerging from the interest in human factors, an area recognised as being key to effective food safety behaviours in the food industry, is food safety culture (Griffith 2009; Yiannas 2009, 2015; Jespersen et al. 2017). This is how all employees think and act towards food safety (when no one is watching them); it embodies their belief in the tools and practices used to do the best job they can in preventing foodborne illness and goes beyond the operator and the plant or foodservice operation. It starts with the most senior person in the organisation and must encompass all functions at all levels. The Global Food Safety Initiative (GFSI) recently commissioned a Technical Working Group to develop a guidance document which will eventually be used for benchmarking the various audit standards and schemes that are becoming available. For a lot more on this see Chapter 15.

4.4.4 Global Food Safety Assurance

We have learned a lot in terms of scientific advances, but, in some ways, all that has done is to emphasise how much further we have to go to get control of our food supply. Consumers have a right to safe food regardless of who makes it – small producer, large producer, in whichever country – it should not matter. Consumers expect their governments to deliver on this. When we take a look at root cause, there are a number of themes in addition to the human factor as described earlier. These are:

- oversight and harmonisation,
- enforcement, and
- the need for a combined approach across multiple systems.

Oversight and Harmonisation

Improving food safety oversight and harmonisation depends on an accurate recognition of the roles and responsibilities of the principal stakeholders in their efforts to assure and verify food safety. Without such recognition of distinct responsibilities, individual parties may work at cross purposes. The resulting confusion or ignorance may lead to a lack of adequate oversight, as demonstrated by the 2009 issues with *Salmonella* in peanut products.

Assuring food safety is primarily the responsibility of the food industry in the broadest sense and not just the manufacturers. The industry is responsible for the safety of food materials throughout the supply chain. Food corporations have most of the knowledge and expertise necessary to identify and control foodborne hazards. In its processing facilities, the food industry is responsible for implementing and maintaining adequate HACCP and PRPs, a responsibility that is literally borne 24 hours/day. The primary role of governmental bodies is to verify that food safety practices in the industry are acceptable and in place. This responsibility is most effectively discharged through the audits of food processors' documentation of their food safety programmes. The effectiveness of current regulatory inspections has been challenged. The United Kingdom has an example of this where a number of children were made ill and one boy died as a result of *Escherichia coli* O157:H7 contaminated food in South Wales (Pennington 2009). Governmental agencies can develop guidance documents, lead risk assessments of newly-detected hazards, and promulgate reasonable and practical rules and regulations when necessary.

Accepted food safety practices vary – between countries and within countries. Regulation varies too, but seeing the efforts of some of the GFSI benchmarked standard owners

as they try to find a way to a common understanding with regards to expectations really drives this home. Codex establishes the principles, but interpretation of these varies. Interestingly, HACCP interpretation varies a lot less than PRPs, possibly because it is a much narrower subject, but problems remain despite that. The time could be right for the creation of a new organisation that could provide coordination of the various efforts, provide oversight, and provide guidance to governments regarding enforcement. As more and more countries regulate in the area of food safety, the differences between them is likely to increase. It is essential that the food industry and governmental bodies collaborate more effectively to fulfil their individual responsibilities for food safety. At the most recent GFSI annual meetings, there were government meetings that took place alongside, and whilst encouraging, this is still a small step that has yet to show progress.

Multinational food companies have worldwide operations that enable them to fulfil their individual responsibilities for food safety. They have developed the HACCP system and spread it worldwide within their supply chains. They are ready to participate in a more effective and consistent global food safety programme that will require them to continually challenge their own systems as well as sharing non-competitive knowledge with others in the supply chain. In particular, better practices must be established and maintained at the myriad points of origination of food commodities and ingredients that enter global food commerce.

There is, however, no comparable array of individual regulatory and health or intergovernmental agencies with the global connections and authority to support necessary improvements in global food protection. Much of the global influence for food safety resides in United Nations' (UN) organisations. The Food and Agriculture Organization (FAO) is principally involved in food security and some elements of food safety, while the World Health Organization (WHO) is principally involved in public health. Both are supported in their missions by the Codex Alimentarius Commission (CAC), which develops food standards, guidelines, and codes of practice to assist in protecting public health and ensuring fair trade. Likewise, the World Organisation for Animal Health (OIE) is responsible for animal health and food safety for products of animal origin.

No single organisation, however, has the necessary accountability, scope, or focus to enhance and ensure global food protection; a situation further complicated by the complex setting of critical public health, animal health, and environmental protection issues in which it must operate. Furthermore, current trends in population growth, climate change, and resource availability will make it even more difficult to protect our food supply. The necessary leadership to make progress, in spite of these trends, can be provided by a new global food industry–intergovernmental collaboration.

It has been proposed that a new intergovernmental organisation be created to complement and expand the industry food protection efforts (Sperber 2008). It could be placed within the UN parallel to WHO and FAO, supported by CAC and OIE, with its sole emphasis on food protection. Named the 'Food Protection Organization (FPO)', its programme would include the many elements necessary to ensure food protection, including, but not limited to:

- promoting global understanding, implementation, and verification of enhanced food protection measures,
- establishing incentives for intergovernmental collaboration,
- providing farm to table coverage with a focus on points of origination,
- requiring the use of HACCP and PRPs,

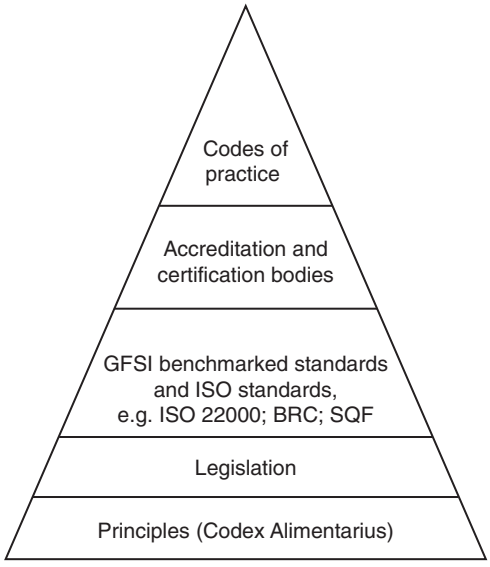

Figure 4.2 The relationship of standards. *Source*: Adapted from Robach (April 2009).

- advancing uniform audit procedures with industry collaboration, and
- establishing traceability systems for food ingredients and products.

The FPO could be considerably more proactive and cost-efficient than the current fragmented system, ultimately enabling the effective use of all applicable resources to enhance food protection for all consumers. Standards set by this organisation must be outcome-based to ensure a degree of flexibility and foster development of new best practices. It needs to provide guidance that has scientific foundation but is risk-based and practical.

The industry, government, academia, non-governmental organisations (NGOs), and consumers need to collaborate openly. Leadership can come from any of these areas (HACCP and GFSI came from industry), but it must inspire, model (the future), and coach in order to combat cultural resistance and the 'it won't work here' attitudes that abound. Globalisation is a reality, and that will not change. We need a way to communicate and collaborate across borders.

There may not be a need for new standards. Plenty exist already (Figure 4.2), but the necessary coordination does not.

Enforcement

In the United States, it is no secret that the FDA has had insufficient resources for enforcement in the field. Other countries have their own particular challenges. Here are a few thoughts on this as we consider the future of food safety and HACCP:

- There is always a benefit in having someone else take a look at your systems, provided that they are competent. This can:
  - provide a learning opportunity,
  - identify areas for improvement,
  - enable sharing of best/different practices, and
  - validate that existing practices and programmes are appropriate.

- A partnership between government enforcement agencies, corporate auditors, or customer auditors (all have an enforcement role) is far more effective than a police mentality.
- An effective and efficient future might look like this:
  - Third-party auditing across *all* businesses by *highly skilled experienced* (in the food sector) auditors.
  - The audit will be carried out by more than one auditor and will take several days. This is a food safety audit and needs to take as long as it needs to do thoroughly. The number of auditors on the team and the length of the audit will depend on the size and scope of the business.
  - The audit should be carried out at the request of the auditee (company being audited).
  - The result of the audit should be shared widely with anyone who wants to see the report (transparency).
  - Audits and inspections (or at least the good manufacturing practice elements) should always be unannounced (i.e. should be a true reflection of the day-to-day condition of the company).

The *benefits* of this new style third-party auditing are worth having. It would negate the need for the masses of customer-supplier audits that still occur each year which will allow suppliers and customers to focus on more specific issues relating to their business transactions (product-specific food safety, sensory, functionality, productivity initiatives). However, third-party audit firms must work from the common standards (perhaps GFSI) and be overseen by the national accreditation bodies who in turn have some additional (not in place today) oversight and accountability. The GFSI approach is still not going deep enough with respect to food safety hazard analysis - there is too little time on the site and often too little knowledge and experience to do it properly as a team of one.

Combined Approach

Often heard at plant level is the request for a combined review of programmes – food safety and quality, environmental health and safety, and now a plea to include sustainability and corporate social responsibility. There are benefits in terms of ensuring that all managers are on site during the audits, but the downside is dilution of effect - inability to review in detail and the impact is not as great when reviewing opportunity areas for each programme. That said, there is a certain amount of overlap and, of course, competing resources. Certainly, at the governmental level, having oversight of issues such as the following could be beneficial:

- public health,
- animal health,
- environmental sustainability,
- food safety,
- food security, and
- food defence.

Combine this list with concerns over the following list (which were discussed in more detail in Chapter 3) and it becomes clear that a more collaborative approach among the food industry, academia, and national, non-governmental, and

intergovernmental organisations will be needed to improve food safety and public health protection:

- Increasing human population. Whilst already at 7 billion people, policy makers seem to calmly accept the fact that the population will increase another 2 to 3 billion in the next 40 years. How can we feed 9 to 10 billion people, and what exactly is expected to happen after 2050?
- Increase in the number of immunocompromised people. It is estimated that about 20% of the human population is immunocompromised by age, pregnancy (in which case the foetus is at greater risk than the mother), or chronic illness. This proportion is expected to increase as human life expectancy increases (Gerba, et al. 1996).
- Pressure to use land for biofuel production, which does not require the same food safety standards and reduces flexibility of use if non-food-grade grain is produced.
- Decreasing availability of water, arable land, and fossil energy sources.
- Climate change is reducing crop production by droughts and by rising sea levels that will flood coastal crop land.
- Food demand is increased by the improving economic status in developing countries.
- Political instability in developing countries and political inaction in developed countries are major obstacles to progress in maintaining an adequate and safe food supply.
- Changes in technology and agricultural practices to improve yields.
- Loss or lack of knowledge.

4.5 Changes in Thinking/Policy Making

4.5.1 Food Safety Objectives

Not exactly new thinking but still not yet widely used in industry, food safety objectives (FSOs) can be used by government (or industry) to communicate food safety targets (ICMSF 2005). FSOs have been defined as:

> *statements based on a risk analysis process which includes an expression of the level of a hazard in food that is tolerable in relation to an appropriate level of consumer protection. When justified by the risk assessment, the FSO should include expression of the level of the hazard as a maximum tolerable concentration and/or frequency* (Hathaway 1999, p. 249).

Thus, they form a bridge between the application of control measures (i.e. HACCP and PRPs) and the acceptable level of risk to the consumer population.

FSOs are distinct levels of foodborne hazards, often microbiological, that cannot be exceeded, but are different to setting microbiological criteria which are used for acceptance and rejection. FSOs can be used for measuring improvement of food safety controls. They can be set at point of consumption or higher up in the supply chain. The principle is that HACCP and PRPs are outcome-based and FSOs are a metric that can be used to assess success. In doing it this way, different control measures, processing technologies, formulations, etc. can be compared for their ability to meet or exceed the objective.

4.5.2 End Product Testing

As pointed out in Chapter 1, the food processing industry after World War II relied heavily upon finished product testing to verify food safety. However, product testing has not provided a practical approach to detecting public health hazards that occur at a low incidence. This dilemma led to the emergence of the HACCP system in the 1960s. Even though companies using HACCP do not usually need to conduct product testing and rely on lot acceptance criteria, many customers still require a wide variety of microbiological tests to be performed on finished products. This is a logical disconnect that seems to have its origins in the 1960s publications by the International Commission on Microbiological Specifications for Foods (ICMSF 1974) and the National Academy of Sciences (NAS 1960; Food Protection Committee 1964; Foster 1971).

These publications detail hazard and risk categories, sampling plans, and microbiological specifications. Together, these can lead to extensive and expensive programmes for product testing. It must be pointed out that these programmes were developed for the analysis of materials of unknown origin and unknown means of control, to be applied anywhere in the global supply chain. They are also necessary to investigate acute problems, such as *Salmonella* in dried eggs in the 1960s or *Salmonella* in nuts in 2009. The logical disconnect that carries over to this day is that many food processors and their customers expect that the same procedures should be applied to all food production, the vast majority of which is of known origin and produced under adequate controls. Such products do not require stringent testing, and, in many cases, any testing at all.

Food suppliers and processors operating under normal controlled conditions are beginning to use microbiological monitoring guidelines rather than microbiological specifications and lot acceptance criteria to verify the safety and quality of their products. Periodic monitoring of the production environment and product build-ups, using indicator tests such as aerobic plate counts and mould counts, can often suffice to verify compliance with sanitation and HACCP requirements. The monitoring results can be shared with customers and inspectors. Finished products should not need to be tested for food safety (Sperber and NAMA 2007), but can be used to build confidence in the system by amassing such verification data over time. A substantial effort is still required to educate the food industry and other stakeholders to reduce or eliminate the use of unwarranted microbiological specifications and testing requirements. With the advent of new capabilities, such as WGS, the ability to detect and connect data has rapidly developed and is proving very effective as a means to understanding the profile of your facility and to connect the dots in the event of an outbreak.

4.5.3 Hazard Analysis versus Risk Assessment

The processes of hazard analysis and risk assessment share a common step: hazard identification. That common step has confused some food professionals to think that hazard analysis and risk assessment are essentially identical, to the point that the risk assessment process could replace hazard analysis in the formation of a HACCP plan (Sperber 1995, 2001). We want to strongly dispel this misguided notion as it has the potential to confuse and undermine the established success and practicality of HACCP systems.

Hazard analysis in Codex terms is the process of identifying hazards at each process step together with determination of which are of such significance that they need to

be controlled. It also includes the consideration of effective control measures. It is a qualitative, local process conducted by the facility HACCP team over a period of several weeks or months. Because of the unique nature of manufacturing facilities, ingredient supply chains, and product formulations, each food processing facility will have a unique HACCP plan. Qualitative databases such as sensitive ingredient lists for bacterial pathogens, mycotoxins, allergens, and foreign materials are useful in this process.

Brainstorming by the multidisciplinary HACCP team is an important means to identify potential hazards associated with new products, processes, facilities, markets, and regulations, thus allowing their evaluation. In the industrial setting (manufacturing plant or foodservice operations), many third-party audit standards and organisations are using the term 'risk assessment' to prompt an evaluation of likelihood and severity during hazard analysis. Also, it is used extensively for evaluation of appropriate controls within a formalised PRP, and these are very good things to be doing.

However, the term 'risk assessment' has (perhaps unfortunately) been used by Codex (1999), in stark contrast to hazard analysis, to describe formal risk assessment; this is a quantitative, global process by which a particular hazard can be numerically quantified for a particular food category. Risk assessments, requiring several months or years to complete, are conducted by a large, sometimes global group that includes food safety experts and risk assessors from academic, industrial, public health, and regulatory entities. Prominent examples of recent risk assessments include *Listeria monocytogenes* in ready-to-eat foods (FAO/WHO 2002) and *Escherichia coli* O157:H7 in ground beef (Food Safety and Inspection Service [FSIS] 2001). One such risk assessment can serve for many years to guide the deliberations of countless HACCP teams around the world.

Hazard analysis and risk assessment in this sense are distinctly different processes. Each should be valued and used for its distinctive purpose.

4.6 Conclusions

The future of food safety and HACCP could be very exciting. It could also be bleak and disappointing if we do not have the courage to take some bold steps when the opportunity arises and if we cannot get the emerging initiatives to take hold. We need to address the urgent need for *knowledge and leadership* across the global food industry (all stakeholders), we need to adopt emerging technology that can help us in the fight against foodborne disease, we need to continue the work aimed at having *common standards* and science-based regulations, and we need a global *infrastructure* to provide global strategy and oversight. We are on the brink of recognising the important role that food safety culture plays in this area, and we are awaiting the changes to the Codex Hygiene and HACCP principles. Since the last edition of this book, it does feel as though change is occurring for the better. Nevertheless, we cannot let another decade go by and *still* be asking the same questions and calling for change.

Part II

Foodborne Hazards and Their Control

5

Recognising Food Safety Hazards

5.1 Introduction

A great many hazards of different types may enter the food supply, making the food potentially harmful when consumed. Product development teams, food safety managers, and HACCP teams must be aware of these hazards when developing products and processes and when conducting hazard analyses so that proper control measures can be established as necessary.

5.1.1 What is a Food Safety Hazard?

A foodborne hazard is 'a biological, chemical, or physical agent in, or condition of food with the potential to cause an adverse health effect' (Codex 2009). The definition is focussed very sharply on food safety considerations. This chapter will describe and explain foodborne hazards according to this globally-accepted Codex definition.

Biological hazards include pathogenic bacteria, fungi, viruses, prions, protozoans, and helminthic parasites. Manifestations of these hazards typically involve foodborne illnesses with symptoms including gastrointestinal distress, diarrhoea, vomiting, and sometimes death.

Chemical hazards include allergens, mycotoxins, heavy metals, pesticides, and cleaning and sanitation chemicals. When ingested, these may cause gastrointestinal distress, organ damage, and immunological reactions that may result in death. Long-term ingestion of foods containing toxic chemicals can lead to chronic effects, including cancer.

Physical hazards typically include materials that enter the food throughout its production chain, such as extraneous vegetable material, stones, bone fragments, wire pieces, broken glass, and wood splinters. Their presence in food may result in choking, or oral or internal cuts, but rarely result in death.

5.1.2 What is not a Food Safety Hazard?

Many types of quality and regulatory defects that occur during food processing are not considered to be food safety hazards because they would not produce an adverse health effect if such food were consumed. Therefore, these defects are not identified as significant hazards during a hazard analysis, and they are not included in the HACCP plan. Rather, they are controlled by the use of prerequisite programmes (PRPs), as described

Food Safety for the 21st Century: Managing HACCP and Food Safety Throughout the Global Supply Chain, Second Edition. Carol A. Wallace, William H. Sperber, and Sara E. Mortimore.

in Chapter 10, and specifications and quality control mechanisms. Spoilage microorganisms may produce flavour, odour, and visual defects without making the food harmful for consumption. Souring of milk, putrefaction of meats, gassing of liquid products, and the appearance of microbial colonies on the surface of foods are examples of quality defects. Regulatory defects occur when a food does not conform to the requirements of particular regulations. The presence of certain foreign materials, undeclared non-hazardous ingredients, extraneous vegetable material, or otherwise mislabelled product containers may violate regulations without representing an overt health hazard. Similarly, diluting agents or other ingredients substituted as part of fraudulent activity may not be hazardous although, in this case, the unknown provenance of materials may mean that other unknown hazards could be present (Chapter 13).

5.2 Biological Hazards

5.2.1 Epidemiology and Morbidity Statistics

Epidemiological data are reported up to several years after the occurrences of illnesses and outbreaks. Therefore, it is somewhat difficult to estimate the current number of foodborne illnesses. Nonetheless, the World Health Organisation (WHO) reports that an estimated 600 million – almost 1 in 10 people in the world – fall ill after eating contaminated food and 420 000 die every year, resulting in the loss of 33 million healthy life years (DALYs). Children younger than 5 years of age carry 40% of the foodborne disease burden, with 125 000 deaths every year (WHO 2015a).

The US Centers for Disease Control and Prevention (CDC) estimated that the annual foodborne illness burden in the United States was responsible for 47.8 million illnesses, 127 839 hospitalisations, and 3 037 deaths (Morris 2011; Scallan, Hoekstra et al. 2011; Scallan, Griffin et al. 2011). Often disparity exists between these types of estimates and surveillance data because many foodborne illnesses are mild and are not reported to public health agencies. The CDC's Foodborne Diseases Active Surveillance Network (FoodNet) recorded 19 542 foodborne illness cases between 2006 and 2014 (Table 5.1). Notifiable diseases not included in the FoodNet programme' (e.g. botulism and trichinellosis) account for further but lower numbers of cases (Table 5.2).

Various government laboratories compile data on outbreaks and cases of foodborne illness as attributed to specific food categories. Recent data from the European Union (European Food Safety Authority [EFSA] and European Centre for Disease Prevention and Control [ECDPC] 2015) shows the distribution of food vehicles implicated in outbreaks; a range of food items are identified with eggs and egg products making up the largest segment at 18.2% (Figure 5.1).

The numbers and types of foodborne illnesses are not well defined in many of the developing regions of the world. Those regions and countries with modern surveillance and reporting systems, including Canada, Europe, Australia, and New Zealand, report statistics similar to those cited previously from the United States (Todd 1997; Notermans and Borgdorff 1997). In contrast, several island nations of the southeast Pacific report a much higher proportion of foodborne illnesses caused by *Vibrio* spp. (Azanza 2006; Su et al. 2005).

Table 5.1 The incidence per 100 000 population of bacterial and parasitic infections and haemolytic uremic syndrome in 2005, 2015, and 2020 targets.

Pathogen	2005	2015	2020 targets
Campylobacter	12.71	12.97	8.5
Listeria	0.31	0.24	0.2
Salmonella	14.81	15.89	11.4
Shigella	6.09		
STEC[a] O157	1.31	0.95	0.6
STEC[a] non-O157	0.46		
Haemolytic-uremic syndrome	1.63		
Vibrio	0.34	0.39	0.2
Yersinia	0.35	0.29	0.03
Cryptosporidium	1.91		
Cyclospora	0.09		

a Shiga Toxin-producing *Escherichia coli*
Source: CDC FoodNet surveillance data (CDC 2007a, 2015)

Table 5.2 Provisional cases of infrequently reported notifiable diseases, United States, 2012–2016.

	2012	2013	2014	2015	2016
Botulism (total)	168	152	161	196	192
Foodborne	27	4	15	37	32
Infant	123	136	127	138	135
Wound and Unspecified	18	12	19	20	25
Trichinellosis	18	22	14	14	27

Source: CDC (2017).

It has long been generally known that most foodborne illnesses occur as a result of food handling and food preparation errors in foodservice operations and in the consumers' homes. Epidemiological data from the Organisation for Economic Co-operation and Development (OECD) member states (representing North America, most of Europe, and four Asian/Pacific countries) document this issue. In an examination of 7191 foodborne illness outbreaks in the period from 1998 to 2001, it was learned that 42% occurred in foodservice establishments and 31% occurred in private homes. Only 3% of the outbreaks were attributed to food manufacturers or retailers. The remaining 24% were attributed to unknown or 'other' locations. The principal contributing factors to these illness outbreaks were determined to be (in descending order of frequency): time/temperature abuse, cross-contamination, improper storage, raw foods, infected persons, and inadequate food handling practices

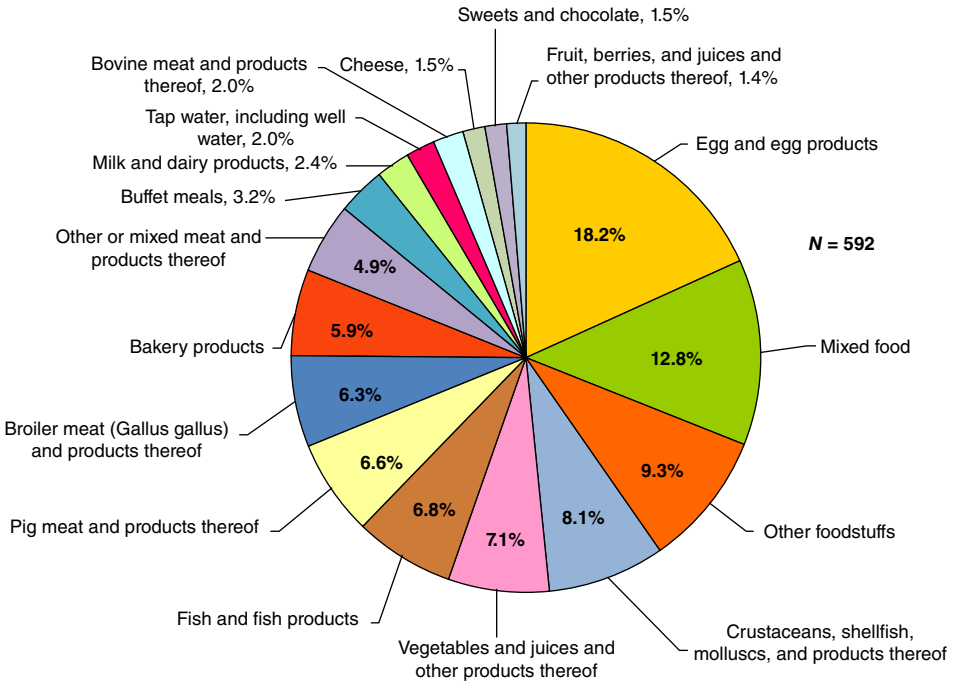

Figure 5.1 Distribution of strong-evidence outbreaks by food vehicle in the European Union, 2014. Data from 592 outbreaks with strong evidence are included: Austria (13), Belgium (16), Croatia (25), Denmark (31), Finland (16), France (122), Germany (28), Greece (1), Hungary (13), Ireland (3), Latvia (3), Lithuania (11), Netherlands (6), Poland (71), Portugal (6), Romania (13), Slovakia (8), Slovenia (4), Spain (143), Sweden (14) and the United Kingdom (45). Other foodstuffs (N = 55) include: canned food products (2), cereal products including rice and seeds/pulses (nuts, almonds) (7), drinks, including bottled water (1), other foods (45). Other or mixed meat and products thereof (29) include: turkey meat and products thereof (4), sheep meat and products thereof (2), meat and meat products (7), other or mixed red meat and products thereof (14), other, mixed or unspecified poultry meat and products thereof (2). Milk and dairy products (14) include: milk (10) and dairy products other than cheeses (4). *Source*: EFSA and ECDPC (2015).

(Rocourt et al. 2003). Further recent data from the European Union (2014) shows a similar location distribution picture (Figure 5.2).

Greig et al. (2007) reviewed food borne illness outbreaks over the past 80 years and revealed that 816 outbreaks could be attributed to errors by food handlers throughout the foodservice industry. The principal etiological agents in the outbreaks were norovirus (41%), *Salmonella enterica* (19%), and hepatitis A virus (10%) (Greig et al. 2007).

5.2.2 Characteristics of Foodborne Illnesses

Types of Illness

Foodborne illnesses can be grouped according to the mechanism of pathogen–host interaction. *Intoxications* (previously called 'food poisoning') occur when a pathogen produces toxin(s) while growing in a food. Upon consumption of a sufficient quantity of 'poisoned' food, the host becomes ill. Botulism and staphylococcal food poisoning are the best-known foodborne intoxications. *Infections* are caused when viable pathogens

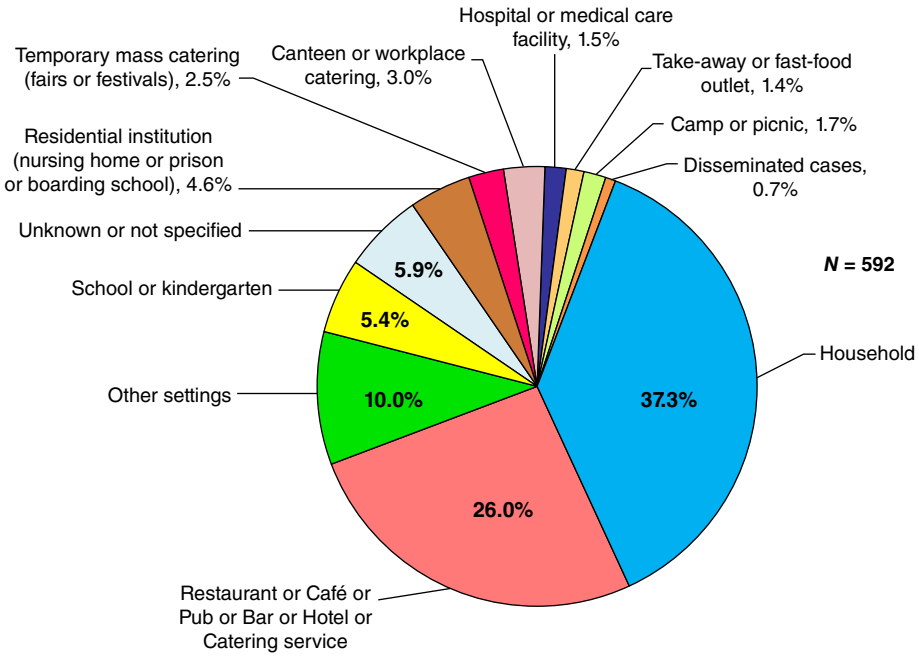

Figure 5.2 Distribution of strong-evidence outbreaks by settings in the European Union, 2014. Data from 592 outbreaks are included: Austria (13), Belgium (16), Croatia (25), Denmark (31), Finland (16), France (122), Germany (28), Greece (1), Hungary (13), Ireland (3), Latvia (3), Lithuania (11), the Netherlands (6), Poland (71), Portugal (6), Romania (13), Slovakia (8), Slovenia (4), Spain (143), Sweden (14) and the United Kingdom (45). Other settings (n = 59) include: farm (3), mobile retailer, market/street vendor (1), multiple places of exposure in one country (1) and other settings (54). Unknown or not specified (35) include: unknown (16) and 19 outbreaks for which information on the setting was not provided. *Source*: EFSA and ECDPC (2015).

in a food survive passage through the host's stomach into the intestine. Enterotoxins may be produced in the intestine, often causing diarrhoea and/or vomiting. Some pathogens may invade the intestinal wall and cause septicaemia or meningitis. Salmonellosis and listeriosis typify these two infective mechanisms, respectively. *Opportunistic* pathogens sometimes cause foodborne *illness* when a host is exposed to very large numbers of a microbe that normally is incapable of causing illness. Often, the host is severely immunocompromised. *Cronobacter* (formerly *Enterobacter) sakazakii* is a recent example of an opportunistic pathogen. It is occasionally implicated in infections of infants born prematurely.

Predisposition to Illness

Humans elicit a wide range of responses when exposed to foods that might be capable of causing illness. Healthy persons with a strong immune system often fend off infectious or toxic doses that would cause illness in less healthy individuals. It is well established that very young (younger than 1 year old) or elderly (older than 70 years) humans are more vulnerable to foodborne illnesses than are humans of intermediate age. Furthermore, humans of any age may be immunocompromised by pre-existing conditions such as autoimmune diseases, chronic illnesses, or immune-suppressive drugs. Cancer, AIDS, and organ transplant patients, for example, are highly immunocompromised.

It is estimated that about 20% of the human population is immunocompromised by age, pregnancy (in which case the foetus is at greater risk than the mother), or chronic illness. This proportion is expected to increase as human life expectancy increases (Gerba et al. 1996). This consideration illustrates the importance of making all foods safe for all people.

Infectious or Toxic Dose

The number of pathogen microbes or quantity of a toxin required to cause illness depends upon the concentration of pathogens or toxins in a particular food, the nature and amount of food consumed, the virulence of the pathogen or toxin, and the health status of the consumer. In some cases, less than 100 pathogen cells are sufficient to cause illness. In other cases, more than 1 million pathogen cells will not cause illness. In the case of foodborne intoxications, the mere presence of a toxigenic pathogen in a food is not sufficient to cause illness. The toxigenic pathogen must first grow in the food and produce sufficient toxin to cause illness. For example, for staphylococcal food poisoning to occur in a healthy adult, *Staphylococcus aureus* must grow to a minimum population of 3 million cells/g of food and the individual must consume about 100 g of the toxic food, the toxic dose being about 1 μg of enterotoxin.

Incubation Period

The elapsed time between the consumption of an implicated food and the onset of illness symptoms is the incubation period. These are typically short (hours or days) for bacterial illnesses and range to weeks, months, and even years for parasitic infections. Foodborne intoxications usually have shorter incubation periods because the toxin is pre-formed in the food. Growth of the pathogen in the host's intestinal tract is not required, as in the case of foodborne infections.

Illness Symptoms

The most common foodborne illnesses typically cause fever, diarrhoea, and/or vomiting. Considered with the incubation periods of the illnesses, these symptoms provide a quick estimation as to the type of foodborne illness (Table 5.3). The less common foodborne illnesses elicit many additional key symptoms (Table 5.4).

Table 5.3 Characteristics of common foodborne illnesses.

Microorganism	Incubation period (range)	Symptoms		
		Fever	Diarrhoea	Vomiting
Salmonella spp.	12 h (6–48)	+	+	+
Staphylococcus aureus	2 h (0.5–8)	–	+	+
Bacillus cereus[a]	1 h (0.5–6)	–	–	+
Clostridium perfringens	12 h (9–15)	–	+	–
Shigella spp.	24 h (12–48)	+	+	–
Hepatitis A virus	28 d (15–50)	+	–	–

[a] emetic toxin-producing strains

Table 5.4 Characteristics of less common foodborne illnesses.

Microorganism	Incubation period (range)	Key symptoms
E. coli O157:H7	4 d (3–9)	Bloody diarrhoea, possible haemolytic-uremic syndrome
Listeria monocytogenes	7 d (3–21)	Septicaemia, meningitis
Clostridium botulinum	24 h (12–40)	Double vision, difficulty swallowing, possible respiratory paralysis
Yersinia enterocolitica	24 h (18–36)	Diarrhoea, vomiting, severe abdominal pain
Vibrio spp.	12 h (4–30)	Fever, diarrhoea, vomiting

Under-Reporting of Foodborne Illnesses

While it may appear simple to determine the cause of a foodborne illness from its incubation period and key symptoms, a great deal of effort is required to confirm the illness and report it to public health offices. Most cases of foodborne illness are mild. The victims often recover in one or several days without seeking medical care. When severe cases require medical attention and even hospitalisation, proof of foodborne illness usually requires isolation and identification of the pathogen or toxin from the implicated food and/or from clinical specimens taken from the patient. It is often estimated that less than 1% of foodborne illnesses are officially reported.

Principal Types and Sources of Foodborne Pathogens

In much of this chapter, we present a great deal of information without tediously documenting every specific data point. The data are accumulated from our own research and experience in the food industry, covering nearly five decades, from several outstanding compilations devoted almost solely to the topic of foodborne pathogens (Doyle 1989; Council for Agricultural Science and Technology [CAST] 1994; International Commission on Microbiological Specifications for Foods [ICMSF] 1996; Lund et al. 2000), and from the indicated references.

Foodborne infections are often zoonotic diseases, meaning that the pathogen can infect both humans and one or more other species of animals. Therefore, the human illnesses are usually linked to raw animal products or the environments in which the animal was raised or processed (Table 5.5). Foodborne intoxications are less directly linked to an animal source. They are often linked to soil and other environmental sources (Table 5.6).

The ability of bacterial pathogens to cause foodborne illness most often depends on their ability to grow in the implicated food. The growth requirements of the principal foodborne pathogens as related to oxygen, temperature, pH, and water activity of the food are summarised in Table 5.7.

Emerging Pathogens

At the beginning of 'modern' food microbiology more than 60 years ago, there were just a handful of pathogens that commanded the attention of the food industry and public health agencies. Today, as evidenced by the remainder of this chapter, dozens of pathogens command the same attention. Epidemiologists predict that food safety

Table 5.5 Sources of bacterial pathogens involved in foodborne infections.

Pathogen	Natural habitat	Associated food sources
Salmonella spp.	Animal intestine	Raw meat, poultry and eggs
	Process environments	Multiple dry foods
Campylobacter jejuni	Animal intestine and soil	Raw poultry and milk
Escherichia coli O157:H7	Ruminant intestine	Raw beef, milk, water, and farm animal contact
Listeria monocytogenes	Soil, animal intestine, and moist processing areas	Raw milk and meat, soft cheeses, and RTE* deli products
Shigella spp.	Animal intestine Human carriers	Freshly prepared foods Foodservice operations
Vibrio spp.	Marine water	Raw shellfish and seafood
Yersinia enterocolitica	Animal intestine and water	Raw milk and water

*RTE, ready-to-eat

Table 5.6 Sources of bacterial pathogens involved in foodborne intoxications.

Pathogen	Natural habitat	Associated food sources
Staphylococcus aureus	Human and animal skin	Raw meat and poultry, and fermented sausage and cheese
Clostridium botulinum	Soil and water	Raw vegetables and fish
Bacillus cereus	Soil, root, and cereal crops	Cooked rice and potatoes
Clostridium perfringens	Soil and animal intestines	Steam table meat and poultry, and stuffed poultry

and public health professionals will be confronted by an ever-increasing number of pathogens. An evaluation of 1407 human pathogens determined that 177 are currently 'emerging', most often from a zoonotic source (Table 5.8).

It has long been recognised that human pathogens may emerge from animal pathogens, the microflora of children, and opportunistic infections of immunocompromised people (Osterholm 2006). The emergence of pathogens is accelerated today by the increased trade of food and raw materials throughout the global food supply chain (Chapter 3), the global trade of live animals, global human travel, microbial evolution, increased susceptibility of the human population, and by the consumer demands for more convenient foods, thereby increasing exposure to food handlers.

The matter of emerging pathogens cannot be taken lightly. Just in the past 30 years, a number of important foodborne pathogens have emerged, including *Listeria monocytogenes, Escherichia coli* O157:H7, *Cyclospora cayetenensis,* and variant Creutzfeld-Jakob disease.

Table 5.7 Growth limits of foodborne bacterial pathogens.

	Temperature (°C)		pH		Water activity
Pathogen	**Minimum**	**Maximum**	**Minimum**	**Maximum**	**Minimum**
Salmonella spp.	6	46	4.0	9.5	0.94
Campylobacter jejuni	27	45	4.9	9.0	0.98
Escherichia coli O157:H7	8	43	4.4	9.0	0.95
Listeria monocytogenes	0	44	4.6	9.2	0.93
Shigella spp.	7	46	4.9	9.3	0.98
Vibrio parahaemolyticus	3	44	4.8	11.0	0.95
Yersinia enterocolitica	0	44	4.4	9.6	0.97
Staphylococcus aureus	7	48	4.2	9.0	0.85[a] 0.92[b]
Clostridium botulinum					
• Proteolytic	10	49	4.8	8.5	0.94
• Non-proteolytic	3	45	5.0	8.5	0.97
Clostridium perfringens	15	50	5.0	8.9	0.95
Bacillus cereus	5	50	4.4	9.3	0.93

[a]Limit for aerobic growth
[b]Limit for enterotoxin production

Table 5.8 Numbers of emerging and re-emerging human pathogens.

Pathogen group	Known pathogens	Emerging pathogens
Bacteria	538	54
Fungi	317	22
Viruses and prions	208	77
Helminths	287	10
Protozoa	57	14
Total:	1407	177

Source: Woolhouse and Gowtage-Sequeria (2005).

5.2.3 Bacterial Pathogens: Special Considerations and Features

Spore-Forming Bacterial Pathogens

Several genera of bacteria, particularly *Clostridium* and *Bacillus*, are able to produce endospores that are resistant to physical and chemical factors such as heat, dehydration, and acidification. They can survive in the environment for a very long time. Upon introduction into a food, the spores may germinate, enabling growth and/or toxin production by the pathogen. In addition, spores can survive heat treatments, grow, and produce toxin in a suitable food (Chapter 6).

Clostridium botulinum This obligately anaerobic (i.e. cannot grow in the presence of oxygen) organism consists of seven serotypes, from type A through to type G, with one or more subtypes. All strains of type A and most strains of type B are proteolytic, mesophilic, and produce very heat-resistant spores. The remaining strains of type B, along with types E, F, and G, are non-proteolytic, psychrotrophic, and produce spores with little heat resistance. Types C and D are pathogenic for animals but not humans. Botulinum neurotoxin is the most potent known biological toxin. Less than 1 ng/kg body weight is sufficient to kill a human (Schecter and Arnon 2000). Death is caused by paralysis of the respiratory muscles. Botulinum toxins are quite heat-labile and are easily inactivated by pasteurisation and cooking procedures. Infant botulism has been recognised as one cause of sudden infant death syndrome (SIDS). Originally believed to be caused by *C. botulinum* spore contamination of honey and other sweeteners used in infant formula, and although honey is still potentially implicated and parents are advised not to give honey to infants younger than 12 months of age (WHO 2016a), it is thought that most cases of infant botulism are caused by ingestion of household dirt and dust (Nevas et al. 2005).

Clostridium perfringens This anaerobic organism, usually found in animal intestines and soil, is commonly associated with hot-held (e.g. steam table/hot buffet) foods such as meats and gravies. It is slightly thermophilic and grows very rapidly without sporulation in the food. After consumption, the cells sporulate in the human small intestine, liberating an enterotoxin during lysis. Because a high number of cells must be ingested to cause the later infection, this illness is known as a toxico-infection. Diarrhoea is the principal symptom of the mild illness caused by *C. perfringens*. The same organism is often involved in wound infections and gas gangrene.

Bacillus cereus Strains of this facultative pathogen can produce one of two general types of toxins. Heat-stable emetic toxin(s) is (are) produced by strains that grow in farinaceous foods such as cooked rice and potatoes. Illnesses associated with these foods can be avoided by adequate refrigeration of the cooked foods. Heat-labile enterotoxin(s) is (are) produced by other strains, some of which are psychrotrophic, that grow in proteinaceous foods.

Non-Spore–Forming Bacterial Pathogens

While illnesses caused by non-spore-forming bacterial pathogens usually result from the ingestion of large numbers of cells, several notable exceptions are described here. This group of pathogens is easily inactivated by heat, yet several of its members are hardy survivors in food processing environments, and one member produces a very heat-stable enterotoxin. All are facultative aerobes.

***Salmonella* spp.** Salmonellosis is one of the most common bacterial foodborne illnesses and the second most common in the United States (Table 5.1). Long recognised as being ubiquitous, salmonellae survive and grow very well outside of their normal habitat, the animal intestine. In particular, salmonellae survive very well in dry environments. They have often contaminated food products that are processed and/or packaged in dry environments, such as dried dairy products, dried egg products, chocolate, soy flour, peanut butter, pet foods, and animal feed. Such contamination incidents are often caused by

the unwise or inadvertent introduction of moisture into otherwise dry processing areas by means of wet cleaning and sanitation procedures, condensation, roof leaks, etc. Typically, salmonellosis is caused in healthy persons by the ingestion of millions of cells. Much lower numbers of cells, about one hundred or less, can infect people who are immunocompromised. Healthy individuals can also be infected by such low numbers if the salmonellae are protected during passage through the stomach, particularly by high-fat foods such as chocolate or peanut butter, or if the pH of the stomach is increased by antacid therapy or a large quantity of food. A global outbreak of illnesses that began about 30 years ago has been associated with shell eggs in which transovarian infection by *Salmonella enteritidis* lead to internal contamination of the egg yolk; however, the risk of this occurring has been reduced in several countries by flock vaccination.

Campylobacter jejuni Campylobacters are another very common cause of foodborne illnesses and the most common in the United States (Table 5.1) and the European Union (EFSA and ECDPC 2015) with about 99% of the cases being caused by *C. jejuni*. It is the most common cause of bacterial foodborne illness in several countries. This pathogen is associated with raw poultry and sometimes raw milk. Illnesses are often caused when cross-contamination between these sources and ready-to-eat (RTE) foods, such as salads, occurs during food preparation. *Campylobacter* are often linked to cases of Guillain-Barré syndrome. This microorganism is more difficult than most to grow *in vitro*, requiring a headspace containing 2–10% carbon dioxide. It does not survive readily in processed foods.

***Escherichia coli* O157:H7** First implicated in outbreaks of foodborne illness in 1982, *Escherichia coli* O157:H7 has been found to be a particularly virulent pathogen. The infectious dose is as low as 10–100 cells. Death can be caused, particularly in children, by haemolytic uremic syndrome (HUS), a condition that may lead to kidney failure. Many serotypes of *E. coli* produce Shiga toxins that are capable of causing HUS, but *E. coli* O157:H7 is the principal serotype associated with foodborne transmission. Originally associated with raw or undercooked ground beef, illnesses caused by this pathogen have more recently been associated not only with meat products, but also with unpasteurised milk and juices, sprouts and other produce, water, and contact with animals on the farm or in petting zoos. The original source of *E. coli* O157:H7 was found to be cattle, in which this pathogen colonises the recto anal junction (Lim et al. 2007). Currently, environmental sources are considered to be equally or more important than cattle or raw ground beef as a source of contamination (Strachan et al. 2006).

Listeria monocytogenes Long known to be a disease of animals or humans closely associated with farm animals, listeriosis was first documented as a foodborne illness in 1981. This microorganism is a relatively weak pathogen; however, it justifiably requires a great deal of attention in the food industry. Although high numbers of cells are required to infect even people who are immunocompromised, the consequences of infections in this group can be drastic. The infections often proceed to septicaemia and/or meningitis and can lead to spontaneous abortion, still birth, and death, with a mortality rate of about 30%. *L. monocytogenes* is psychrotrophic. It can grow to infectious numbers in cooked RTE refrigerated foods of extended shelf life that were contaminated at some point between the cooking and packaging operations or during multiple uses in foodservice

operations or the home. For this reason, control of *L. monocytogenes* receives a great deal of attention in food processing plants that produce these types of food products and in retail establishments that sell or serve them.

***Shigella* spp.** Most shigellae foodborne illnesses are caused by *S. flexneri*. Similar to *E. coli* O157:H7, this pathogen produces a Shiga toxin that can cause HUS. It does not survive very well in processed foods and is transmitted principally by food handlers via the faecal-oral route.

***Vibrio* spp.** Vibrios are halophilic microorganisms that thrive in warm marine or estuarine environments. They are a common part of the microflora of fish and seafood. *V. parahaemolyticus* is most commonly associated with foodborne illness. It is psychrotrophic and often found in shellfish. *V. vulnificus* is found in shellfish harvested from warm waters. It causes a serious infection, with a 50% mortality rate in persons who have a liver dysfunction, such as hepatitis. *V. cholera* causes cholera, which is primarily a waterborne infection.

Yersinia enterocolitica This pathogen is psychrotrophic and sometimes causes illnesses that are associated with raw milk or water. It can cause extreme abdominal pain, sometimes resulting in erroneous emergency appendectomies.

Staphylococcus aureus *S. aureus* produces many serological types of enterotoxins, classified as types A through H. Type A staphylococcal enterotoxin is most commonly associated with foodborne illness. It is very heat stable, surviving 10 minutes at 121°C or more than 20 minutes at 100°C. The toxic dose of this toxin is about 1 μg. Historically, staphylococcal food poisoning has been associated with fermented foods such as cheeses and sausages. Slow fermentation or starter culture failure enables *S. aureus* to grow to high numbers and produce toxic levels of enterotoxin. Cream-filled bakery products have also been a common cause of staphylococcal illness. These are usually caused by contamination from food handlers during the filling operation.

Mycobacterium avium* subsp. *paratuberculosis This pathogen is known to cause Johne's disease in cattle. Though there is no definitive proof, it is suspected to cause a similar disease in humans, Crohn's disease (Gould et al. 2004), and this has led to changes in recommendations for milk pasteurisation in some countries. Its primary food sources are raw milk, raw meat, and water.

Cronobacter* (formerly *Enterobacter*) *sakazakii This microorganism is a prime example of an opportunistic pathogen. A common coliform bacterium, it can be detected in a great many food and environmental sources, but it rarely causes illness (Friedeman 2007). It has been on very rare occasions found to be the cause of infection and death of premature infants. These rare infections are caused by mishandling (extreme temperature abuse) of rehydrated infant formula in the clinical setting (Gurtler et al. 2005). Nonetheless, a heavy burden to eliminate *C. sakazakii* in dried ingredients is rightly being placed on food processors that supply the producers of dehydrated infant formulas.

5.2.4 Viral Pathogens

Foodborne viral pathogens are obligate parasites that grow only in human cells. Therefore, the primary source of these viruses is human faeces. Viruses are transmitted

Table 5.9 Characteristics of viral foodborne pathogens.

Virus	Incubation period [d] (range)	Key symptoms
Hepatitis A	28 (15–50)	Hepatitis, jaundice
Norovirus	1 (1–2)	Projectile vomiting
Rotavirus	2 (1–6)	Infects primarily very young people

hand-to-mouth or by food handler contamination of prepared food, facts that have led to the 'golden rule of food safety': wash your hands! The major symptoms of viral foodborne illnesses are gastroenteritis and hepatitis (Table 5.9).

Several zoonotic viruses are receiving attention in the food safety arena because of their potential to become foodborne.

Influenza viruses

Currently receiving the most attention are the H5N1 avian influenza virus and the H1N1 swine influenza virus. Foodborne transmission of avian influenza viruses will not occur if poultry is cooked to 70°C (Thiermann 2007). However, in contrast to the avian influenza virus, the swine influenza virus is not contracted directly from swine; it also would be inactivated by cooking pork products.

While human influenza outbreaks, including widespread epidemics with many deaths, have confronted humanity since antiquity, avian influenza was first recorded in Italy in 1878. Known then as fowl plague, outbreaks in birds became common, appearing in North America in the 1920s. A deadly epidemic in humans at this time was caused by influenza strain H1N1. In 1955, fowl plague was found to be caused by an influenza virus. Today, there are three types of influenza viruses: types A, B, and C. The most common type of influenza, type A, causes epidemics in humans and also infects domestic animals such as swine and birds. Types B and C affect only humans. Highly pathogenic avian influenza (HPAI) strain H5N1 was found in humans in Hong Kong in 1997. It has since spread through countries in Asia, Africa, and the Middle East. To this date, several hundreds of infected humans have died, whilst millions of birds have died or been culled to prevent spread of the disease. Public health officials remain concerned that H5N1 could mutate into a more pathogenic form such as H1N1, thereby causing much larger outbreaks and mortality in humans who come into contact with infected birds.

In recent years, wild birds in many countries have been infected with a new strain of HPAI, H5N8. This virus, and several related viruses, was detected early in 2016 in 11 European and Asian countries in dead ducks, swans, gulls, geese, turkeys, and laying hens, and a Chinese farmer contracted H5N6 avian flu and died (National Wildlife Health Center 2016). Similar infections have been detected in the United States in wild birds that travel the Pacific, Central, and Mississippi flyways (migratory bird paths); US Department of Agriculture ([USDA] 2016). Whilst the infected wild birds have little impact on the human population, they can infect flocks of domestic birds. In the past two years, many infected commercial flocks were sacrificed at great cost to the growers.

SARS and MERS

A flare-up of sudden acute respiratory syndrome (SARS) in 2003 (www.who.int) revealed a new zoonotic virus whose host appeared to be civet cats in Asia. Whilst

not thought to be foodborne, SARS, is a prime example of an emerging zoonosis. It demonstrates that food safety and public health professionals must always be prepared to 'expect the unexpected'. A related and again not foodborne illness, Middle East respiratory syndrome (MERS) is a viral respiratory disease caused by a novel coronavirus (Middle East respiratory syndrome coronavirus, or MERS-CoV) that was first identified in Saudi Arabia in 2012. Although the majority of human cases of MERS have been attributed to human-to-human infections in healthcare settings, current scientific evidence suggests that dromedary camels are a major reservoir host for MERS-CoV and an animal source of MERS infection in humans (WHO 2017).

Foot and Mouth Disease

Foot and mouth disease (FMD) is not a zoonosis because it does not infect humans. It is, however, of great economic importance to the food and agricultural industries. FMD is a severe and highly communicable disease of cloven-hoofed ruminants – cattle, sheep, goats, and deer – and swine (Haley 2001). FMD outbreaks are controlled by quarantine zones and the destruction of sometimes millions of animals, whether infected or not. In a world of increasingly limited resources, procedures to protect the food use of these animals could be developed, as the FMD virus does not infect humans and is inactivated by cooking.

Porcine Epidemic Diarrhoea Virus

Common in Europe and Asia for the past 40 years, the first case of porcine epidemic diarrhoea virus (PEDv) occurred in the United States in 2013. It has since spread to 26 states, killing about 1 million pigs. The disease is much more severe in suckling pigs younger than 7 days old. It is characterised by a profuse, yellow, watery diarrhoea. The pigs vomit, stop eating, become dehydrated, and die. Infected pigs cannot be treated except with oral electrolytes. PEDv cannot infect humans; there is no health risk if pork products from infected pigs are accidentally consumed. (In any event, pork should be well cooked). The best means of prevention are strict biosecurity and sanitation. As a result of PEDv, many states have stopped showing pigs at county and state fairs (Estill and LeaMaster 2014).

5.2.5 Prions

Originally thought to be 'slow virus diseases' because of their long incubation periods, the causative agent was discovered to be not a virus, but a misshapen normal cellular protein called a *prion* (Table 5.10). The infectious prion causes disease by catalysing a change from normal to infectious state and the crystallisation of prions in brain cells. With the destruction of sufficient brain cells, microscopic holes appear in the brain, hence the term *transmissible spongiform encephalopathy* (TSE).

Kuru

Kuru, a neurological disease that affected mostly the Fore tribes in New Guinea, became well known to the rest of the world when it reached its peak in the 1950s (Phillips 2016). Individuals became infected after eating the brains of dead family members as a way of paying respect to the deceased. As kuru can have a very long incubation period, the cause and effect of kuru were not understood earlier. The study

Table 5.10 Features of prion diseases of animals and humans.

Disease	Host	First detected	Incubation period (y)
Scrapie	Sheep and goats	1732	2–5
BSE	Ruminants and felines	1986	4–5
vCJD	Humans	1996	10–15

Source: Hueston and Bryant (2005).

of kuru, the first neurodegenerative disease resulting from an infectious agent, led to the discovery and research on a new class of diseases that includes Creutzfeldt-Jakob disease, Gerstmann-Straussler-Scheinker disease, fatal familial insomnia, scrapie, and bovine and feline spongiform encephalopathies. These diseases of the brain affect primarily the cerebellum, which controls muscle coordination and balance. Their outcome is always fatal.

Scrapie

Scrapie, known for at least 250 years, affects the central nervous system of sheep and goats. Female animals sold from infected flocks can spread scrapie to other flocks. Scrapie can be transmitted to hamsters, mice, rats, voles, gerbils, mink, cattle, and some species of monkeys by inoculation. There is no evidence – after 250 years – that it poses a threat to human health. Symptoms of the disease include scratching and rubbing against fixed objects, hence the name, *scrapie*. However, the disease has been transmitted throughout most of the world. Only two countries, New Zealand and Australia, are recognised by the United States as being free of scrapie (APHIS 2004).

Creutzfeld-Jakob Disease

Creutzfeld-Jakob Disease (CJD) is a TSE that regularly occurs throughout the human population at an incidence of about one case per million people each year and should not be confused with variant CJD, which, although unfortunately named, is linked to the BSE epidemic. Minnesota, population about 5 million, has 5 CJD deaths per year. The United States, population about 320 million, has been recording about 300 CJD deaths per year. Minnesota and the United States have many people dying from CJD but have had little or no contact with BSE; only four cases have been detected in the past 20 years, during which time at least 6000 people died of CJD.

BSE and vCJD

A new TSE was identified in 1986 when Bovine Spongiform Encephalopathy (BSE, or 'mad cow disease') was detected in UK cattle. Eventually it was determined that BSE had originated from sheep scrapie prions. In 1996, it was determined that a new human disease, inaptly called 'variant Creutzfeld-Jakob Disease (vCJD)' had emerged from BSE. Although it is unrelated to conventional CJD, each reported case of CJD tends to cast suspicion on beef products because of the vCJD misnomer.

BSE was found to be transmitted between cattle by the consumption of contaminated meat and bone meal. Lack of adequate feed controls enabled the spread of BSE by 2003 to nearly every European country and Japan, with two cases detected in North America. The United States banned the importation of live ruminants from countries where BSE

was known to exist in native cattle. Ultimately, nearly 200 000 head of cattle contracted BSE. Millions more were incinerated as a precautionary measure and about 200 humans have died of vCJD.

BSE can be transmitted to humans and other animals by the consumption of brain or spinal cord material from infected cattle. The infectious agent is extremely stable and cannot be denatured by existing food processes. Therefore, stringent control of infected animals, prevention of animals older than 30 months entering the food chain, and complete removal of all tissues likely to contain prions – specified risk material (SRM) – from cattle, sheep, and goats became the main control mechanisms in the United Kingdom. Derogation of the 'over-30-month-rule' was later granted in 2008, but only for slaughterhouses operating to a 'Required Method of Operation' (RMOP) that has been approved by the Secretary of State (UK Statutory Instrument 2008).

The important lesson from this outbreak was that what had begun as a long-recognised disease of sheep – scrapie – in the span of 15 years became a serious public health and food safety matter. The emergence and initial mismanagement of the BSE epidemic emphasises the importance of managing food safety from farm-to-table and throughout the global food supply chain.

5.2.6 Protozoan Parasites

A number of protozoan parasites have been associated with human illnesses that were caused by the consumption of contaminated raw foods or water (Table 5.11). Typical symptoms of protozoan infections, which can persist for months, include diarrhoea, fever, and enteric distress.

5.2.7 Parasitic Worms

Numerous tapeworms and roundworms are involved in foodborne infections (Table 5.12). Most have long incubation periods and are associated with the consumption of raw or undercooked meat or seafood and raw fruits and vegetables, principally soil crops.

5.2.8 Biological Hazards, Zoonoses, and Food Chain Biosecurity Issues

Food biosecurity typically refers to efforts to protect animals from epidemic diseases such as avian influenza, FMD, BSE, etc. Global food trade can be diminished by the occurrence of such epidemics in the raising of domestic animals. Existing biosecurity programmes also strengthen the foundation of food defence programmes

Table 5.11 Protozoan parasites of humans associated with raw foods or water.

Protozoan	Incubation Period (d)
Toxoplasma gondii	10–23
Cryptosporidium parvum	1–12
Cyclospora cayetanensis	7
Giardia lamblia	5–25
Entamoeba histolytica	14–28

Table 5.12 Parasitic worms of humans associated with food consumption.

Parasite	Incubation period	Typical food source
Tapeworms		
Taenia solium	8 weeks to 10 years	Undercooked pork
T. saginata	10 to 14 weeks	Undercooked beef
Diphyllobothrium latum	3 to 6 weeks	Undercooked fish
Roundworms		
Ascaris lumbricoides	2 to 8 weeks	Raw fruits and vegetables and soil
Trichinella spiralis	8 to 15 days	Undercooked meat
Anisakis simplex	1 to 14 days	Undercooked marine foods

(Fuhrman 2014). The protection of animals from epidemic diseases is also important because some zoonotic illnesses can be transmitted to humans. Some of the diseases (e.g. scrapie in sheep) have been known for several centuries, while others, such as BSE, appeared only about 20 years ago in 1986.

The control of animal diseases is necessary not only for animal health, but also to protect human health and to maintain trade in the global food economy. The lack or poor administration of protective measures will lead not only to animal and human illnesses, but also to a loss of domestic and international sales, damaged reputations, and a decline in employment. As mentioned previously, biosecurity controls will also support food defence programmes (Fuhrman 2014). Many biosecurity measures are prerequisite programmes and further discussion of this can be found in Chapter 10.

5.3 Chemical Hazards

A very wide variety of chemical hazards may appear in food products either by natural occurrence in a raw material or by deliberate or unintentional addition during processing. The health effects of the chemical hazards can range from rather benign (e.g. residual cleaning compounds) to acutely toxic or carcinogenic (e.g. some mycotoxins or persistent organic pollutants). Whilst chemical hazards require control because of their overt food safety risks, food producers must also contend with two additional consequences of the presence of unwanted chemicals – regulatory non-compliance and trade disruptions. This situation has become more complex because of different chemical residue limits around the world (Chapter 3) and the tendency to 'chase zero' when knowledge of threshold tolerances is not available.

5.3.1 Allergens

Allergens are naturally occurring proteins to which some persons develop a hypersensitivity or immunological response. Concentrations of allergenic material as low as 1 ppm can induce responses in a matter of several minutes or less. Allergens affect up to 2% of adults and 7% of children. Symptoms range from rashes and nausea to anaphylaxis and death.

Food intolerances or sensitivities are often confused with allergic responses. These are, however, non-immunological responses and are associated with non-proteinaceous

compounds (Timbo et al. 2004). Food intolerances may be caused, for example, by sulphites at concentrations greater than 10 ppm, monosodium glutamate, food colours such as yellow #5 (tartrazine), lactose, and histamine (Section 5.3.3).

The principal global foodborne allergens are associated with groundnuts (peanuts), tree nuts, crustaceans, fish, eggs, milk, soybeans, and wheat (Hefle and Taylor 1999). Regional allergens are associated with, for example, celery (European Union), buckwheat (Southeast Asia), and rice (Japan) and numerous others. Minor allergens include the seeds of cotton, sesame, sunflower, and poppy, as well as legumes and molluscs, and cross-reactivity with other allergens (e.g. reaction to apple in individuals who are sensitive to birch pollen) can cause further problems for sensitive consumers. Properly-refined oil produced from allergenic seeds is not itself allergenic, as all of the proteins have been removed. Allergen hazards may be introduced during food processing by poor control of reworked materials, addition of the wrong ingredient to a food, or mislabelling of the consumer product. They may also be introduced by cross-contamination during food preparation in the home or foodservice operations.

5.3.2 Mycotoxins

Ergotism is an illness that has been known for millennia, long before awareness of mycotoxins emerged in 1961. Ergot is produced during the growth of *Claviceps purpurea* in grassy cereal groups such as rye, oats, wheat, and barley. It is contained in sclerotia that range in size from mouse droppings to several centimetres. The threat of ergotism can easily be avoided by proper grain-handling practices.

Thousands of mycotoxins are produced as secondary metabolites during mould growth. They can enter the food supply when substantial mould growth occurs in field crops. Most mycotoxins are produced by only three mould genera – *Aspergillus, Fusarium,* and *Penicillium* (Murphy et al. 2006).

Aflatoxin, named after *A. flavus*, was discovered after contaminated feed caused the deaths of turkeys in the United Kingdom in 1961. Since that time there have been numerous animal feed recalls due to aflatoxin, particularly in horse feed given their sensitivity to this particular contaminant. It is a potent liver carcinogen. Aflatoxin is a normal hazard in peanut crops during wet years and in corn (maize) crops during dry years when drought-stressed plants are vulnerable to mould infestation. Four serological types (B_1, B_2, G_1, and G_2) of aflatoxin can be produced. Aflatoxin B_1 can be altered in the digestive tract of ruminant animals, appearing as aflatoxin M_1 in their milk.

Patulin can be produced in damaged fruits, particularly apples. Therefore, it is of some concern in products such as apple juice.

Ochratoxin can be produced during mould infestations of wheat, corn, or oats. It can contaminate the meat or milk derived from animals that consumed ochratoxin-contaminated grains. It is of most concern in Africa and the European Union.

Zearalenone, sometimes produced in grain crops, is a mycoestrogen that can disrupt steroidal hormone functions.

Deoxynivalenol (DON), also called 'vomitoxin', is one of 180 trichothecene mycotoxins. Typically produced in wheat and barley during wet years, it often is responsible for feed refusal in animals fed contaminated grain. It is a protein synthesis inhibitor.

Fumonisin was first detected in 1990 after the unexplained deaths of horses. Unlike other mycotoxins, it possesses no aromatic ring structure and is highly water soluble.

Its three serologically-distinguished forms – B_1, B_2, and B_3 – are produced principally in corn (maize). Fumonisin B_1 can cause leukoencephalomalacia, a condition that causes the brains of horses to be dissolved. It is also a suspected cause of human oesophageal cancer (Chu and Li 1994).

Of the several thousand identified mycotoxins, only two – aflatoxin B_1 and fumonisin B_1 – are known to be overt animal pathogens. These are suspected, but not proven, to be carcinogens in humans. Many mycotoxins, however, pose substantial regulatory and trade hazards to the food industry. Even in these matters, global concern is largely limited to aflatoxin and patulin.

5.3.3 Marine Foodborne Toxins

Shellfish Poisoning

Several illnesses are associated with bivalve molluscs such as mussels, clams, and oysters. The molluscs filter large quantities of seawater, thereby concentrating pathogenic dinoflagellates or diatoms that produce a number of toxins. Illnesses caused by contaminated molluscs are more likely during red tides (Liston 2000).

Paralytic shellfish poisoning can be caused by several genera of dinoflagellates, including *Alexandrium, Gymnodinium, Pyrodinium,* and *Saxidomus*. The last produces saxitoxin, a very heat-resistant and lethal toxin. The illness is characterised by tingling, nausea, and potential respiratory paralysis and death. The lethal dose is 2 mg. The US Food and Drug Administration (FDA) enforces an action level of 80 μg/100 g meat (0.8 ppm).

Diarrhoeic shellfish poisoning results in a mild gastroenteritis, also caused by dinoflagellates.

Neurotoxic shellfish poisoning is a gastrointestinal illness with a low fatality rate. It is caused by brevetoxin, produced by the dinoflagellate *Gymnodinium breve*.

Amnesic shellfish poisoning, also called *domoic acid poisoning*, begins as gastroenteritis and can proceed to neurological symptoms, coma, and death. First recognised in 1987, it is caused by the genus *Pseudonitzchia*, a diatom that produces domoic acid.

Finfish Poisoning

Ciguatera poisoning is caused by ciguatoxin produced by the dinoflagellate *Gambier discus toxicus*. It can be associated with about 400 species of tropical fish. Ciguatoxin also causes gastroenteritis and can proceed to neurological symptoms and death.

Scombroid (or histamine) poisoning is associated with a family of fishes, involving most often tuna, mahi-mahi, and mackerel, that contain high levels of free histidine in their flesh. *Proteus* spp. can grow on improperly chilled fish, decarboxylating histidine to histamine, which produces symptoms that mimic an allergenic response.

Puffer fish (fugu) poisoning is caused by tetrodotoxin, an often lethal neuroparalytic toxin that is produced in the liver or internal organs of the puffer fish by several genera of Gram-negative bacteria including *Vibrio, Alteromonas, Aeromonas, Plesiomonas, Pseudomonas,* and *Escherichia*. It has typically been reported in Japan and Southeast Asia due to the inadequate removal of the internal organs during food preparation.

5.3.4 Genetically Modified (GM) Foods

Genetic modification is the alteration of an organism by the introduction into its genome, or chromosomes, of one or more genes from a different organism. Numerous

crop applications have been developed to prevent plant diseases without using chemical pesticides (BT corn) or to reduce herbicide applications (herbicide-resistant soybeans) (WHO 2007c). Originally, theoretical public health concerns regarding the potential altered allergenicity of GM crops were raised. At this point there is no indication that GM foods are unsafe. In the interests of due diligence, however, food safety assessments need to be conducted on all new GM applications. Whilst no overt food safety issues have been identified with GM foods, major logistical and regulatory difficulties can be caused by the need to segregate GM from non-GM crops, and in the labelling of GM-containing consumer foods.

5.3.5 Antibiotics

Potential food safety and public health issues related to the presence of antibiotic residues in food are not well understood. The hypothesised concern is that the use of antibiotics in animals, either therapeutically or as growth promoters, may give rise to the occurrence of antibiotic-resistant pathogens in the food supply or in humans. Therefore, when therapeutic antibiotics are used to treat animal diseases, adequate clearance times before harvesting are enforced by veterinarians to prevent human consumption of the antibiotic.

Regulatory problems occur because antibiotics that are approved for use in some countries may not be approved in other countries, or their use may be approved at various levels in different countries. In 2003, European Union member states established harmonised minimum required performance reporting limits for the detection of residues of nitrofurans at 1 ppb and chloramphenicol at 0.3 ppb (Food Standards Agency [FSA] 2003). Nevertheless, nitrofurans became a temporary, but severe, regulatory problem in 2004. At that time nitrofurans were legal for use in Thailand poultry, but not in the United Kingdom, whose regulatory limit of 1 ppb in poultry was near the limit of detectability, essentially a zero tolerance. An Irish laboratory applied a new technology that could detect nitrofurans with a much greater sensitivity (i.e. chasing zero). Although in regulatory compliance when the original testing method was used, Thai poultry was banned in the United Kingdom when it yielded positive results with the new testing method.

5.3.6 Persistent Organic Pollutants (POP)

Several thousand complex chemicals have been synthesised since the 1930s for use as pesticides or industrial chemicals. These are generally chlorinated or brominated aromatic compounds that are very resistant to microbial or chemical degradation. Therefore, they persist for a very long time in soil and sediments. Most of these compounds are lipophilic, bioaccumulating in fatty tissues in the food chain (Jones and de Voogt 1999). Because many of the compounds are volatile, they can be airborne for great distances from their point of use.

POPs in aquatic sediments can be accumulated in algae and plankton, which in turn are ingested by fish. Humans and other animals further accumulate POPs when eating contaminated fish. In the 1960s, birds of prey became nearly extinct because DDT accumulated in fish reduced the birds' egg shell thickness. On land, POPs carried by air can contaminate forage which is consumed by grazing animals. The meat or milk from

these animals can transfer the POP to humans. In humans, POPs may elicit chronic effects. They are known or suspected carcinogens, and can function as sex hormone, endocrine, or immune system disruptors.

The principal POPs are well described by Ulberth and Fiedler (2000):

Pesticides. Aldrin, Chlordane, DDT, Dieldrin, Endrin, Heptachlor, Mirex, and Toxaphene are applied to a wide variety of crops. They must be applied according to proper schedule. Crops cannot be harvested until the prescribed clearance period has elapsed.

Industrial chemicals and contaminants: Hexachlorobenzene (HCB) and polychlorinated biphenyls (PCB). Used as a fungicide in crop seeds such as wheat, HCB causes human illness when the seed grain is mistakenly used as food, even though the treated seeds are coloured to discourage consumption. PCBs are used in industrial applications, such as coolants in electrical transformers. The inadvertent or deliberate contamination of feed-grade oils or fats with transformer fluid can occur (Larebeke et al. 2001). The US action level for PCBs in red meat (fat basis) is 1 ppm (FDA 2000).

Dioxins. The principal human exposure to dioxin is through consumption of contaminated fish, meat, or dairy products (Peshin et al. 2002). The contamination of fats used in animal feed with industrial oil led to a massive recall of food products because of dioxin contamination in Belgium in 1999. The European Union has established action levels for dioxins in human food and animal feed ranging from 0.5 to 4.5 ppt (Larebeke et al. 2001; Commission of the European Communities 2002).

POPs and organophosphate pesticides present a significant toxic hazard to pesticide applicators and workers who handle the treated crops. Whilst POPs were widely used in developed countries during the 1950s and 1960s, their toxic effects led to diminished usage and outright bans. While POP usage in developed countries is either limited or banned, developing countries can have wider usage. For example, DDT remains an important mosquito control agent in malaria-endemic regions. Although banned in developed countries, PCBs are present in older electrical transformers and capacitors. Improper maintenance or disposal of these units can lead to contamination of the food supply chain.

5.3.7 Heavy Metals

Heavy metals in the food can have a wide variety of toxic effects in humans and animals including tunnel vision, deafness, chronic brain damage, congenital defects, peripheral neuropathy, hyperkeratosis, nephrotoxicity, and skin cancer (Peshin et al. 2002). Heavy metals typically enter the environment from industrial effluents, coal-fired power plants, and municipal garbage incinerators.

Mercury. Historically recognised as the cause of 'mad hatter's disease', metallic mercury is transformed to methyl mercury in marine and freshwater environments. It is bioaccumulated in the food chain in the same manner as POPs. Methyl mercury-treated seed grain, when mistakenly used as food, has been responsible for foodborne illnesses. Mushrooms obtained near mercury and copper smelters often cause illness. The United States has an action level of 1.0 ppm for methyl mercury in fish, shellfish, and wheat (FDA 2000).

Lead. Lead poisoning can be caused by ceramic ware used for serving food. In addition to neurological symptoms, lead can also cause kidney damage. The action level in various types of ceramic ware ranges from 0.5 to 7.0 ppm (FDA 2000).

Cadmium. Sometimes associated with rice, cadmium is a nephrotoxicant. It can also be associated with ceramic ware, for which action levels of 0.25 to 0.5 ppm have been established (FDA 2000).

Arsenic. Used in various compounds as a rodenticide or fungicide, arsenic is a well-known human poison. Chronic exposure can result in cancer or skin lesions. Arsenic naturally found in rocks or minerals can be released into the groundwater by biological or chemical processes. Whilst groundwater contamination with arsenic occurs globally, it is thought to be a more serious problem in Southeast Asia (Sakai 2007).

Uranium. The heaviest of naturally-occurring metals, the toxic effects of uranium are emerging as a serious public health matter. The 1986 meltdown of a nuclear reactor at Chernobyl caused widespread contamination of soil and crops in Eastern Europe with radioactive fallout. Responsible for many human deaths and congenital defects, the full effects of this tragedy have not yet been realised. More recently and following a similar event which occurred in Japan in 2011 (World-Nuclear.org 2017), the FDA decided to recognise radiological hazards within the 2011 Food Safety Modernization Act.

A new hazard has been associated with uranium because of its density more than its radioactivity. During the enrichment of uranium^{235} for use in nuclear power plants, large quantities of the natural isotope, uranium^{238} (U^{238}) are left over. Massive quantities of low-radioactivity U^{238} are being used to produce 'hardened' ammunition and armour plating for military vehicles. The heat of explosions or impacts vaporises U^{238}. Contemporary war zones are becoming contaminated with U^{238} at levels that are hazardous to the indigenous populations and that will contaminate animals and food crops.

5.3.8 Chemicals Used in Food Processing Environments

A great number and variety of chemicals are used in food processing plants for the routine operation, maintenance, and cleaning of the processing equipment. Care must be taken to prevent cross-contamination of food materials with the chemicals used in food processing environments. Representative chemicals include boiler additives, lubricants, refrigeration fluids, detergents, sanitisers, and pesticides.

5.3.9 Chemicals Used in Food Packaging Materials

Care must be taken in the selection of food contact packaging materials, as plasticisers and additives used in their manufacture may leach into the food product. Adequate knowledge of the chemicals used and their toxicity should be obtained. For example, in 2008, research was begun to understand the public safety impact of bisphenol A that leached into water and foods packaged in polycarbonate plastic bottles or metal cans that had been manufactured with the use of bisphenol A. Testing procedures, requirements, and standards for the migration packaging additives into foods have been republished in England (Statutory Instrument No. 205 2009).

5.3.10 Unanticipated Potential Chemical Hazards

The myriad of naturally-occurring and synthetic chemicals can interact in foods to create derivatives or analogues that may come under suspicion as foodborne hazards. At these times, food safety and public health professionals sometimes need to act quickly in order to assess and control the potential hazard.

Acrylamide has long been used to synthesise polyacrylamide, which is widely used for water treatment, soil conditioning, laboratory applications, and in the production of paper, textiles, and cosmetics (Friedman 2003). The WHO guideline for acrylamide in drinking water is 0.5 ppb. Also produced in cigarette smoke, acrylamide has neurotoxic effects in humans and animals. The serendipitous discovery[1] in 2002 by the Swedish National Food Authority of acrylamide in foods caused temporary alarm throughout the food industry. It was determined that acrylamide is formed when glucose and asparagine interact during the baking or frying of foods at temperatures above 120°C. It is not presently thought that acrylamide is a significant foodborne hazard (WHO 2007a).

Other instances of potential chemical foodborne hazards can occur through deliberate adulteration of food. Chemical adulteration can change the nutritional profile and utility of a food. A 2007 outbreak of cat and dog illnesses and deaths due to kidney failure was caused by the economic adulteration of wheat flour in China with melamine and its analogues – cyanuric acid, ammelide, and ammeline – so that the flour could be sold as wheat gluten. The toxic effects are greatest when melamine and cyanuric acid can interact in the host (FDA 2007). Used in the production of fertilisers and plastics, melamine is a nitrogen-rich compound that can mimic the presence of protein in analytical tests. Cyanuric acid is commonly used in chlorine-based cleaning powders. While this outbreak of pet illnesses was quickly contained without known human exposures, it dramatically emphasised the need for effective food safety controls and verification procedures in global trade. However, just 1 year later, a similar outbreak occurred in China, when 11 infants died when fed milk that had been adulterated with melamine (Jiang 2008; Schoder 2016). In a separate incident in 2004, at least 13 Chinese children died of malnutrition while being fed counterfeit milk that had no nutritive value (Anonymous).

The production and trading of adulterated or counterfeit foods are criminal acts in most countries. Such acts undermine confidence in the safety of the food supply and must be handled swiftly and firmly to discourage further incidents. In November 2009, the Chinese government executed a dairy farmer and a salesman and jailed 19 others for their roles in the melamine contamination of milk.

5.4 Physical Hazards

Foodborne physical hazards are commonly called ‘foreign materials’ or ‘foreign bodies’ because their presence in food is unnatural. Foreign materials in food can be potentially harmful or merely undesirable.

5.4.1 Sources of Foreign Material

Foreign material can enter foods at almost every point of the food supply chain. The general sources of contamination are the environment, the food itself, the food processing facilities, and personal objects.

Soil and stones are typical environmental contaminants during harvesting. During harvesting or by later infiltration, food may be contaminated by insects, rodents, or reptiles. These may be disintegrated during harvesting or processing so that body parts or excreta are the residual evidence of contamination.

1 When testing blood samples of workers in the acrylamide industry, the Swedish authority found similar levels of acrylamide in a set of control workers who had no industrial exposure, leading to its discovery in certain foods.

Some foreign material contamination originates with the food itself. Examples include fruit pits, stones, and stems; bones or bone chips from fish and meat; pieces of corn cobs; nut shells; and hardened or crystallised sugars.

A great deal of foreign material contamination originates in food processing facilities. Metal shavings, nuts and bolts, and lubricants from the processing equipment can enter the food. Nails, cut wires, and broken utility blades can be dropped into the food stream by maintenance workers. Pieces of glass, hard plastic, and wood splinters can enter the food from other fixtures and utensils in the processing area.

Personal objects used or worn by maintenance and line workers and by food handlers in foodservice operations often fall into the food. These may include rings, pencils, papers, earrings, nose rings, buttons, thermometers, hair, and gloves.

5.4.2 Injuries Associated with Physical Hazards

Because of their relatively low occurrence and severity, foreign materials are often not considered to be significant hazards in foods. Whilst most incidents of foreign material ingestion do not result in overt bodily harm, up to 5% of such incidents do result in injury (Hyman et al. 1993; Olsen 1998). Slender, pointed objects such as bone slivers and glass shards are the most hazardous. These can cause oral or gastrointestinal lacerations or perforations. Sharp foreign materials about 2 to 5 cm long are most likely to be involved in intestinal perforations. In these rare cases, subsequent abdominal infections can result in death.

It is generally considered that objects smaller than 7 mm in their longest dimension are not likely to cause injury in adults, as these can pass through the digestive tract without causing harm. However, some particles less than 7 mm may cause harm in infants. Because it is readily softened in the food or upon ingestion, paper is usually not considered to represent a risk of injury.

Many small toys and other objects are marketed with food products to increase their appeal to children and their parents. Objects that are less than about 3 cm in diameter or 6 cm long can present a choking hazard for infants and small children. Larger objects that cannot be swallowed do not present a choking hazard.

Some foods (e.g. grapes or pieces of meat) due to their physical condition (size and shape) may present a choking hazard for small children. For certain animals (older horses are especially vulnerable), choking can also be a significant hazard due to the absence of a reflux mechanism.

5.5 Conclusions

A complete awareness and understanding of the potential biological, chemical, and physical foodborne hazards must be maintained by product development teams, food safety managers, and HACCP teams. Such knowledge is necessary to conduct product and process research and to conduct a responsible hazard analysis and determination of the appropriate control measures that will need to be implemented at critical control points and in prerequisite programmes. All food safety professionals must also remain vigilant in order to be able to quickly respond to unanticipated hazards. 'Expecting the unexpected' is an underappreciated aspect of food safety management.

6

Designing Safety into a Food Product

6.1 Introduction

This is the first of several chapters that will describe the development and application of control measures to assure the safety of food products. A great many physical, chemical, and biochemical technologies can be used to control potential hazards in food.

We have reached the conclusion that, at its core, HACCP consists of two essential processes – product design and control, and process design and control. Both the product and process design requirements are typically defined by research and development groups. It is during this period that control measures must be identified, tested, validated, and incorporated into the product formulation (Mortimore and Wallace 1998; Sperber 1999). Upon completion, the design requirements are communicated to manufacturing teams that scale-up and validate the design requirements at a commercial production level. Individual plant HACCP teams complete the HACCP plan for each product and process and establish the monitoring, verification, and recordkeeping procedures.

This chapter describes product design and control, which is based on the adjustment and control of factors that are intrinsic to the food product. These factors include the ingredients that are included in the food and the equilibrium chemical and biochemical properties of the finished food product.

6.2 Formulation Intrinsic Control Factors

A number of intrinsic, or inherent, food properties (e.g. water activity [a_w] and pH) can be controlled to assure food safety, as well as to inhibit microbiological spoilage and to protect product quality. These two intrinsic properties in particular have been used, perhaps crudely, since ancient times to preserve foods by salting, drying, acidification, and fermentation. As professional food scientists in the 21st century, it is sobering to contemplate that some of our most effective food safety control measures have been used for millennia. In modern times these intrinsic properties are better understood and can be used more precisely to minimise microbial growth without degrading product quality.

Food Safety for the 21st Century: Managing HACCP and Food Safety Throughout the Global Supply Chain, Second Edition. Carol A. Wallace, William H. Sperber, and Sara E. Mortimore.

6.2.1 Water Activity

All microorganisms, of course, require water for growth. The a_w value of a food product has a significant effect on the growth rates and types of microorganisms that can grow in the food. It provides an indication of the availability of water to support microbial growth. Some of the water in a food is unavailable to support microbial growth because it is hydrogen-bonded to constituent molecules in the food. It has long been known that the microbiological stability of a food can be improved either by removing water (e.g. dehydration) or by adding one or more solutes (e.g. salts and sugars). Early efforts to quantify and control these factors involved determination of the percentage of moisture in the product and, eventually, the percentage of the principal solutes. Both of these are relatively crude measures in terms of their ability to estimate the control of particular microorganisms in a food. Modern food product developers need to maximise the inhibition of microorganisms by water activity reduction without creating organoleptic defects because of increased solute concentrations.

The modern use of a_w as a control factor in food product development was greatly facilitated by Scott (1957) as he clearly described its relationship with several physico-chemical properties that can be measured or calculated:

$$p/p_o = n_2/(n_1 + n_2) = ERH/100 = a_w$$

The earliest accurate measurements of a_w involved manometric determinations of vapour pressures and dividing the vapour pressure of a solution or food (p) by the vapour pressure of pure water (p_o). The ideal a_w of a solution or food can be determined by dividing the moles (gram molecular weight) of solvent (n_2) by the sum of the moles of solvent and the moles of solute (n_1). For example, the addition of 1 mole of a salt or sugar to 1000 g (55.5 moles) of water would give a 1.0 molal solution with an ideal a_w of 55.5/56.5 = 0.982. Of course, solutes do not act ideally (ideal behaviour is conceived as the impact of one molecule of solute in an infinite volume of solvent). Therefore, a_w values for solutions with different solutes will vary from ideality (Table 6.1). More recently, it has become feasible to accurately determine a_w values by using instruments that measure the equilibrium relative humidity (ERH) of a food. The a_w of a food is simply its ERH/100 (Scott 1957). Because ERH readings are limited to the range of

Table 6.1 Molalities of different solutes required to provide a particular water activity value.

	Molality			
	Ideal value	Actual value		
a_w		NaCl	Sucrose	Glycerol
0.980	1.13	0.61	1.03	1.11
0.940	3.54	1.77	2.72	3.32
0.900	6.17	283	4.11	5.57
0.850	9.80	4.03	5.98	8.47

Source: Scott (1957).

Table 6.2 Representative water activity values of foods and ingredients.

Food or ingredient	Water activity
Water	1.00
Fresh meat, poultry, and seafood	0.99
Mayonnaise and salad dressings	0.90
Icing, frosting, and pancake syrup	0.80
Dried fruit	0.65 to 0.75
Saturated sodium chloride	0.75
Corn syrup	0.70
Wheat flour, freshly milled	0.65
Wheat flour, 55% high fructose corn syrup	0.60
Dry pasta, spices, milk, and cocoa	0.1 to 0.4

Source: Sperber (1983) and Christian (2000).

0% to 100%, a_w readings will range from 0 to 1.0. In laboratories today, a_w determinations are made quickly and accurately by the instrumental determination of dew point depressions.

The ability of a solute to reduce a_w is inversely proportional to its molecular or ionic weight. For this reason, food product developers favour the use of solutes of low molecular weight, as reduced quantities of a particular solute could be used to achieve the desired a_w value. For example, the average ionic weight of sodium chloride is 29.25, whereas the molecular weight of sucrose is 342. On a theoretical basis, sodium chloride would be about 12 times more effective than sucrose in reducing a_w.

The a_w values of foods and food ingredients (Table 6.2) provide a good indication of the types of microorganisms that can spoil a particular food (Table 6.3). Microorganisms that have a low tolerance for increased osmotic pressure can only grow in high-a_w foods such as fresh meats and beverages. Highly osmotolerant microorganisms such as osmophilic yeasts can grow at a_w values as low as 0.60. No microbial growth has been reported in foods at a_w values lower than 0.60.

The ability of some types of microorganisms to grow at lower a_w values is often related to their ability to accumulate 'compatible' solutes such as glycerol. When a microorganism is exposed to increased osmotic pressures, the movement of water out of the cell will greatly slow or stop its metabolism and growth. Those microbes capable of growth at lower a_w values have been shown to accumulate small solute molecules or ions to restrict the outward flow of water (Sperber 1983; Csonka 1989). Enteric bacteria can grow at a_w values as low as 0.95 by accumulating potassium ions. Continued accumulation of potassium ions is toxic to the enteric bacteria, so growth below a_w 0.95 is not possible. Some of the more osmotolerant microorganisms can grow by accumulating non-ionic solute molecules, which permit their growth at a_w values lower than those provided by ionic solutes (Table 6.4).

Table 6.3 Minimum water activity values and pH ranges that support the growth in foods of various microorganisms.

Microorganisms	Minimum a_w	pH range	
		Minimum	Maximum
Alicyclobacilli	0.98	2.0	6.0
Pseudomonads	0.97	—	—
Enteric bacteria	0.95	4.5	9.0
Clostridium botulinum			
non-proteolytic strains	0.97	5.0	8.5
proteolytic strains	0.94	4.8	8.5
C. perfringens	0.95	5.0	8.9
Salmonella spp.	0.94	4.0	9.5
Bacillus cereus	0.93	4.4	9.3
Listeria monocytogenes	0.93	4.6	9.2
Staphylococcus aureus			
toxin production	0.92	4.2	9.0
aerobic growth	0.85	—	—
Lactic acid bacteria	0.92	3.5	9.0
Moulds	—	0.5	11.0
normal spoilage	0.84	—	—
xerotrophic spoilage	0.62	—	—
Yeasts	—	1.5	8.5
spoilage	0.90	—	—
osmophilic	0.60	—	—

Source: Doyle (1989), Jay (2000) and Sperber, unpublished data.

Table 6.4 Effect of solute on the minimum water activity that will support the growth of microorganisms.

Microorganism	Water activity achieved by:		
	NaCl	Glycerol	Sucrose
Pseudomonas fluorescens	0.957	0.940	ND
Clostridium sporogenes	0.945	0.935	ND
Saccharomyces cerevisiae	0.92	ND	0.89
Candida dulciaminis	0.86	ND	0.81

ND = test not performed or not reported
Source: Sperber (1983), Deak and Beuchat (1996) and Christian (2000).

6.2.2 pH

The pH value, total acidity, and type of acidulant are important intrinsic factors that affect the types of microorganisms that can grow in foods. The pH value is expressed as:

$$pH = -\log_{10} 1/[H^+]$$

Table 6.5 Representative food pH values.

Food	Typical pH value
Carbonated beverages	2.0
Vinegar	3.0
Apple juice	3.1
Orange juice	3.6
Tomato juice	4.2
Cheddar cheese	5.2
Minced beef	6.2
Milk, bovine	6.4
Maize, peas, and honeydew melons	6.5
Fresh fish	6.7
Surface-ripened cheeses	>7.0
Hominy	8.5
Nixtamalised maize	10.0

Source: Lund and Eklund (2000) and Sperber, unpublished data.

where $[H^+]$ is the hydrogen ion concentration. Because pH is a logarithmic function, doubling or halving the amount of acid or hydrogen ions in a food will alter the pH by 0.3 units ($\log_{10} 2 = 0.3$). Pure water is defined as having a neutral pH, 7.0. Values below 7.0 are acidic, whereas those above 7.0 are basic, or alkaline. pH values can range from 0 to 14.

Collectively, microorganisms can grow over most of the pH range, at values ranging from 0.5 to 11.0 (Table 6.3). Some pathogens and extremophiles have evolved elaborate acid tolerance responses in order to survive and grow in reduced pH environments. Most foodborne bacteria grow in a narrower pH range, from pH 4.5 to 9.5. Most foods are in the acidic range, below pH 7.0 (Table 6.5).

The type of acidulant(s) used in a food can have a major effect on the growth of microorganisms (Table 6.6). Some of these are short-chain organic acids (e.g. acetic acid) that impose an inhibitory effect substantially greater than the effect that would be expected from pH reduction alone.

6.2.3 Chemical Food Preservatives

Contrary to common consumer and media perceptions, chemical food preservatives are not harmful. Almost all of those described here occur naturally in foods. Early food scientists observed the antimicrobial activity of certain foods, isolated the antimicrobial agents, and learned how to produce and use them as food preservatives. The commercial use of chemical preservatives is often limited by organoleptic considerations, particularly flavour and odour.

Organic Acids

The inhibitory effect of short-chain fatty acids on the growth of some microorganisms has led to the widespread use of sorbic acid, propionic acid, benzoic acid, and

Table 6.6 Influence of the type of acidulant on the minimum pH growth limit for salmonellae.

Acidulant	Minimum pH for growth
Citric, hydrochloric	4.05
Tartaric	4.10
Gluconic	4.20
Malic, fumaric	4.30
Lactic	4.40
Succinic	4.60
Glutaric	4.70
Pimelic, adipic	5.10
Acetic	5.40
Propionic	5.50

Source: Chung and Goepfert (1970).

parahydroxybenzoic acid (parabens) as food preservatives. Sorbic acid is found in European mountain ash berries. Propionic acid is produced in Swiss cheese by propionibacteria. Benzoic acid is found in cranberries. Parabens are synthesised by additions to benzoic acid.

Two properties of food preservatives are of utmost importance and require careful consideration during the research and development of their uses in specific foods. These are the dissociation constant (pK_a) and the partition (or distribution) coefficient (PC).

Food preservatives exert antimicrobial effects by interfering with internal metabolism, which requires their passing through the microbe's cytoplasmic membrane. Only the undissociated form of organic acids can pass through the cytoplasmic membrane. The pH of a food directly affects the proportion of the preservative that can enter the cell, as described by the Henderson-Hasselbalch equation (Lund and Eklund 2000):

$$pH = pK_a + \log_{10}[A-]/[HA]$$

where [A−] is the concentration of dissociated acid, or anionic form, and [HA] is the concentration of undissociated acid, or acid form.

When the concentrations of the anionic and acid forms are equal, $pH = pK_a$, meaning that 50% of the added preservative is undissociated and can be effective as a preservative. When the pH is 1.0 unit below the pK_a value, the preservative is about 91% undissociated. When the pH is 1.0 unit above the pK_a, the preservative is about 9% undissociated. Thus, the antimicrobial effectiveness of organic acids increases as the pH value of the food is lowered.

Most organic acids are lipophilic, being more soluble in fats and oils than they are in water. Therefore, fat and oil-containing foods can concentrate the acids in their fat phase, effectively blocking their antimicrobial properties. This is a most important consideration because microorganisms can grow only in the water phase of food products. In some foods that are water-in-oil emulsions (e.g. butter), microbial growth is physically restricted by the very small size of the water droplets that are encased in fat.

Table 6.7 Chemical properties, usage, and antimicrobial effectiveness of major food preservatives.

	Preservative			
Property	**Sorbic acid**	**Propionic acid**	**Benzoic acid**	**Methyl paraben**
Dissociation constant	4.76	4.87	4.20	8.47
Partition coefficient	3.0	0.17	6.1	6.0
Typical usage (% w/w)	0.1–0.3	0.2–0.8	0.1	0.1
Principal usage	Many foods, salads, syrups, and beverages	Yeast-leavened bakery products	Fruit drinks, and soda	Beverages
Relative effectiveness against:				
Bacteria	++	–	+	+
Yeasts	++++	–	++++	++
Moulds	++++	++	++	+++

+, inhibition; –, no inhibition.
Source: Raczek (2005) and Sperber, unpublished data.

The distribution of the preservative in the fat and water phases of the food is quantified as:

$$\text{PC} = \text{proportion of compound in fat phase/proportion of compound in water phase}$$

Higher PC values indicate that the preservative is increasingly less soluble in water. The relatively high PC values and low pK_a values of most preservatives limits their effectiveness to acidic foods (<pH 5.5) and lower-fat foods (Table 6.7). There are several exceptions to this general situation. Methyl paraben has a high pK_a (8.47), meaning that it can be effective in foods of all pH values. Propionic acid is about six times more soluble in water than in fat (PC = 0.17), enabling it to be a more effective antimicrobial agent in higher-fat foods.

Organic acids are generally difficult to incorporate into the water phase of food. Therefore, they are almost always used in their salt forms, which are more easily solubilised in water (e.g. potassium sorbate, calcium propionate, and sodium benzoate). Sorbic acid/potassium sorbate is the most broadly effective preservative available for food use, being inhibitory to bacteria, yeasts, and moulds. However, as depicted in Table 6.7, food preservatives are generally much more effective against yeasts and moulds than they are against bacteria. A major exception is the fact that calcium propionate is not inhibitory to yeast metabolism. Therefore, it is widely used as a mould inhibitor in yeast-leavened bakery products, in which yeast inhibition would be highly undesirable.

One of the authors experienced a dramatic example of the influence of the PC on preservative effectiveness (Table 6.8). A product development team had commercialised a successful refrigerated, unbaked, pastry product, represented by Formulation 1 in this example. Several potential product improvements were investigated in Formulation 2, in which the sodium chloride and shortening concentrations were decreased and the water content was increased. The increase in moisture content raised the a_w of Formulation 2 from 0.92 to 0.94, but its pH and concentration of potassium sorbate were unchanged.

Table 6.8 Influence of partition coefficient (PC) on the mould-free shelf life of a refrigerated, high-fat, unbaked pastry product.

Ingredient (%, w/w)	Formulation 1	Formulation 2
Wheat flour	47.9	48.3
Water	20.0	25.0
Shortening or lard	30.0	25.0
Sodium chloride	2.0	1.6
Potassium sorbate	0.1	0.1
Total:	100.0	100.0
Properties		
pH	5.0	5.0
Water activity	0.92	0.94
Mould-free shelf life at 7°C	70 d	>100 d

Given the increased moisture content and a_w value of Formulation 2, even an experienced food product developer would have predicted that Formulation 1 would have a longer mould-free shelf life than Formulation 2. Quite surprisingly, the mould-free shelf life of Formulation 2 proved consistently to be about 50% longer than that of Formulation 1. This counterintuitive result could be explained only by an altered distribution of potassium sorbate (PC = 3) between the product's fat and water phases. The reduction of fat and increase in water contents in Formulation 2 allowed more of the potassium sorbate to remain in the water phase and provide greater mould inhibition. The calculated 43% increase of potassium sorbate in the water phase of Formulation 2 closely correlated to the observed increase in product shelf life.

The preservatives discussed earlier are not universally inhibitory to fungi. Sorbate-resistant *Penicillium* spp. (Marth et al. 1966) and benzoate-resistant yeasts (Pitt 1974) have been reported.

Seemingly countless research papers have been published about a great many chemical preservatives. Comprehensive reviews have been published by Foegeding and Busta (1991) and Lund and Eklund (2000). Some of the putative preservatives (e.g. antioxidants) have not proved practical for commercial use as antimicrobial agents in foods. They are not included in this chapter. Several additional commercially-practical examples will be described here.

Sulphur Compounds

Sulphur compounds have been known to inhibit microbial growth since early civilisations burned sulphur in barrels to preserve wine quality. Sodium bisulphite is used today to prevent yeast spoilage of dried fruits and wine. It is also used to prevent the growth of bacterial spore formers during the production of products such as dehydrated potatoes. A thorough description of sulphur chemistry has been provided by Block (1991).

Sodium Nitrite

Sodium nitrite is the major antimicrobial component of curing salts that are used in many meat, poultry, and seafood products. In addition to inhibiting the germination

and outgrowth of bacterial spores, it has desirable organoleptic properties, particularly colour stabilisation and a characteristic flavour. It is sometimes required by regulation because of its ability to reduce the risk of botulism in cured products.

Nisin

Nisin is the primary example of bacteriocins, small proteins that are usually produced by lactic acid bacteria. Much like sodium nitrite, it inhibits the germination and outgrowth of bacterial spores. The use of nisin and other bacteriocins are subject to regulatory limitations. Nisin has been approved in the United States for use in pasteurised cheese spreads and liquid pasteurised eggs.

Carbon Dioxide

Carbon dioxide is an effective antimicrobial inhibitor, though it is usually not considered in discussions of chemical preservatives. A feedback inhibitor of aerobic respiration, carbon dioxide, at sufficient concentrations, inhibits the respiration and growth of obligately aerobic organisms such as pseudomonads, moulds, and humans (its use in food production environments can pose an occupational safety hazard). It is frequently used as a component of headspace gases in modified atmosphere packaging of bakery and meat products (see Chapter 7). It also provides a secondary preservative benefit in carbonated beverages, where the active moiety is quite likely carbonic acid, because of the low beverage pH (J. I. Pitt 1982, personal communication).

Essential Oils

Essential oils from spices, herbs, and other plants have been found to have antifungal properties (López-Malo et al. 2005). Along with other naturally-present flavour compounds (e.g. diacetyl and smoke), essential oils may contribute to effective microbial inhibition in food products through interactions and hurdle effects.

6.2.4 Oxidation-Reduction Potential

The types of microorganisms that can grow in food are sometimes influenced by the food's oxidation-reduction potential, also referred to as the O/R potential, redox potential, or Eh. The electromotive force in a food (Eh) can be directly measured. It ranges from a minimum value of −421 mV (highly reduced) to a maximum value of +816 mV (highly oxidised). Eh values in food are largely 'poised' or buffered by food constituents. The surface Eh may be raised by exposure to atmospheric oxygen (Jay 2000; Morris 2000).

Obligate aerobic microbes are favoured to grow in foods with positive Eh values, whilst obligate anaerobic microbes require highly reduced microenvironments for growth. Most foods are naturally poised at a negative Eh value. Therefore, the growth of obligate aerobes is usually restricted to the surface of a food that is exposed to the atmosphere. The interior portions of low-acid canned foods when opened and exposed to the atmosphere can support the growth of obligate anaerobes such as *Clostridium botulinum* because of their low internal Eh value.

Fresh or cooked foods that are typically exposed to the atmosphere can support the growth of obligate anaerobes (e.g. *C. botulinum*) if access to oxygen is eliminated, or if the interior of the food sustains a sufficiently low Eh. A potential botulism hazard

was detected in the early 1970s when fresh mushrooms for commercial sale were packaged with oxygen-impermeable film. Respiration of the mushrooms removed oxygen in the package's headspace, providing anaerobic conditions suitable for the growth of *C. botulinum*. This potential hazard is easily eliminated by creating one or more small holes (3 to 6 mm) in the packaging material (Sugiyama and Yang 1975).

An outbreak of botulism, consisting of 28 cases and one death, was caused by sautéed onions that were held on the side of a restaurant grill for long but indeterminate times. The onions were used throughout the day in the restaurant's popular grilled sandwiches, and were possibly kept on the grill for one or more days. The interior of a mound of onions sautéed in margarine was shown to readily support growth and toxin production by *C. botulinum*. It is possible that the fat content of the margarine increased the botulism hazard by blocking the access of oxygen to the onion surfaces (Solomon and Kautter 1986). One of the authors and his family ate at the implicated restaurant during the period of the outbreak in 1983. Fortunately, all had ordered grilled sandwiches *without* onions. This curious fact remains of some importance to the surviving author.

6.2.5 Interactions between Preservative Factors

Many preservative factors (e.g. pH, a_w, chemical preservatives, and temperature) can be used to control microbial growth. Microorganisms also vary in their resistance to the inhibitory effects of individual preservative factors (Figure 6.1a). In some instances, the required degree of food safety and quality assurance can be achieved simply by increasing the amount of a preservative factor (Figure 6.1b).

Of course, no food is microbiologically stabilised by a single preservative factor, as every food has its characteristic pH, a_w, and storage temperature. However, the additive effects of the individual preservative factors can sometimes suffice to protect the food during its expected shelf life (Figure 6.1c). The use of multiple preservative factors can permit the development of a food in which no single preservative factor imparts an

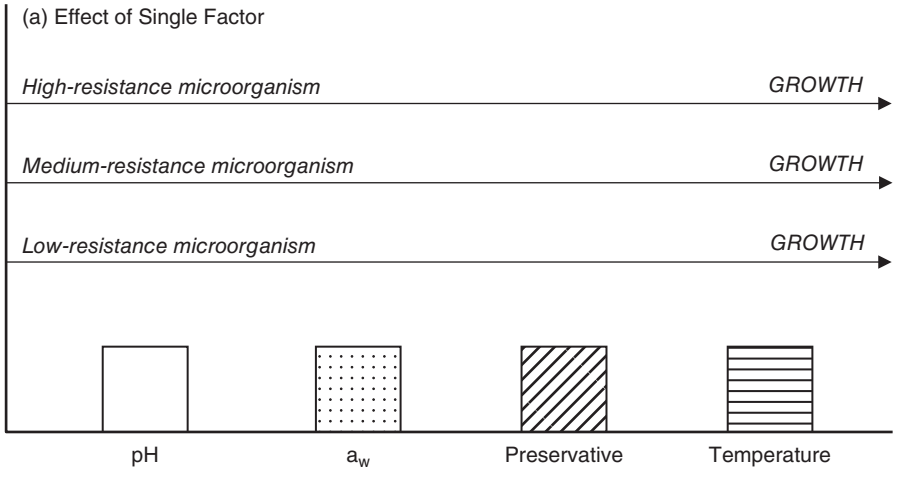

Figure 6.1 The effect of various factors on microorganism growth: (a) Effect of single factor, (b) Effect of single factor with increased concentration, (c) additive effects of combined factors, and (d) interactive effects.

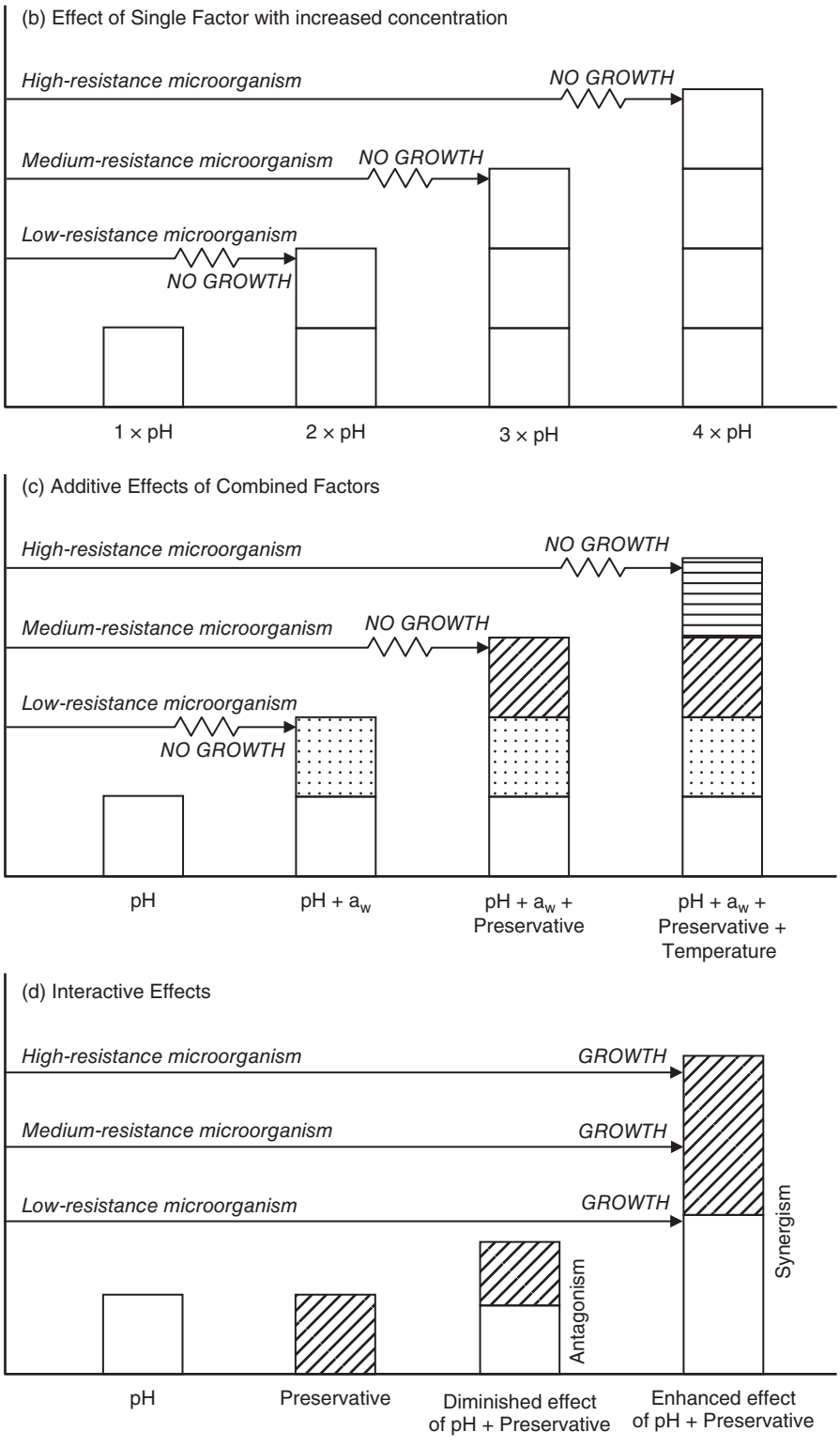

Figure 6.1 (*Continued*)

Table 6.9 Combined effects of water activity and pH on the growth of *C. botulinum* type B.

	pH				
a_w	**7.0**	**6.0**	**5.5**	**5.3**	**5.0**
0.997	+	+	+	+	+
0.99	+	+	+	+	–
0.98	+	+	+	+	–
0.97	+	+	+	–	–
0.96	+	–	–	–	–
0.95	–	–	–	–	–

+, growth; –, no growth.
Source: Baird-Parker and Freame (1967)

undesirable organoleptic property. For example, the use of multiple preservative factors could be used to stabilise a food with only a slight reduction in a_w, rather than a more drastic dehydration of the food. Modern technology enables food scientists to incorporate multiple preservative factors at the appropriate levels to optimise the functional performance and organoleptic properties of the food. The use of multiple preservative factors to inhibit microbial growth is commonly known as 'hurdle technology' (Leistner and Gould 2002).

The additive effects of preservative factors to control microbial growth have long been understood. Various combinations of pH and a_w can be used to prevent the growth of *C. botulinum* without resorting to extreme reductions in either factor (Table 6.9). Guynot et al. (2005) showed that pH, a_w, and chemical preservatives could interact to inhibit mould spoilage of bakery products. Properly-designed research and analysis can be used to demonstrate intricate interactions between preservative factors. Antagonistic interactions can occur when two or more preservative factors interact to diminish the combined effectiveness expected from observations of the individual effectiveness of the factors. Synergistic interactions occur when the combined preservative factors produce a greater inhibitory effect than that expected from a simple additive effect of the individual factors (Figure 6.1d).

The diagrams in Figures 6.1c and 6.1d differ from those commonly used to explain hurdle technology. A microorganism introduced into a particular food encounters all of the food's preservative factors simultaneously, rather than sequentially (as depicted in Leistner and Gould 2002, p. 19).

6.3 Use of Experimental Design and Analysis

6.3.1 Challenge Testing

During the research and development of food products it is usually necessary to conduct challenge testing in which the food is inoculated with one or more types of microorganisms, incubated, and periodically evaluated to learn the fate of the target microbes. Challenge testing can be conducted for one or more of the following purposes:

to develop and validate food safety control measures, to ascertain potential product quality and shelf life issues related to microbial spoilage, to optimise new product formulations, and to verify changes made in existing commercial formulations.

Care must be given to the selection of the microorganisms used to challenge a product. Generally, a minimum of two or three strains of each microorganism is used in order to account for potential response variability between strains (Doyle 1991). The purity and identity of each culture should be confirmed before it is used in a challenge test. This important task is typically performed regularly by the curator of the laboratory's culture collection. Important strains of particular pathogenic microorganisms can be obtained from commercial culture collections (e.g. the American Type Culture Collection). Strains of spoilage microorganisms are best obtained from spoiled samples of the product being evaluated, or from a very similar food product. In this case, the spoilage microorganism should be isolated, identified, and shown to be responsible for the observed spoilage defect before it is used in a challenge test.

Individual strains of vegetative microorganisms need to be cultured by conventional procedures, usually for 24 hours, to produce a predictable number of viable stationary-phase microbes. As a guide to the number of bacteria in a culture medium, it is useful to remember that the maximum population of vegetative bacteria in a mature culture is about 10^9 cells/ml. The strains can be used individually, but are generally pooled in order to facilitate inoculation of multiple strains into the food. The actual population density of the pooled inocula and the inoculated food are usually determined at the beginning of the challenge test. Preparations of dormant bacterial spores are often maintained for weeks or months at known population levels under refrigerated or frozen conditions. Depending on the type of product, the spores may be heat shocked before being inoculated into the food. If a heating step is involved in the food's processing after spore inoculation, this step would serve as the heat shock treatment.

It is important to challenge food products with a reasonable microbial load. After processing, the typical microbial load of a commercial food product, whether in the spore or vegetative forms, is quite low. Therefore, an initial inoculation level of about 10^2 colony forming units (cfu)/ml or gram of food is recommended in situations where the growth potential of the target microbe is being evaluated. Higher inoculation levels could overwhelm the food's preservative system, giving a false indication of spoilage or a food safety hazard in the commercial product, which would never be naturally contaminated at such high levels. In situations in which the destruction of the target microbe by heat, acidification, or other process steps is being evaluated, the target inoculation level should be at least 10^6 cfu/g of food so that a quantifiable reduction in population can be readily determined. In certain situations in which the growth potential of a particular microorganism is completely unknown, an intermediate inoculation level of 10^4 cfu/g of food can be used, affording the opportunity to readily observe growth, death, or stasis of the target population.

The challenge test should replicate the conditions of commercial production as closely as practical. A food manufacturing company struggled in the 1960s to identify the spoilage microorganism that was responsible for a large outbreak of spoilage in salad dressing at the retail level. The spoiled dressing readily yielded a large population of a particular yeast which was duly isolated and used for subsequent challenge studies. None of the salad dressing formulations inoculated with the putative spoilage

yeast spoiled during months of storage. Drummed starch paste had been used in the manufacturing plant to provide a desirable texture to the salad dressing. Interviews with production personnel revealed that several months before the spoilage outbreak, one drum of starch paste had a 'funny' odour. Rather than 'waste' a drum of starch paste, the production operator portioned small amounts of spoiled starch paste, along with the required balance of unspoiled starch paste, into 19 consecutive days of salad dressing production. Within several months, about 1 million jars of salad dressing had spoiled. Armed with this knowledge, company microbiologists then inoculated starch paste with the putative spoilage yeast and incubated it for several days before using the paste to produce salad dressing. All of the salad dressing samples spoiled quickly. It seemed that the starch paste provided conditions that enabled the spoilage yeast to adjust to the harsh (acetic acid) environment of the salad dressing (Sperber 2009b). Food researchers need to be alert to such possibilities when designing challenge studies for new food products.

The above example will be mentioned in later chapters as it superbly demonstrates the need for adequate training and awareness on the part of all plant personnel involved in processing operations. This example also illustrates a potential very important product safety hazard. Whilst yeast spoilage might not seem to be a food safety hazard, it must be pointed out that the salad dressing was packaged in glass jars with screw-on lids. Vigorous yeast fermentation in the affected products caused many jars to explode, the consequences of which could have been serious to any person near an exploding jar. Many food products formerly packaged in glass containers are now packaged in plastic containers. Nonetheless, the potential hazard of exploding glass jars cannot be ignored for the remaining products packaged in glass containers. Of course, the desired remedy for such a problem would be proactive attention to product design and process controls so that such spoilage outbreaks would not happen.

Careful attention must also be given to the method of product inoculation in challenge studies. It is vital that product characteristics such as a_w and pH not be altered in the inoculated products. Another earlier incident, this one from the 1970s, readily proved this point. Soon after the 1973 adoption of canned foods regulations in the United States, some food safety officials questioned the potential safety of pasteurised processed cheese spreads. The canned foods regulations required that any shelf-stable canned food above a_w 0.85 or pH 4.6 be autoclaved to assure control of the potential botulism hazard. Pasteurised processed cheese spreads typically have an a_w value around 0.93 and a pH value around 5.5. Unlike retort-processed low-acid canned foods, the cheese spreads were simply hot-packed into glass jars and distributed without additional processing. Despite the disparity between the cheese spread a_w and pH and the regulatory requirements for low-acid shelf-stable canned foods, no cases of botulism and negligible spoilage of commercial shelf-stable cheese spreads had been noted during several decades of widespread distribution and consumption. It had been assumed that the interaction between the a_w and pH of the cheese spread was sufficient to control the growth of *C. botulinum* and other bacterial spore formers that could survive the cooking and hot-filling process.

Nonetheless, the food safety officials quite correctly decided to validate the safety of shelf-stable cheese spreads by conducting challenge tests. Fifty jars each of five commercial cheese spreads were injected with 0.1 ml aqueous *C. botulinum* spore preparations. After incubation nearly 100% of the samples of two of the cheese spreads tested positive

for botulinum toxin (Kautter et al. 1979). Additional research was then conducted by others to verify the above results, which were not in harmony with the observed experience of several decades of commercial production and consumption. In these projects, 11 formulations of cheese spreads were inoculated with *C. botulinum* spores during mixing of the product, which was then cooked and hot-packed into glass jars, steps which closely matched the commercial process. None of the incubated samples in these trials was found to contain botulinum toxin (Tanaka 1982). It was concluded that the original demonstration of botulinum toxin production was made possible by the means of inoculation by injection. At least some of the water in the spore inoculum remained in the injection site and was sufficient to increase the a_w in microenvironments to permit toxin production.

In many challenge tests it is possible to mix the test inoculum thoroughly into the product and subject it to relevant process steps before packaging and incubation. Sometimes, it is necessary to inoculate the product surface in order to evaluate spoilage. In these cases, it is necessary to prepare the inoculum in a substrate that will not alter the product's properties. For example, a suspension of mould spores can be prepared in dry flour or starch, precisely quantified, and verified for stability before sprinkling onto a product surface. It is also possible to use an aqueous suspension of any microorganism and transfer it to a product surface with a negligible transfer of water by using small sterilised squares of a bristly painting pad (R. B. Ferguson, personal communication).

The evaluation of microbial growth or death in challenge tests can be accomplished with the use of a wide variety of non-selective and selective microbiological media to quantify, isolate, and identify the test microbes as necessary (Downes and Ito 2001).

6.3.2 Accelerated Shelf Life Testing

Challenge test product samples should be stored at the commercial distribution temperature and evaluated over the entire expected product shelf life, or until the product exhibits quality defects or fails to meet food safety requirements. When the primary purpose of the challenge test is to validate the safety of the product (e.g. a *C. botulinum* challenge test in which toxin production represents a failure), the test should be continued for 1.5 times the anticipated shelf life, or until toxin production is demonstrated (Doyle 1991).

Quite often, in research and development projects and in commercial plant production, it is impractical to store products at the expected commercial distribution temperature for the full shelf life to observe whether or not a food spoilage defect or potential food safety hazard will develop. It is, however, generally possible to store products at temperatures higher than the commercial distribution temperature for shorter periods of time. Within practical ranges, chemical reaction rates and microbial growth rates in foods will increase as temperature is increased (Labuza and Schmidl 1985), and this facilitates accelerated shelf life testing (ASLT), where samples are periodically evaluated for types of product failure over a shorter period.

In the case of research and development ASLT tests, it is usually important to monitor the samples for many types of product failure. In the case of commercial production samples, the ASLT conditions can be tailored to accurately predict the potential occurrence of the product's principal failure mechanism before the end of shelf life. The example in Table 6.10 describes the ASLT conditions that can predict potential product

Table 6.10 Practical example of ASLT conditions to predict the shelf life of a refrigerated food.

Storage Temperature (°C)	Storage Time (days)
4	90
7	28
15	10
20	4
25	2

Source: Adapted from Sperber (2009a).

failure caused by excessive growth of lactic acid bacteria. The expected commercial shelf life of this product category is 90 days at refrigerator temperatures (4°C). Any of the other sets of temperatures and times in Table 6.10 can be used in this company's laboratories to evaluate the growth of lactic acid bacteria. For example, evaluation of samples stored for 2 days at 25°C or 4 days at 20°C can accurately predict potential lactic spoilage of this particular product category within the 90-day expected shelf life at 4°C. When premature product failure is predicted by analysis of the ASLT samples, the manufacturer can take action to hasten the distribution cycle of the product or to prevent product distribution.

6.3.3 Predictive Microbiology and Mathematical Modelling

The use of conventional research and development methods, including challenge tests, can consume months or even years before a safe product of high quality is commercialised. Food researchers have been increasingly assisted in the past several decades by the development and use of computer-based programmes for experimental design, analysis, and prediction (Ross and McMeekin 1994).

Before the revolution in information technology, experimental design at its best consisted of the production of a large number of samples in which individual preservative factors would be tested at various levels. In complex foods, up to hundreds of formulations would be prepared and evaluated separately. The advent of simple factorial designs permitted the simultaneous testing of two or more preservative factors providing a modest increase in information yield.

Today, computer-based programmes such as response surface methodology, predictive microbiology, and advanced mathematical computations can provide far more information with far fewer samples (Whiting 1995). These technologies permit the simultaneous evaluation of multiple intrinsic and extrinsic preservative factors in a single product formulation. Quantitative estimates of the effects of each individual preservative factor as well as all possible combinations of two or more factors are produced. The relative speed of these technologies permits ready optimisation of product formulations, as well as the identification of antagonisms or synergisms between preservative factors that would likely have not been detected by conventional procedures.

Mathematical models are the latest advance to assist the food product development team. These are strictly a computer-based activity in which relevant product

information and microorganism characteristics are entered into the database. The programme calculates the desired output (e.g. the amount of microbial growth or destruction), and the time for toxin production or the end of shelf life. A detailed description of the use of a mathematical model has been provided by McMeekin et al. (1997). A model for the growth of *Pseudomonas* spp. in raw poultry has been published by Dominguez and Schaffner (2007).

The US Department of Agriculture (USDA) has for some years developed, continually improved, and made freely available its Pathogen Modelling Program (Agricultural Research Service [ARS] 2007). Its current version (7.0) will predict growth rates of 11 pathogens, cooling and growth rates of 2 pathogens in cooked meat products, survival of 4 pathogens, thermal inactivation of 3 pathogens, and radiation inactivation of 2 pathogens.

In 2003, the USDA joined the Food Standards Agency of the United Kingdom and the Norwich-based Institute of Food Research to establish the ComBase Consortium, a combined database for predictive microbiology. ComBase can generate graphs and predict the rates of growth, survival, or inactivation of a very wide array of spoilage and pathogenic microorganisms. ComBase is accessible online without charge at http://www.combase.cc.

6.3.4 Theory versus Reality

Mathematical modelling permits the researcher to conduct a great deal of research on the computer, virtually at the speed of light. One simply inputs the product and microbial characteristics and gets a quick estimate of preservative efficacy, the impact of changing one or more preservative factors in a food, inactivation rates during heat treatments, and so on.

Researchers must be aware that such powerful tools should be used alongside expert judgement and interpretation and cannot be used as the ultimate assurance of food safety. Ultimately, challenge tests with appropriate pathogenic or spoilage microorganisms must be conducted to validate product safety, quality, and shelf life. Predictive modelling programmes can be used advantageously to sort through a great many factors before final development and validation is confirmed in the 'real' world. Keep in mind that, useful and powerful as they have proven to be, predictive modelling programmes are no substitute for laboratory confirmation. Ultimately, food safety is not a computer game. Food safety is, rather, ultimately assured by the common sense application and validation of necessary product and process control measures.

6.4 Ingredient Considerations

The selection, handling, and use of ingredients require careful consideration both in product design and process control activities. Relatively small quantities of ingredients used in the production of research samples can present the same food safety and public health hazards that can be presented when very large quantities are used in commercial food production. Therefore, research laboratories must provide the same assurance of the safety of test samples that manufacturing facilities must provide for consumer food products.

6.4.1 High-Risk Ingredients

Whilst the term *sensitive ingredient* has long been used in the United States, much of the world refers to these as *high-risk ingredients*. We will use the latter term throughout this book. High-risk ingredients have a history of potential contamination with pathogenic microorganisms, mycotoxins, and so on. Therefore, measures are taken to control high-risk ingredients so that contamination of food products does not occur.

Salmonella was the first foodborne pathogen to merit the description 'ubiquitous'. While its natural habitat is the animal intestine, *Salmonella* grows well in food processing environments and it survives well in dry environments. In the past 50 years, it has received more attention from the food industry than any other pathogen. A number of ingredient categories became known as '*Salmonella* high-risk ingredients'. Chief among these are cooked meat and poultry products, dried milk and egg products, and soy products.

Aflatoxin, the first identified mycotoxin, has also received a great deal of attention from the food industry because of its high toxicity and suspected role as a liver carcinogen. Peanut and corn products receive the most attention because aflatoxin can be produced in the peanut and corn field crops and, unless properly controlled, persist into a wide variety of food products. Ingredients receiving lesser attention include tree nuts, dried coconut, tapioca flour, cottonseed meal, and figs.

Staphylococcus aureus, one of the earliest detected foodborne pathogens, had in earlier years been a regular problem in fermented sausages and cheeses. In the event of poor starter culture performance, *S. aureus* could grow to very high numbers, producing heat-stable enterotoxins. These problems have largely been eliminated and can be controlled simply by monitoring and verifying a timely pH drop during fermentation. Other outbreaks of staphylococcal food poisoning have been traced to foodservice products which were stored or transported without adequate temperature controls, enabling the growth of *S. aureus*. In these cases, the source of contamination can be food handlers or cross-contamination from ingredients such as hand-deboned meat and poultry products.

Listeria monocytogenes has relatively recently been identified as a potential hazard in refrigerated, ready-to eat foods of extended shelf life that will support its growth. Refrigerated foods typically implicated in listeriosis outbreaks include soft, ripened cheeses; cooked meat, poultry, and seafood products; delicatessen meats, and fluid milk. Whilst these foods do not easily transfer a listeriosis hazard to processed compound food products, the product development team must be alert to the potential listeriosis hazard whenever ingredients of this type are used.

Bacillus cereus has long been recognised as a risk in starchy foods. Much like staphylococcal enterotoxin, the emetic toxin of *B. cereus* is heat stable. *B. cereus* spores can also survive cooking processes. Therefore, its presence can pose a risk in cooked or dried potatoes and in cooked rice that is not stored under adequate refrigeration before preparation as refried rice.

A summary of some of the key microbiological and chemical hazards associated with high-risk ingredients is provided in Tables 6.11 and 6.12. Extensive information on high-risk and other ingredient control measures is provided in Chapter 7.

As detailed in Chapter 11, all food prototypes must be safe for consumption. This requirement pertains to samples tasted in the test kitchen, or evaluated by internal

Table 6.11 Pathogenic microorganisms that are associated with high-risk food ingredients.

Microorganism	Food Ingredient
Salmonella spp.	Eggs and egg products
	Dried dairy products
	Milk chocolate
	Soy flour
Staphylococcus aureus	Fermented cheese above pH 5.4
	Fermented sausages above pH 5.4
Listeria monocytogenes	RTE* perishable delicatessen meat and poultry products
	Soft, fresh cheeses
	Surface-ripened cheeses
Escherichia coli O157:H7	Raw, ground beef
	Raw milk
	Fresh vegetables

*RTE, ready-to-eat.

Table 6.12 Chemical agents that are associated with high-risk food ingredients.

Chemical Agent	Food Ingredient
Mycotoxins	
Aflatoxin	Peanuts (groundnuts) and peanut products
	Dry corn products
	Tree nuts
Fumonisin	Dry corn products
Deoxynivalenol	Barley, wheat
Ochratoxin	Barley
Zearalenone	Barley, corn
Ergot	Rye
Allergens	Peanuts and peanut products
	Tree nuts
	Crustaceans
	Fish
	Eggs and egg products
	Milk and dairy products
	Soybeans and soy products
	Wheat and wheat products

sensory panels and during external central location consumer tests, home-use tests, and market trials before product commercialisation. It is vital that the product development team coordinate its development activities with the product safety assessment team so that the safety of all sensory analysts and consumers is assured.

6.4.2 Novel Ingredients

There is an emergence of novel ingredients, including use of plants like Aloe Vera as a base flavour for yogurt, various types of seeds such as flax and chia, and supplements such as Ginkgo Biloba, which allegedly have healthy properties, now being used in main stream products, and not just those found in 'health food' stores. There are also those which are developed through years of scientific research and formed through new technologies. Some of these products and ingredients are traditional foods within particular cultures which are now being used more widely (e.g. insects and insect products). Here we will focus on insects as one example of changing needs within the global food supply chain.

The Food and Agriculture Organization of the United Nations predicted in 2017 that the global human population will increase to 9 billion people by 2050. Combined with a deteriorating environment for the production of food and potential political obstacles, some billions of people will likely be threatened by food shortages. The use of insects as a food or a food supplement is being researched with the goal to provide novel means to increase the food supply (http://www.fao.org/edible-insects/en/).

As noted previously, in some regions the food supply may be inadequate because of wasted and spoiled food and inefficient production practices. Whilst the production and consumption of edible insects may not be immediately welcomed in affluent regions, their use seems likely to become necessary and welcomed in many other regions worldwide (Poma et al. 2017). Much of the research is focused on the use of fresh mealworm larvae and house crickets (Vandeweyer et al. 2017). The insects can be cooked and disinfected to eliminate potential pathogens. Further treatments such as drying and acidification will permit storage of the insects when refrigeration is not available. The cooked and dried insects can also be ground into flour, mixed with water, and subjected to fermentation by lactic acid bacteria to prevent the growth of pathogens (Klunder et al. 2012).

Edible insects have been eaten around the world because of their high nutritional value, typically with high fat, protein, and mineral contents. It is likely that they can be used as a substitute for fish meal in the production of animal feed, further assisting the efforts to sustain the human population (Rumpold and Schlueter 2013).

6.5 Considering the 'Unintended' Use

Discussion of safe food product design would not be complete without consideration of how consumers might use products in ways that are not the intended use. This can include direct (raw) consumption of products that are intended to be cooked (e.g. raw pizza and cookie dough) or deliberate inadequate cooking of products intended to be fully cooked (e.g. rare hamburgers). In addition, use of powdered mixes such as soup mixes and hot drinks mixes as flavourings for yogurts and dips could be an issue if the

product formulation relies on addition of boiling water for safety. Similarly, prolonged refrigerated storage of unfrozen ingredients could be an issue if *Listeria monocytogenes* is present at low levels in the initial product or gains access through contaminated utensils. Some of these products have been involved in previous food safety incidents (Chapter 2). In designing safe products, it is necessary to think carefully about how consumers might use the product and this should be considered as part of individual product safety assessment (Chapter 11) as well as in consideration of intended use in HACCP (Chapter 12).

6.6 Conclusions

The design of product formulations by the product development team is a most important first step in the production of a safe food product and with new consumer uses and novel ingredients, it is not getting easier. If appropriate control measures based upon the product's intrinsic factors are not researched and validated at this step, significant time may be lost in order to correct the early mistakes. Worse, a product that is potentially unsafe or of reduced quality and shelf life might be produced and distributed. It is crucial to ensure not just the link between the design of products and processes, but to ensure that safety is considered throughout, including through use of individual product safety assessment and HACCP.

7

Designing a Safe Food Process

7.1 Introduction

As indicated at the beginning of the previous chapter, we have reached the conclusion that, at its core, HACCP consists of two essential processes – product design and control, and process design and control. Both the product and process design requirements are typically defined by research and development groups. It is during this period that control measures must be tested, validated, and incorporated into the product formulation (Mortimore and Wallace 1998; Sperber 1999). As is the case for product design, the process design activity is best performed by an experienced team that typically includes food safety specialists, microbiologists, food scientists, process engineers, and packaging engineers. Upon completion, the process design requirements are communicated to manufacturing teams that scale-up and validate the design requirements at the commercial production level. Individual plant HACCP teams complete the HACCP plan for each product and establish the monitoring, verification, and recordkeeping procedures.

This chapter describes a complete range of practical food processing technologies that are applied extrinsically to the food product in order to control identified foodborne hazards. The product development team should consider that the extrinsic control factors described in this chapter might interact with the intrinsic control factors described in Chapter 6. For example, the effectiveness of chemical preservatives may be enhanced at reduced storage temperatures. Whilst many of the control measures described in this chapter are most appropriate for the control of microbiological hazards, similar measures and considerations of controls must be undertaken by the HACCP team for the control of chemical and physical hazards.

Some educators refer to the 'three *Ks*' as a comprehensive programme of microbiological hazard control in food production, these being: 'Kill them', 'Keep them from growing', and 'Keep them out'. Described more scientifically, these three procedures are:

1) *Destruction of microorganisms*. Many well-established and several novel procedures are available to kill microorganisms. These include thermal processes such as cooking, pasteurisation, and sterilisation; and non-thermal processes such as irradiation, high hydrostatic pressure, and pulsed electric fields.
2) *Prevention of microbial growth*. The primary extrinsic factors used to control microbial growth are refrigeration, freezing, and drying. The intrinsic factors used to control microbial growth are described in Chapter 6.

Food Safety for the 21st Century: Managing HACCP and Food Safety Throughout the Global Supply Chain, Second Edition. Carol A. Wallace, William H. Sperber, and Sara E. Mortimore.

3) *Prevention of contamination*. Many potential microbiological hazards can be avoided by preventing cross-contamination from raw materials and the processing environment to processed foods. Cleaning and sanitation procedures and personnel practices used in food processing facilities are most important in this regard.

Chemical and physical hazards are generally controlled by prerequisite programmes and by the use of detection devices. Programmes must be in place to avoid contamination of the processed food with chemical hazards such as undeclared allergens and physical hazards such as insects, metal, wood, and glass fragments.

7.2 Process Control of Microbiological Hazards

7.2.1 Destruction of Microorganisms

Microorganisms in food materials can be killed by thermal processes and non-thermal processes, including chemical disinfection. Because the reduction of microbial populations occurs logarithmically, several terms have come into common usage in order to easily compare the lethal effects of various treatments (Joslyn 1991). The 'D value', or decimal reduction time, is the amount of time at a particular temperature required to reduce a microbial population by 90%, or one $\log_{10}$ unit. The 'z value' indicates the amount of change in temperature (°C) that is required to shift the D value by 90%, or one $\log_{10}$ unit. For example, if a microorganism has a $D_{110°C}$ value = 5.0 minutes and a z value of 10°C (a value typical of bacterial spores), it would have a $D_{120°C}$ value = 0.5 minutes and a $D_{100°C}$ value = 50.0 minutes.

Thermal Processes

The importance of proper thermal processing for food safety led to a number of regulations in the United States. First written in 1923, the Pasteurized Milk Ordinance (PMO) deals with the pasteurisation of milk (Food and Drug Administration [FDA] 2015c). In 1973, the FDA promulgated regulations for low-acid canned foods (CFR 2008a) and for acidified foods (CFR 2008b). All of these are HACCP-based regulations. They deal with time and temperature process controls, sanitary design and sanitation requirements, and administrative requirements, including recordkeeping. As explained in Chapter 1, the PMO preceded the origin and evolution of the HACCP system by about 50 years. The canned foods regulations, a collaborative effort in which The Pillsbury Company assisted the FDA, sprang directly from the early HACCP developments (Chapter 1).

Pasteurisation In conventional usage, the term *pasteurisation* refers to the destruction of vegetative microbial cells and viruses in food products. Several official definitions are more extensive and specific. Pasteurisation is: 'Any process, treatment, or combination thereof that is applied to food to reduce the most resistant microorganism(s) of public health significance to a level that is not likely to present a public health risk under normal conditions of distribution and storage' (NACMCF 2006). A more specific definition is: 'Pasteurization is a microbiocidal heat treatment aimed at reducing the number of any pathogenic microorganisms in milk and liquid milk products, if present, to a level at which they do not constitute a significant health hazard' (Codex 2009). Pasteurisation

Table 7.1 Thermal resistance properties of vegetative bacterial cells.

Microorganism	°C	D(minutes)	z
Pseudomonas fluorescens	55	1–2	—
Escherichia coli	55	4	—
E. coli O157:H7[a]	60	0.75	—
	71	0.01	—
Salmonella spp.[a]	70	0.05–0.5	—
S. senftenberg (775W)[a]	60	10.8	6
Staphylococcus aureus[a]	60	7.8	4.5
Listeria monocytogenes[a]	70	0.1–0.3	–

[a]Pathogens
Source: Derived from Doyle (1989), Lewis and Heppell (2000) and Farkas (2001).

conditions are designed to effectively destroy the organisms *Mycobacterium tuberculosis* and *Coxiella burnettii* '(Codex 2009)'. Thermal property values of representative vegetative microorganisms are presented in Table 7.1.

Most often, pasteurisation involves a cooking or heating procedure conducted at atmospheric pressure. It is used to protect the public health by killing pathogenic microorganisms and to extend product shelf life by killing spoilage microorganisms. Pasteurised products are not sterile. They must be refrigerated during further distribution unless they are otherwise preserved, for example, by water activity or pH reduction.

The pasteurisation of some foods has such prominent public health significance that the time and temperature requirements are the subject of regulations (Table 7.2). It is important to note that both time and temperature must be considered. As the pasteurisation temperature is increased, the required processing time is reduced.

Table 7.2 Examples of pasteurisation requirements in the United States.

Product	Time	Temperature (°C)	Reference
Milk	30 min	63	FDA 2015c
	15 sec	72	FDA 2015c
	1 sec	89	FDA 2015c
Ice cream mix	30 min	69	FDA 2015c
	25 sec	80	FDA 2015c
Liquid eggs	3.5 min	60	CFR 2008c
Salted eggs or yolks	3.5 min	63.3	CFR 2008c
Spray-dried egg albumen	7 days	54.4	CFR 2008d
Blue crab meat	1.0 min	85	Ward et al. 1984
	4.2 min[a]	85	Cockey and Tatro 1974

[a]For 12-log kill of *Clostridium botulinum* type E spores

The tabulated parameters are the minimum time and temperature that must be applied to the respective products. In practice, food processors typically use somewhat higher temperatures and/or heating times (operational limits – see Chapter 12) in order to provide a margin of safety, both for food safety and for regulatory compliance considerations. It is difficult, but not impossible, to pasteurise dried materials. The treatment of dried egg albumen at 54.4°C for 7 days is known as 'hot-boxing'. Storage of the albumen, packed in approximately 20kg boxes, under such conditions will usually kill residual salmonellae that may have contaminated the albumen during packaging. Similar hot-box treatments can be used for milled cereal grains, starches, etc., that are to be used in infant or geriatric formulations to provide a greater degree of assurance of the absence of vegetative microbial pathogens. A comparison of the markedly longer times required to pasteurise dried eggs versus the short times required to pasteurise liquid eggs (days versus minutes) indicates the difficulty in inactivating microorganisms with dry heat.

Most pasteurised products require refrigeration to prevent the growth of spoilage microorganisms and pathogenic spore formers whose spores survive pasteurisation. However, products with a sufficiently low water activity (usually below 0.85, such as sugar syrups) or pH value (usually below 4.0, such as acidified foods) will be microbiologically stable at ambient temperatures if properly handled and packaged. Such products are usually cooked and hot-filled at 80°C to 100°C into the final consumer package. The residual heat in the product is sufficient to kill vegetative microorganisms that may have been in the container, as well as airborne microorganisms that may have entered during the filling operation. Bottled products usually need to be inverted for 2 minutes so that the bottle neck and cap interior are adequately pasteurised. The product's reduced water activity and/or pH is sufficient to prevent the germination and growth of bacterial spores.

Bakery products are pasteurised during the baking process. However, during the cooling period before packaging, the surface of the bakery product will become contaminated with airborne mould spores, which can spoil the product before consumption. Such products can be further heat-treated in the final sealed consumer package to prevent spoilage and to extend shelf life. Several heat sources such as convection ovens, microwaves, or infrared bulbs can be used to heat the product inside its commercial package. The internal generation of steam will kill mould spores that have contaminated the product surface or package interior (Bouyer 1970; Richardson and Hans 1978). Upon cooling, the generated moisture is absorbed by the product. The expansion of the package during heating verifies the integrity of the package seals. This technology can also be applied to other products, such as irregularly-shaped cooked meats, for the surface destruction of *Listeria monocytogenes*.

Many consumers cook shell eggs for a short time so that the yolk remains soft. This process is adequate to kill surface microorganisms, including salmonellae, which are common contaminants of raw poultry and eggs. The interior of the egg, particularly the yolk, is usually sterile. Therefore, soft-cooked shell eggs had been considered safe for consumption. However, over the past several decades a 'pandemic' of salmonellosis was linked to the consumption of soft-cooked shell eggs. Investigators soon discovered that a new strain of *Salmonella* Enteritidis infected laying hens and was deposited in the ovaries into the newly produced egg yolk. Protected during the soft-cooking of shell eggs, *S.* Enteritidis would survive to cause illness upon consumption. Procedures have

been developed by egg producers to heat shell eggs before distribution for consumption. Shell eggs are heated in warm water at times and temperatures adequate to produce a 5-log reduction of salmonellae in the egg yolk without cooking the egg. Treated in this manner, soft-cooked shell eggs are considered safe for consumption (US Department of Agriculture [USDA] 1997). Widespread vaccination of laying flocks has significantly reduced egg infection by *S.* Enteritidis, eliminating the need for specialised heat treatments. Vaccine trials conducted in the United States from 1997 to 1999 found that shell eggs from 8.1% of non-vaccinated flocks contained *S.* Enteritidis. None of the eggs tested from 93 vaccinated flocks contained *S.* Enteritidis (Mirandé 2000). Vaccination of laying flocks is widely used in some countries, for example the UK 'British Lion' eggs scheme (https://www.egginfo.co.uk/british-lion-eggs).

A collaborative research effort in 1998 between the Excel Corporation and Frigoscandia Food Process Systems, Inc., was undertaken to reduce bacterial populations on the surfaces of commercially slaughtered beef carcasses by exposing them to 82.2°C steam in enclosed cabinets for 6.5 seconds. Reductions in microbial counts, as collected with sterilised sponge swabs, averaged 0.9 $\log_{10}$ CFU/100cm^2. Whilst such reductions are inadequate to qualify as critical control points (CCPs), this use of steam pasteurisation will reduce the potential for pathogenic microbes in the resulting beef products.

Sterilisation Practical sterilisation procedures for foods involve high-temperature thermal processes. Many foods to be sterilised are packaged into metal, glass, or plastic retail containers, hermetically sealed and processed under pressure with steam at 121°C or higher. Some foods are sterilised by ultra-high temperature (UHT) procedures and filled into separately sterilised containers. Such processes are designed to kill bacterial spores that could otherwise cause product spoilage or foodborne illness upon consumption of the food. The thermal properties of the relevant bacterial spores are summarised in Table 7.3. Sterilised foods are processed to provide 'commercial sterility', that is, they are not absolutely sterile. Quite likely, spores of obligate thermophilic bacteria such

Table 7.3 Thermal property values of representative bacterial spores.

Bacterial spores	°C	D (minutes)	z
Bacillus coagulans	121	0.01–0.1	—
B. stearothermophilus	121	4–4.5	7
Clostridium sporogenes	121	0.1–1.5	9-13
C. botulinum, proteolytic types A & B[a]	100	25	10
	121	0.2	10
	141	0.0025	10
non-proteolytic types B, E, & F[a]	100	0.05	—
Bacillus cereus[a]	100	3	—
C. perfringens[a]	90	1–9	—
	110	0.5–1.5	—

[a]Pathogens

Source: Derived from Doyle (1989), Lewis and Heppell (2000) and Farkas (2001).

as *Bacillus stearothermophilus* will be present in sterilised foods. They are, however, incapable of growth in sterilised foods under normal conditions of storage and transportation at ambient temperatures. An important consideration is that such foods might spoil if stored at very high temperatures, for example, above 50°C, but they would not be capable of causing illness. Obligate thermophilic bacterial spore formers are not pathogenic. Commercial sterilisation processes are not adequate to inactivate prions, the infectious proteins that are responsible for spongiform encephalopathies in many mammals, including humans (Hueston 2003).

Canning Processes Low-acid canned foods require a minimum process to assure a 12-D 'botulinum cook', to ensure the absence of spores of *Clostridium botulinum*. As can be calculated from the data in Table 7.3, the 12-D botulinum cook would be at least 2.4 minutes at 121°C. In practice, longer times than the minimum botulinum cook are used by canning operators to provide a margin of safety and to ensure the destruction of mesophilic spore formers that are more heat resistant than *C. botulinum* and could spoil the canned foods during storage and distribution. Many additional factors are controlled to assure the safety and stability of sterilised canned foods, including, but not limited to: product processing conditions, product temperature before can filling, product viscosity, can headspace, can seam integrity, and chlorination of can cooling water.

A commercial sterilisation treatment as applied to low-acid canned foods is not necessary for the production of acidified canned foods. Acidified canned foods either have a natural pH below 4.6, or are acidified so that the pH is below 4.6, or have a water activity value below 0.85. Under these conditions, surviving bacterial spores cannot germinate and grow. Acidified canned foods are usually heated to about 100°C. They may be heated in the retail package, or they may be hot-filled as described in the Pasteurisation section. In the United States, canning processes are defined by regulations (CFR 2008a, 2008b).

UHT Processes Foods may be sterilised at UHT for a very short time (e.g. 140°C to 150°C for several seconds). In an enclosed system, the UHT-treated foods are aseptically packed into packages that have been separately sterilised by chemical sterilants such as hydrogen peroxide, flame sterilisation, superheated steam, or high-intensity UV irradiation (Lewis and Heppell 2000). Whilst microbiologically stable, UHT foods might be susceptible to spoilage by food enzymes, some of which are very resistant to UHT treatment.

Dry Heat Processes Dry hot air can be used instead of steam to sterilise materials; however, very long times are required (Table 7.4). Whilst seldom used directly for food sterilisation, dry heat is commonly used for the sterilisation of laboratory glassware and sampling devices.

In 2009, the FDA initiated a recall of refrigerated cookie dough in which it found *Escherichia coli* O157:H7. Reportedly, 76 people in 31 states who had been infected recalled eating the raw cookie dough. The FDA found one sample of the cookie dough to be contaminated with *E. coli* O157:H7 but it did not match the strain that was found in the infected consumers. Nevertheless, this outbreak stimulated interest in heat-treating the dry flour that is used in producing raw cookie dough. This practice has generally been found by the milling industry to be impractical and ineffective (Sperber and NAMA 2009; Sosland 2010).

Table 7.4 Time and temperature requirements for sterilisation by hot air treatments.

Temperature (°C)	Time (minutes)
170	60
160	120
150	150
140	180
121	'overnight'

Source: Joslyn (1991).

Non-thermal Processes

The thermal processes described earlier can be generally applied to foods that are cooked, canned, baked, fried, and so on. Non-thermal processes can be used in specific applications that are intended to minimise organoleptic changes that are caused by thermal processes. Non-thermal processes tend to be more costly and less effective in reducing microbial populations than thermal processes. Therefore, they are more suitable for pasteurisation rather than sterilisation processes. Furthermore, the extensive research and development expenses and the costs of commercial applications make many of the non-thermal processes impractical for commercial use. For these reasons, processes such as pulsed light, non-thermal plasma, oscillating magnetic fields, and ohmic heating will not be discussed here. Some non-thermal processes are practical for particular applications; these are discussed below.

Filtration can be used to remove microbes, particles, and some chemicals from clear liquids and gases (Levy and Leahy 1991). Microbes can be removed from liquids to produce sterile products when filters with an effective pore size of 0.22 to 0.45 μm are used. Similar filters can be used to filter the incoming air supply for food production areas, thereby minimising product contamination during production and packaging. Many organic compounds can be removed from liquids and gases by filtration through columns of activated carbon. A UK dairy filters pasteurised milk in order to extend its shelf life.

Chemical disinfectants can be used to reduce microbial loads in liquid or dry food materials (Parisi and Young 1991). Chlorine compounds and ozone are often used to sanitise water that may be used in the dipping of fruits and vegetables, as ingredient water, and in the cleaning of food processing equipment. Gaseous disinfectants, including ethylene and propylene oxides, chlorine dioxide, beta-propiolactone, and formaldehyde can be used to disinfect production rooms and packaging materials. Ethylene and propylene oxides were formerly used to kill mould spores in nuts, dried fruits, and cocoa powder. However, ethylene oxide has fallen into disuse because of its carcinogenic and mutagenic properties. Propylene oxide is little used because of its relative ineffectiveness in killing mould spores.

Ultraviolet (UV) light has a number of food safety and public health applications, even though its antimicrobial effectiveness is diminished by its low penetrating ability and by the shadowing effects of particles in air or liquids (Schechmeister 1991). Major uses of

UV light for disinfection involve arrays of high-intensity UV bulbs over which liquids flow. Very large arrays are used to disinfect municipal water supplies; smaller arrays are used in food processing plants to disinfect recycled flume water. UV arrays can also be used in ventilation systems to disinfect air that is supplied to food production areas.

Ionising irradiation can be used to pasteurise some food materials. Whilst theoretically possible, it is not usually used to sterilise foods with irradiation, as the very high doses can create organoleptic defects. The typical ionising radiations in food applications are gamma rays from radioactive isotopes such as cobalt^{60} or high-energy electron beams (Silverman 1991). The irradiation doses used in food processing are measured in kilograys (kGy). One kGy equals 10^5 rads; 1 rad equals 100 erg/g. The irradiation D values presented in Table 7.5 illustrate several important points. The lethal effect of ionising irradiation is caused by its ionisation of molecules it happens to strike. The ionised molecules in turn can react with and denature important cellular molecules such as DNA. Therefore, large targets such as parasitic worms are much easier to inactivate with irradiation than are smaller targets such as bacteria and viruses. Bacterial spores are more difficult to kill with irradiation than are vegetative cells. Regulatory approvals have been granted for the use of irradiation to treat a wide variety of foods; for example, in the United States, this list includes milled cereal grains, fruits, vegetables, spices, seeds for sprouting, and meat and poultry products. The legitimate commercial use of irradiation processes is greatly limited by consumer scepticism about their safety due to misinformation and lack of education.

High hydrostatic pressure (HHP) treatments at pressures up to 1000 megaPascals (MPa) for several seconds to several minutes can be used to reduce the microbial populations

Table 7.5 D values of representative microorganisms treated with ionising irradiation.

Organism/Molecule	D (kGy)
Clostridium botulinum[a]	3.3
Bacillus subtilis	0.6
Enterococcus faecium	2.8
Salmonella Typhimurium[a]	0.2
Pseudomonas spp.	0.06
Aspergillus niger	0.5
Saccharomyces cerevisiae	0.5
Foot and mouth virus	13.0
Complete inactivation of:	
Enzymes	20–100
Insects	1.5
Trichinella spiralis	0.2–0.5

[a]Pathogens
Source: Silverman (1991).

in packaged foods. One MPa is equal to 10 atmospheres of pressure, or 150 psi. HHP is an adiabatic process; the product temperature at the end of treatment is the same as its initial temperature. However, at very high pressures the product temperature during the pressure treatment will increase about 10°C for each 100 MPa increase in pressure. Therefore, some of the lethal effects during HHP processing are as a result of the increase in temperature during the process. A major benefit of this process is that it does not alter product texture and other organoleptic properties, yielding products of higher quality and extended shelf life. It is favoured for the treatment of high-value, perishable, refrigerated products that would be altered by thermal processes. The process can be applied to moist foods in which the high pressure is transferred uniformly throughout the food product. It cannot be used to treat dried foods. The very high pressure treatment alters the conformation of proteins and nucleic acids by disrupting non-covalent bonds, such as hydrogen bonds, thereby killing microbial cells (Jay 2000; Ross et al. 2003). A limiting factor in the commercial application of HHP is the fact that it must be used in batch operations.

Pulsed electric fields (PEF) can be similarly used to pasteurise liquid foods, such as milk, eggs, and juices, by passage through a high-voltage electric field, up to 80 kV/cm, that is pulsed at microsecond intervals. Commercial applications have been limited by difficulties in scalability (Ross et al. 2003).

7.2.2 Prevention of Microbial Growth

The principal process controls to prevent the growth of microorganisms in foods include refrigeration, freezing, hot-holding, modified atmospheres, and moisture control.

Refrigeration

The widespread availability of mechanical refrigeration for the distribution and storage of foods in commerce and in homes enables consumers to have a wide variety of foods available throughout the year. Despite the shelf life extension provided by refrigeration, some spoilage and pathogenic microorganisms are able to grow in refrigerated foods. Each microorganism has a distinct growth range as related to temperature. The optimum growth temperature is much closer to the maximum growth temperature than it is to the minimum growth temperature (Table 7.6). As the growth temperature is decreased, intracellular metabolism slows. Below its minimum growth temperature, a microorganism is no longer able to grow. The generally accepted temperature for optimum refrigeration is 5°C or lower. Five of the pathogens in Table 7.6 can grow, albeit slowly, below this temperature.

It is important to remember that there can often be interactions between preservative factors that can sometimes be used for commercial or organoleptic advantage. For example, at 27°C osmophilic moulds can grow at a minimum water activity value of 0.65, whereas at 7°C they cannot grow below the water activity value of 0.83. Therefore, a product developed for distribution at 27°C could be reformulated to a higher water activity value for distribution at 7°C (Sperber, unpublished data).

The shelf life of many refrigerated foods ranges from several weeks to several months. Eventually almost every food will be spoiled by microorganisms if the storage temperature is too high, the storage time too long, or if the food has a higher than normal initial load of spoilage microorganisms.

Table 7.6 Temperature growth parameters of bacterial pathogens.

Microorganism	Growth Temperature (°C)		
	Minimum	Optimum	Maximum
Listeria monocytogenes	0	37	44
Yersinia enterocolitica	0	33	44
Vibrio parahaemolyticus	3	37	44
Clostridium botulinum (non-proteolytic)	3	30	45
Bacillus cereus	5	30	50
Salmonella spp.	6	37	46
Staphylococcus aureus	7	37	48
Escherichia coli O157:H7	8	37	43
C. botulinum (proteolytic)	10	40	49
C. perfringens	15	44	50
Campylobacter jejuni	27	42	45

Source: Doyle (1989) and Herbert and Sutherland (2000).

For many decades, sprouted seeds were distributed under refrigeration and became popular as healthy dietary supplements. However, since the sprouts were grown at high humidity and at room temperature or higher, they often supported the growth of microbial pathogens. Given increasing reports of sprout-borne illnesses, the FDA considered banning such sprouts, but settled on a recommendation to treat seeds with 20 000 ppm calcium hypochlorite (Sperber, personal communication). Even at such extreme concentrations this treatment was ineffective commercially, as verified by a recent summary of global sprout-borne illness outbreaks published in *Food Safety News*. Between 1973 and 2016, there were 74 sprout-associated outbreaks in total, and 62 of these were outbreaks in the United States or Canada. Outbreaks involved a range of pathogens, including *Salmonella* spp., *E. coli* O157:H7, *Listeria monocytogenes,* and *E. coli* O104:H4 (*Food Safety News* 2016).

A recent innovation in the production of green sprouts seems likely to reduce the risk of pathogen growth during production such that further illnesses and outbreaks should be rare. That innovation involves planting the sprouting seeds and growing them at refrigerator temperatures; thus the sprouts purchased by consumers will have never been held above refrigerator temperatures. Whilst this may help to prevent many illnesses, it would not necessarily control pathogens that can grow at refrigeration temperatures (e.g. *Listeria monocytogenes*) or account for pathogens already present in seeds that may be able to cause illness with a low infective dose; in this latter case, irradiation of the seeds at the ingredient stage would be an option.

Freezing

The shelf life of refrigerated perishable foods can often be extended by frozen storage. Commercially produced frozen foods are usually stored at –18°C, a temperature that prevents the growth of all foodborne microorganisms. Some microbial growth is possible in foods stored at temperatures above –18°C but below 0°C; as food solutes prevent some water from freezing at the normal freezing point of pure water. Bacterial growth

has been detected in foods at –3°C; mould growth has been found in foods at –8°C (Lund 2000). Microorganisms can generally grow more quickly in thawed meat and produce products than in the fresh counterparts because of the release of intracellular nutrients when frozen meat and produce cells are thawed.

Some degradative enzymes remain active after vegetables are frozen. Therefore, vegetables are blanched in steam or hot water at temperatures about 90°C in order to inactivate the enzymes. Blanching, of course, also serves to pasteurise the vegetables.

Hot-Holding

'Keep cold foods cold and hot foods hot' is a wise saying in public health circles. 'Cold' is generally defined as 4°C or cooler and 'hot' as 60°C or higher; regulatory requirements may differ slightly in various countries. Foods held at temperatures between these limits should not be held for more than 6 hours without prompt refrigeration or heating (FDA 2005). The hot-holding temperature provides a margin of safety; none of the foodborne pathogens are capable of growth above 50°C (Table 7.6).

Widely used in foodservice operations, hot-holding is sometimes a necessary procedure for food processors. When food products or ingredients are cooked, they are sometimes stored in a holding tank until final processing or packaging. It is important that the temperature of such materials does not fall below 60°C. Leftover hot-held materials may be 'toted off' and placed into refrigerated storage; however, the centre of large containers filled with hot food will take several days to reach refrigerated temperature. Therefore, it is important to rapidly chill the food before placing it into a large container or to portion the food into small containers so that the food will chill to optimum refrigeration temperature within 6 hours.

Modified Atmosphere and Vacuum Packaging

Some perishable food products are packaged in containers with a headspace of air under atmospheric pressure. Other factors permitting, aerobic microorganisms can grow freely in such products. Their growth can be inhibited or prevented by the removal of headspace oxygen (vacuum packaging) or the addition of inhibitory gases (modified atmosphere packaging). In each case it is important that the packaging material is impermeable to the appropriate gases and that the final package is hermetically sealed to prevent the entry of oxygen or the escape of inhibitory gases.

The most practical benefit of modified atmosphere or vacuum packaging is the inhibition or prevention of mould growth. Packaging products in such a manner could create a potential hazard by providing opportunities for the growth of anaerobic pathogens, as previously described for fresh mushrooms (Section 6.2.4). The opportunities for such a hazard must be prevented by other means, such as refrigeration.

In vacuum packaging, it is very difficult to remove all of the air and oxygen. The growth of some moulds can occur at oxygen levels as low as 0.4%. Some commercial applications have been developed in which residual oxygen in vacuum packages is removed by oxygen scavengers (Smith et al. 1986). It has long been recognised that a similar phenomenon occurs in fat-or oil-containing foods that are hermetically packaged with a small headspace volume, for example, salad dressings, mayonnaise, and refrigerated ground beef. Residual oxygen combines readily with vegetable oil, thereby preventing the growth of aerobic yeasts and moulds in salad dressings and mayonnaise (Sperber 2009b). Similarly, absorption of residual oxygen by the fat in refrigerated

ground beef will prevent the growth of aerobic microorganisms, including psychrophilic spoilage bacteria. The elimination of atmospheric oxygen in this case further selects for the growth of lactic acid bacteria, which in turn provides additional protection against the growth of spoilage and pathogenic microorganisms (Frazier 1958).

Carbon dioxide gas is often used in modified-atmosphere packaging to prevent the growth of aerobic microorganisms. It can be used in combination with other gases that are used to back-flush a product headspace after a vacuum is drawn. Shelf life of fresh fruits and vegetables can be extended with gas mixtures of 8 to 10% carbon dioxide, 2 to 5% oxygen, and the remainder as nitrogen (Jay 2000; Farkas 2001). As expected with most preservative factors, there is an interaction between carbon dioxide levels and temperature to prevent microbial growth. The growth of mould on bakery products can be retarded at 5°C by a mixture of 30% carbon dioxide and 70% nitrogen. However, at ambient temperatures, a mixture of 70% carbon dioxide and 30% nitrogen is required to inhibit mould growth (Cook and Johnson 2009).

7.2.3 Prevention of Contamination

The third type of process controls to enhance the protection of food products against microbial defects is the prevention of contamination by relevant spoilage and pathogenic microorganisms. Several types of effective controls to keep undesirable microorganisms out of food products are well understood, but sometimes overlooked by food processors.

High-Risk Ingredient Control

The first of these is the control of high-risk ingredients, as briefly introduced in the previous chapter. In principle, high-risk ingredients are more readily addressed as an extrinsic hazard than as an intrinsic hazard. High-risk ingredients are those that have been historically associated with particular microbiological or chemical hazards (e.g. *Salmonella* contamination of dried egg products or aflatoxin contamination of peanut products). Over the years, many participants in the global food supply chain have agreed informally on the major types of high-risk ingredients (Chapter 6; Tables 6.11 and 6.12). Validation and verification of supplier capability is the most effective means of high-risk ingredient control.

Beginning in the 1960s, the potential hazards in high-risk ingredients were controlled by quarantine and laboratory testing. These ingredients were released from quarantine only after an agreed sampling plan was followed and negative results were obtained for the identified hazard. Similarly, finished products manufactured with the sensitive ingredients were often quarantined and tested before being released into commerce.

Obviously, the extensive ingredient and product testing plans did not fit well with the modern product design and process control features of HACCP programmes, which focus on real-time observations and measurements. Nor did the extensive quarantine period (often several weeks) fit well with the modern global system of just-in-time (JIT) manufacturing. Therefore, since the 1990s, in the food industry the mode of ingredient control has shifted from quarantine and testing to validation and verification of supplier capabilities.

In those rare circumstances that may require ingredient or product testing, responsible specifications, as detailed by the National Research Council (1985), and responsible sampling plans, as developed by the International Commission on Microbiological Specifications for Foods (ICMSF 2002), must be followed. Microbiological testing has been found to usually be an impractical means to assure the safety and quality of ingredients and food products. Whenever possible, the use of specifications, lot acceptance criteria, and ingredient or product tests should be replaced by the use of microbiological monitoring guidelines in the food production environment (Sperber and NAMA 2007).

Allergenic Ingredient Control

A great many allergenic ingredients can be used in food products. The major allergens are peanuts (groundnuts), tree nuts, crustaceans, fish, eggs, milk, soy and wheat. Minor or regional allergens include celery, buckwheat, rice, legumes, molluscan shellfish, and the seeds of cotton, sesame, sunflower, and poppy.

A key control measure to protect allergen-sensitive consumers is adequate product labelling so that the consumer is aware of the real or potential presence of an allergen. Many operational measures can be taken to minimise the use of known allergens or to prevent the contamination of foods that are not expected to contain allergens. A non-allergenic ingredient can be substituted for an allergen when feasible. Many food products can be reformulated to eliminate the use of minor amounts of an allergenic ingredient that is not essential to maintain functional or organoleptic properties of the food. It is always necessary to prevent cross-contamination with allergens in product development kitchens, pilot plants, sensory testing areas, and food manufacturing facilities. Allergen control measures are presented in greater detail in Section 7.3.1.

Aqueous Ingredient Control

Numerous aqueous ingredients or subassemblies are used in food products. These are often minor ingredients that are used in small quantities. Therefore, the ingredient or stock solution may be used over long periods during its storage at ambient or refrigerator temperatures. If such a material were contaminated with a pathogen or toxic substance, it could contaminate finished products for several days, weeks, or even months. Many flavours, colours, preservatives, and processing aids could be used in this manner.

A prominent example of this potential hazard was detected and controlled before it could develop into a public health problem. Routine testing of one company's research samples produced for sensory evaluation revealed the presence of enteric bacteria. Further evaluation showed that a colour solution stored in a 2 L bottle at ambient temperature supported the ready growth of salmonellae to a level of about 10 million cells/ml. The use of this colour solution at a 0.1% level in the product would have yielded 10 000 salmonellae/g in the product. Used in the company's manufacturing facilities, the same colour solution was prepared and stored at ambient temperature in a 2000 L tank, a quantity sufficient to support, and potentially contaminate, 4 weeks of production. Had salmonellae grown in this storage tank, a major illness outbreak could have occurred. This particular colour solution was stabilised against the growth of all bacteria (including salmonellae) by the incorporation of 15% propylene glycol (Sperber, unpublished data).

After this incident we learned quickly that many aqueous-based ingredients or subassemblies used in food production can present similar potential hazards. It is incumbent upon the product development team to be aware of such hazards, to evaluate ingredients that could present such a hazard, and to implement effective control measures when necessary. The following control measures for aqueous-based ingredients have proved effective:

1) Control a_w at or below 0.85,
2) Control pH at or below 4.0,
3) Use approved preservatives (e. g. propylene glycol), and
4) Use validated combinations of the above three measures.

If none of the above measures can be used, the aqueous subassembly must be used on the same day it is prepared. It should not be stored, even under refrigeration, for further use.

Sanitary Design and Sanitation

Other principal means to prevent food product contamination are imbedded in prerequisite programmes (PRPs; Chapter 10), particularly sanitary design of food processing equipment and cleaning and sanitation procedures. We have observed that food safety and food quality failures are often associated with a lack of adequate cleaning and sanitation procedures. In turn, the inadequacy of such procedures is sometimes associated with the improper sanitary design of food processing equipment and facilities. The matters of sanitary design and proper sanitation are of utmost importance as microorganisms can grow in substrates that are similar, and sometimes identical, to the food product that must be protected against such microbes. For example, the spoilage of chemically-leavened refrigerated dough products was a major commercial problem in past decades. Some of the dough-handling equipment was designed in such a manner that it could not be properly cleaned and sanitised. Dough accumulations in the bearings and crevices of such equipment served as continual incubators for lactic acid bacteria, the principal spoilage microorganism of the dough products. Eventually, spoilage was essentially eliminated because of the use of new equipment whose design permitted easy and effective cleaning and sanitation. Similar types of product quality defects were caused in yeast-leavened doughs simply because dough mixers were cleaned only once per week, rather than daily.

Moisture Control

The inadvertent and unsuspected presence of moisture can contribute to food safety and food spoilage incidents. Bakery mix products produced in a seven-level tower facility were found to be contaminated with *Salmonella*. According to facility managers, the facility was completely dry and could not support the growth of *Salmonella*. Thorough evaluation of the bakery tower by a friendly microbiologist revealed 43 sites of moisture contamination, including air control valves, open windows, hand-wash sinks, floor mop pails, and condensation on cold exterior walls. Several sites were found to harbour salmonellae. These could likely have contributed to the products' contamination.

Condensation in ventilation systems has been shown to be a source of *Listeria monocytogenes* that contaminated dairy products during packaging. Even blast freezers operated at –40°C can become a source of unsuspected microbial contamination. Some

foods are blast frozen before packaging. Blast freezers are usually operated and kept cold during the production week and cleaned on weekends. During production, loose product material can be blown onto the conveyor tracks and accumulate on the floor of the blast freezer. During the day-long thawing procedure before cleaning, the accumulated food debris becomes an incubator for microbial growth. It is difficult to remove all of the food debris and to adequately clean and sanitise all of the equipment and utility surfaces of the blast freezer. Unless these steps are satisfactorily completed, the microbes will become airborne when the blast freezer is put back into operation and can contaminate new foods that enter the freezer. Strict attention to sanitary design and adequate cleaning and sanitation procedures can prevent many potential microbiological safety and quality problems (Troller 1993).

7.3 Process Control of Chemical Hazards

Food manufacturing facilities should maintain a chemical control plan to prevent contamination of their products with allergens, mislabelled or adulterated ingredients, and cleaning and maintenance chemicals. As with all food safety and quality practices, employee training and awareness is an essential factor in minimising the risk of chemical hazards in foods.

7.3.1 Allergen Control

In recent years, a great deal of regulatory attention has been given to the presence of undeclared allergenic ingredients in food products. Food processors must enact effective control measures to prevent the occurrence of this regulatory and potential public health hazard (Taylor and Hefle 2005; Jackson et al. 2008). Some of the necessary measures are taken during product design and commercialisation, as described in Chapter 11. These include verification of the accuracy of the ingredient declarations on product labels, and the implementation of suitable prerequisite controls for the receipt, storage, and use of high-risk ingredients.

Additional allergen control measures need to be applied in the food production facility. Allergen-containing ingredients need to be clearly labelled and stored separately from non-allergen-containing ingredients. Dedicated storage bins, utensils, and conveying equipment are often used for specific allergenic ingredients, such as peanuts. Sometimes dedicated food processing equipment is used. Large corporations can dedicate a production line or even an entire production facility solely to the production of a specific allergen-containing or allergen-free food. Production sequencing and scheduling can be a useful separation technique when multiple foods are produced on a single production line. In a given production run, all non-allergen-containing foods can be produced before those that contain allergens, and thorough cleaning plus verification of allergen absence will be necessary at the end.

The use of product rework can be a source of contamination with food allergens. For example, in the era before foodborne allergens became a public health concern, it was common practice for ice cream producers to rework leftover ice cream from all flavours into chocolate ice cream, whose colour and flavour would tend to mask the presence of ingredients normally foreign to chocolate ice cream. Of course, some of the foreign ingredients were significant allergens such as peanut butter, tree nuts, and so on.

Whilst it remains an economic necessity to rework leftover ice cream, responsible producers today have a strict 'like into like' rework policy in which leftover peanut butter ice cream can be reworked only into peanut butter ice cream, and so on. Similarly, in the past, leftover enrobing chocolate and remelted chocolate bars would be reworked without consideration that they may have been contaminated by nuts.

Adequate cleaning and sanitation procedures are essential to preventing the contamination of non-allergen-containing foods with residual allergens from foods produced on the same equipment. Complete wet-cleaning and sanitation is the best way to remove residual allergens. When dry-cleaning procedures must be used, wiping, vacuuming, or rinsing with vegetable oils can be done. Air pressure hoses should never be used in place of vacuum hoses, as the former will simply spread dry allergenic material to other production equipment. Longer production runs with allergen-containing foods can be used to minimise the number of cleaning and sanitation periods. After cleaning, the absence of specific allergens should be verified by using one of various enzyme-linked immunosorbent assay (ELISA) or dipstick test procedures that are commercially available. These tests can detect the presence of allergens at or near 1 ppm, which is the threshold level considered necessary to cause an allergic response in a sensitive individual for some allergens.

7.3.2 White Powder Control

Many food processors attempt to implement 'white powder control' procedures. Hundreds of food ingredients – salts, leavening agents, preservatives, acidulants, sugars, flours, starches, and proteins – are white powders (as are cleaning agents and other non-food chemicals). Several control steps are important to be certain that the white powders are used correctly. Upon receipt at the facility, a sample of the white powder should be tested by visual, organoleptic, or chemical means to verify its identity. The accuracy of the ingredient labels should be confirmed when placed into storage. Quite often, minor ingredients are weighed, combined, and blended in a separate area and later front-loaded into product mixers. Quality assurance and production personnel must verify that the ingredients are added correctly to product mixers or preblend operations. The mistaken use or omission of a particular 'white powder' could lead to a significant quality or product safety defect.

7.3.3 Cleaning and Maintenance Chemicals

Each food processing facility should establish a chemical control plan to organise control and monitoring procedures to prevent food product contamination with chemicals that are used throughout the facility but that are not intended for use in foods. Chief among these are many cleaning and sanitation chemicals and pesticides. All such chemicals need to be stored in a confined, locked area and not be used during periods of food production. When food production is halted, all food materials must be properly stored before these chemicals can be removed from storage and used. It is essential that ingredient or product containers are never used to store or handle non-food chemicals such as cleaning agents, lubricants, and pesticides that are used in the food processing facility. Occasional contamination of consumer food products with floor cleaners, hydraulic fluids, and so on has occurred when this restriction is not in place and enforced.

7.4 Process Control of Physical Hazards

Many types of foreign materials may contaminate food products during processing and packaging. For example, major recalls in the United States of food products because of foreign material contamination were caused by metal, wire, glass, and hard plastic fragments (Peariso 2007). The primary causes of contamination were attributed to:

- Inadequate maintenance of processing equipment and facilities,
- Lack of supplier management systems,
- Lack of HACCP programme, and
- Flawed hazard analysis.

Foreign materials can also include extraneous vegetable material (e.g. nut shells), and insects, rodent hair and droppings, bird feathers, and small animals. As with the control of biological and chemical hazards, many elements of prerequisite programmes are essential for the control of foodborne physical hazards.

There are three principal means to control physical hazards in foods:

- Exclusion: including programmes for glass, wood, personnel practices, and pest control.
- Removal: by the use of devices such as magnets, sifters, screens, and stone traps.
- Detection: by using instruments such as metal detectors, X-rays, and optical sorters.

7.4.1 Exclusion Techniques

Control of Glass and Brittle Plastic Contamination

Most food processing facilities maintain a strict prohibition on the use of glass or brittle plastic instruments, utensils, or food storage and handling vessels in order to avoid the possible entry of glass fragments into the food product. Necessary light bulbs – incandescent, fluorescent, and UV – must be constructed with shatterproof glass or installed in shatterproof fixtures.

Control of Wood Contamination

Once a major problem in food processing facilities, the contamination of food with wood splinters has largely been eliminated by the exclusion of wooden pallets and wooden handles on tools and maintenance equipment used in all production areas. Contamination with wood (and other foreign material) may remain a problem in some developing countries, emphasising the need to implement effective control measures throughout the global supply chain.

Personnel Practices

Implementation and training in personnel practices is essential to eliminate the hazard of items falling into the product stream. Employees should not wear items of jewellery (except, usually, for a solid wedding ring). Employee uniforms and hair/beard covers are usually required. The uniforms should have no pockets, so that items such as pens and pencils cannot be carried in the pockets and fall into the product. Maintenance workers must necessarily use many tools in the production area. These must be clean and used with care so that they cannot be left in the production equipment.

Pest Control

A great deal of effort must be expended to keep insects, rodents, and birds out of food plants. Should they get into the plant, the food products can be contaminated with animal parts, insects, faecal droppings, and feathers. In our experience, a large bird (pigeon) got into a flour bin and was beaten through a rotary sifter as the flour was metered into a horizontal dough mixer. Not noticed at the time, a large product recall was later necessary to retrieve the products that contained pigeon feathers (and other parts, quite likely). Similar stories are told in many sectors of the food industry.

Insect activity can be minimised inside facilities by the use of insect light traps that attract flying insects with a UV light. The insects are killed by electrocution (electric insect killers [EIKs]) or by entrapment on glue boards. The light traps should be mounted on interior walls near entry doors, facing inward so that insects are not attracted from outside the facility. They are to be used in areas peripheral to the facility's food handling and production areas, thereby preventing flying insects from entering these areas.

Many facilities ban the use of rodent bait stations inside the facility. Rather, mechanical traps and glue boards can be used to monitor and limit internal rodent activity. Poison bait stations are permitted outside of the plant, the intent being to control rodents before they get inside the plant. Because of the many technical and regulatory difficulties in the application of pesticides, many facilities employ professional pest control operators for this purpose. Pesticides are used in maintenance and other areas peripheral to the food production areas.

Bird control programmes include keeping the plant exterior free of food, especially grains and other seeds, and using irregularly timed air guns to frighten the birds away. To the maximum extent possible, all plant openings to the exterior should be kept closed or screened.

7.4.2 Removal Techniques

Control of Metal Contamination

Routine equipment maintenance and inspection are essential to prevent contamination with 'tramp metal' or 'swarf' (e.g. pieces of machinery or its fasteners that can become loose, break off, or be ground off into the food product stream). Many types of in-line magnets are used by food processors on incoming ingredients, processing equipment, and packaging operations, both to protect the equipment from damage by tramp metal and to avoid product contamination. Used primarily with dry powder or liquid materials, magnets are usually installed in gravity flow systems that permit all of the material in the food stream to pass over the magnets. Magnets are typically composed of alnico (aluminium-nickel-cobalt), ceramic material (pressed barium ferric oxide), or rare earth metals (neodymium-iron-boron). The last type of magnetic material has substantially greater pulling power than the other types. Magnets can be constructed in many shapes that can be used in routine or specialised applications. Typical shapes include plate, hump, bar, grate, ring, pulley, drum, and cartridge (Imholte and Imholte-Tauscher 1999). It is important that the food processor use an expert resource or vendor to select the magnet type and establish performance specifications. Generally installed inside pipes, magnets must be accessible for regular inspection and cleaning. To function effectively, magnets must be cleaned regularly to maintain pull strength. The types of metals found at each inspection and cleaning should be monitored and recorded. The type, size, and

shape of metal contaminants are noted; the metal pieces can be kept in the record book for further reference. This information is often necessary to determine the need for further investigations and equipment repairs when unusual findings are observed.

Control of Foreign Material in Product Streams

In addition to magnets and metal detectors, a wide variety of filters, screens, and sifters can be used to detect or remove physical contaminants in ingredient and product streams. Often used for product quality considerations, filters can be used in bottling or loading operations for oils, syrups, and other clear liquids, thereby simultaneously reducing the hazard of foreign material contamination in the product. Sifters and sieves are often used to separate foreign materials from dry food materials. The screens for these devices should be made of non-metallic ('Nytex') materials. If metal must be used to construct a screen, it should be made of magnetic (ferrous) metal that could be removed or detected by magnets and metal detectors. Aspirators use pressurised air in a falling product stream to separate dense materials, such as cereal grains, from lighter contaminants, such as insects, weed seeds, and dirt that may have entered during growing, harvesting, and transportation.

7.4.3 Detection Techniques

Several technologies are available to detect the presence of foreign materials in a food. The most common of these are metal detectors that can be used on-line or for packaged products (Imholte and Imholte-Tauscher 1999). Materials in which metal is detected are diverted for further inspection to determine the need for corrective actions. X-ray devices can be used to inspect containers before packaging operations. With image-enhancing capabilities, X-ray devices can be used to detect dense foreign material inside food products, such as bone chips in meat products (Graves et al. 1998).

Optical technologies, using visible or UV light, are used with fruits, vegetables, and nuts to detect surface defects and the presence of extraneous vegetable matter, stones, and so on. Peanut product producers use optical scanning to remove dark-coloured nuts, thereby reducing the risk of aflatoxin contamination in finished products. Additional detection technologies are being used on a research basis but are not widely used in commercial product testing. These include electrostatic techniques with parallel plate capacitors, microwave, nuclear magnetic resonance, and ultrasonics.

7.5 Conclusion

The design of process controls by the product development team is a most important first step in the production of a safe food product. If appropriate extrinsic measures to control the potential hazards are not researched and validated at this step, significant time may be lost in order to correct the early mistakes. Worse, a product that is potentially unsafe or of reduced quality and shelf life might be produced and distributed.

Part III

Systematic Food Safety Management in Practice

8

Overview of a World-Class Food Safety Programme

8.1 Introduction

A world class food safety programme is a multifaceted approach to the management of food safety and the protection of consumer health. Traditionally food safety programmes would have been thought of as the systems put in place by manufacturers and larger foodservice operators to assure the safety of their individual products and processes; however, the picture is now a lot more complicated and needs to reflect control of food safety throughout the global food supply chain, as we have seen in the chapters of Part 1. In practice, the systems are still managed at the company level; however, we now see increasing communication and sharing within the supply chain, as companies seek to understand and manage the hazards and risks inherent in their own increasingly complex, raw materials supply and product distribution chains.

When applying food safety management in the 21st century we must learn from the experiences of the past, both the positive experiences of what works well and the more traumatic experiences when things have gone wrong (see Chapter 2). This has led the authors to be firm believers in a 'back-to-basics' approach, particularly in the need to revisit HACCP and prerequisite programmes (PRPs) and ask challenging questions about the ability of existing systems to protect the consumer. It is our experience that a shadow of complacency has crept over food safety systems, resulting in beliefs that HACCP has been 'done' and is something that manufacturing companies have had in place for years so does not need worrying about. The incidents in Table 2.1 (Chapter 2), and many others like them, show us that this simply is not the case. We must pay careful attention to how we manage food safety and make sure that systems are effectively planned, developed, implemented, verified, and reviewed and updated. These requirements tie in with the principles of continuous improvement of management systems and the Deming Plan-Do-Check-Act Cycle that we will meet again in Chapter 9. However, in addition to paying attention to the effectiveness of existing food safety programme elements like HACCP and PRPs, it is also important that we continue to scan the horizon and understand and manage new threats to the global supply chain. Since the first edition of this book, issues around food fraud and food defence have come more sharply into focus, and whilst food fraud is not always directly linked to food safety, these are additional key elements that need to be considered in building the world-class food safety management programme.

Food Safety for the 21st Century: Managing HACCP and Food Safety Throughout the Global Supply Chain, Second Edition. Carol A. Wallace, William H. Sperber, and Sara E. Mortimore.

This short chapter provides an introduction to the following six chapters on specific elements of systematic food safety management. Taken together, the seven chapters of this section will tell you how to develop, implement and maintain a world-class food safety programme in practice. From the point of view of both companies who are starting out on the journey towards food safety management and companies who have recognised the need to review and strengthen their existing systems, this will provide knowledge of best practice approaches backed up by experience and research in real food manufacturing environments.

8.2 Preliminary Concepts and Definitions

8.2.1 The Evolving World-Class Food Safety Programme

In the previous edition of this book, the fundamental elements of a world-class food safety programme were described as safe product/process design, PRPs and HACCP supported by management practices which ensure consistent application of system elements both within the business and outwards through the links of the global supply chain. Our definition included these essential elements but also indicated the need for effective management practices to provide the necessary foundations and ongoing support for continuous delivery of safe food products (Figure 8.1). We defined a world-class food safety programme as:

> *A programme based on the principles of safe product/process design, prerequisite programmes and HACCP that is supported by essential management practices, thus controlling the operational, environmental and process conditions necessary for consumer health protection through the consistent production of safe food* (Wallace et al. 2011, p. 126)

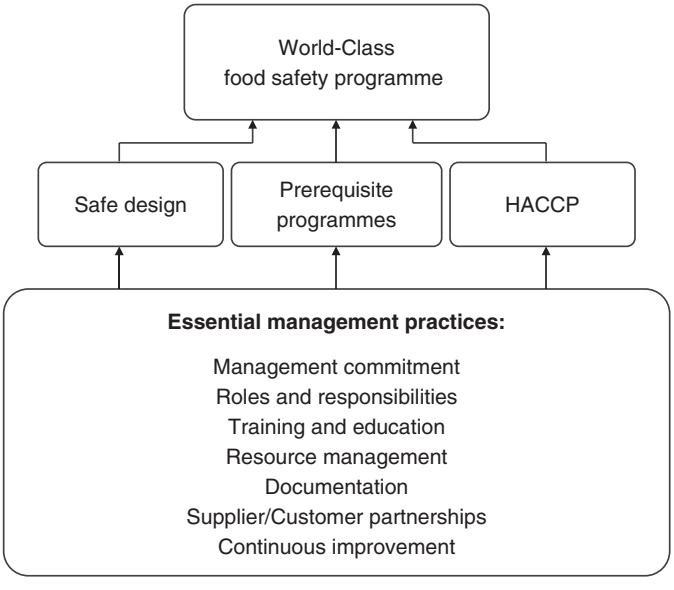

Figure 8.1 Previous thinking on Fundamental elements of the world-class food safety programme. Wallace et al. (2011).

Experiences within food supply chains in the intervening years between the first and second editions have emphasised the complexity of food safety management and the overlap of other system elements that might not have been traditionally considered fundamental elements of food safety programmes. Several high-profile cases of food fraud, such as the horsemeat incident in Europe (Elliott 2014) and the melamine incident which affected both pet food and infant formula beyond China (Schoder 2016) have emphasised the need for effective food fraud prevention systems. Also known as economic adulteration, food fraud is perpetrated by individuals and organisations wishing to make money in unscrupulous ways, usually by substituting a food or food ingredient with a cheaper alternative, unbeknown to the customer or consumer. As will be discussed in Chapter 13, food fraud is not always a food safety issue because substituted products/ingredients could still be safe; however, the nature of fraudulent activity means that, at best, information on the safety status might be hidden (e.g. it may be impossible to tell the hygienic operating standards in the supply chain even for a safe substituted material). At its worst, food fraud results in unsafe foodstuffs in the global food supply chain. For this reason, it is important that food fraud prevention is considered an element of world-class food safety programmes.

Similarly, food defence and biosecurity measures have come to the forefront of thinking on food protection, and whilst these were discussed in the previous edition (Wallace et al. 2011), it is fitting that they are now considered as essential elements of the world-class food safety programme. In recent years there has also been increasing recognition of the important role of culture in the effectiveness of food safety management programmes. Whilst this is an area that is still poorly understood within the food industry as a whole, ongoing research is helping us to understand the dimensions of food safety culture as well as how to measure and improve culture within a business. Food safety culture is not an element of a food safety programme in the same way as PRPs, HACCP, and so on, but rather an overarching condition that is in place in all businesses within the global food supply chain. The important consideration here is that there needs to be a supportive, positive food safety culture to support effective application of the world-class food safety programme elements, rather than a negative food safety culture that could result in the failure of food safety efforts. The updated World-Class Food Safety Programme Model is shown in Figure 8.2.

It is clear that to meet the objective of consistent safe food production, the programme must cover all operations at each facility, must be fully implemented in practice, and regularly challenged with stringent verification procedures to demonstrate ongoing effectiveness and currency.

8.2.2 Key Definitions of Relevance to World-Class Food Safety Programmes

There are several terms of relevance to world-class food safety programmes that have been used in different ways by different stakeholder groups. To prevent confusion within the global supply chain, it is useful to consider the meanings of key terms here. Additional terms will be defined in the following six chapters of this part of the book.

Food safety is the *assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use* (Codex 2009a). In line with this definition and, as previously stated, the primary focus of food safety programmes is the protection of consumer health. Although '**food protection**' is also a commonly used term, few clear definitions exist in the literature. However, this term is generally used to

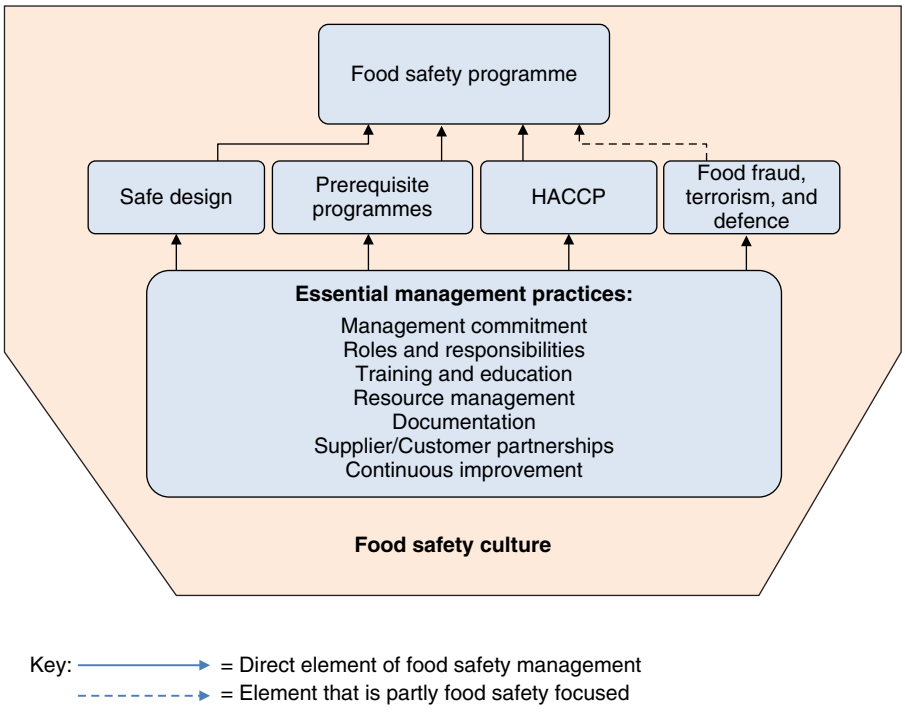

Figure 8.2 Evolution in fundamental elements of the world-class food safety programme.

describe all measures and programmes in place to protect the safety of the food supply and, as such, is often described as *an umbrella term encompassing food defence and food safety* (Food Protection and Defense Institute, n.d.). This means that food protection includes both 'food safety' programmes that are in place throughout the supply chain to assure safety of food products through the prevention and control of significant hazards and also 'food defence' measures that protect food products from malicious contamination. For food protection to work effectively, it is clear that all elements of the world-class food safety programme (Figure 8.2) need to be in place and that multiple stakeholders will be involved with 'professional interests converging from multiple disciplines and sectors' (Schenck-Hamlin et al. 2011).

'**Food defence**' is the collective term used in the United States by the Food and Drug Administration (FDA), US Department of Agriculture (USDA), Department of Homeland Security (DHS), and others to encompass activities associated with protecting the nation's food supply from deliberate or intentional acts of contamination or tampering. Food defence is defined as '*the effort to protect food fromintentional acts of adulteration where there is an intent to cause wide scale public health harm*' (FDA 2016b).

Thus, food protection can be considered to include both food safety to control the naturally occurring hazards in the food chain and food defence to prevent and manage deliberate acts of hazardous contamination.

Food security is a completely different concept relating to access to food but one which has been confused with food safety and food defence from time to time.

The World Food Summit of 1996 defined food security as existing *'when all people at all times have access to sufficient, safe, nutritious food to maintain a healthy and active life'* (World Health Organisation [WHO] 2010). Although safety is mentioned within this definition, it is relating to availability of safe food rather than food safety management.

Biosecurity is a *strategic and integrated approach to analysing and managing relevant risks to human, animal and plant life and health and associated risks to the environment* (Food and Agriculture Organisation [FAO] 2007). Food biosecurity measures relate to the protection of the food chain from issues pertaining to food safety, zoonoses, animal and plant diseases and pests, the introduction and release of living modified organisms (LMOs) and their products (e.g. genetically modified organisms or GMOs), and the introduction and management of invasive alien species (FAO 2007). Many biosecurity measures relate to PRPs, as will be discussed in Chapter 10.

Food fraud is *the deliberate adulteration or misrepresentation of foods or food ingredients for economic gain* (HM Government 2014). As mentioned previously, food fraud may or may not have food safety impacts; however, prevention of food fraud is increasingly addressed as part of food safety programmes. Additional definitions are important in this rapidly developing area and will be discussed in Chapter 13.

Food safety culture is *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* (Griffith et al. 2010)

From the above, it is clear that the world-class food safety programme will form a cornerstone of food protection. Although prevention of deliberate contamination has previously been considered to be outside the scope of food safety programmes, the evolution of food safety programmes means that this is increasingly being seen as part of food safety management and therefore we include it as part of the world-class food safety programme model (Figure 8.2). Certainly the detailed understanding of food processes and supply chains that comes from food safety management, make it possible to identify areas that are vulnerable to tampering, fraud, natural hazards, and biosecurity issues, and the aim of the world-class food safety programme must be to establish and implement effective preventative measures for all of these conditions.

We will now consider the elements of the world-class food safety programme in more detail.

8.3 World-Class Food Safety Programmes: System Elements

As shown in Figure 8.2, the system elements of a world-class food safety programme are safe product/process design, PRP and HACCP systems, linked with prevention procedures for food defence and food fraud. These system elements are supported by the essential management practices within a strong food safety culture.

8.3.1 Safe Product/Process Design

Safe product/process design relies on both the understanding of hazards and formulation/process control capabilities at the development stage and the application of formal procedures to evaluate and sign off the safety of each new development before its

implementation. The chapters of Part 2, Foodborne Hazards and Their Control, provide an in-depth discussion of food safety hazards (Chapter 5) and give guidance on the design of safe products (Chapter 6) and processes (Chapter 7). In this part of the book, we outline how to evaluate the safety of proposed products and processes using product safety assessment (Chapter 11).

8.3.2 Prerequisite Programmes

PRPs are *the practices and conditions needed before and during the implementation of HACCP and which are essential to food safety* (WHO 1999). PRPs provide a hygienic foundation for the HACCP system (NACMCF 1997) by enabling environmental conditions that are favourable for the production of safe food (CFIA 2015). Like the HACCP system, there is international agreement on the general principles required (Codex [Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission] Committee on Food Hygiene 2009b), and these essential characteristics of PRPs are discussed in Chapter 10, against the following headings for application to food chain establishments:

- Design and facilities,
- Control of operation,
- Maintenance and sanitation,
- Personal hygiene,
- Transportation,
- Product information and consumer awareness, and
- Training.

As part of PRPs, food biosecurity measures are important to protect raw material sources within the food supply chain as well as preventing the spread of new and emerging pathogens from food supply animals to humans (zoonosis).

8.3.3 HACCP

The HACCP system has already been introduced right at the start of this book (Chapter 1), and since the system has been in the public record for more than 45 years, it is likely that many readers of this book will have been exposed to HACCP systems previously. However, weaknesses in HACCP systems within a samples of multinational manufacturing facilities (Wallace 2009; British Retail Consortium BRC 2014) lead us to believe that deeper focus on the application of HACCP Principles (Table 8.1) is essential. Chapter 12, therefore, provides a detailed discussion on the application of HACCP Principles for effective HACCP plan development, plus a thorough examination of the important considerations in implementing a HACCP system so that it really works in practice. Maintenance of these fundamental elements of the world-class food safety programme is considered in Chapter 14.

8.3.4 Food Fraud and Food Defence

The prevention of food fraud is clearly important in the food supply chain both to protect the consumer (food safety) and to protect food businesses and brands (non-safety impact food crime). Food defence measures are therefore essential to protect the food

Table 8.1 The HACCP Principles.

Principle 1	Conduct a hazard analysis.
Principle 2	Determine the Critical Control Points (CCPs).
Principle 3	Establish critical limit(s).
Principle 4	Establish a system to monitor control of the CCP.
Principle 5	Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.
Principle 6	Establish procedures for verification to confirm that the HACCP system is working effectively.
Principle 7	Establish documentation concerning all procedures and records appropriate to these principles and their application.

Source: (Codex 2009b).

supply from fraudulent and malicious contamination. Chapter 13 provides a discussion of the current state of understanding of food fraud and food terrorism, including examples of incidents in the food supply chain and practical procedures for identifying food fraud risks and implementing preventative measures.

8.4 World-Class Food Safety Programmes: Fundamental Supporting Elements

8.4.1 Essential Management Practices

Whilst it is commonly understood that there will be management practices that are essential to the effective running of any food safety or quality management programme or any food business, when considering systems for the consistent realisation of safe products on a continuous basis, there is less agreement on exactly what these practices entail. Our definition of essential management practices is as follows:

Essential management practices (for food safety) *are management practices and procedures that support effective application of safe product/process design, PRPs, including biosecurity measures, HACCP systems, and food fraud prevention/food defence, and assure their ongoing capability to protect the consumer*.

These essential management practices are all about making sure that there is ownership and responsibility throughout the company structure and that resources supporting the fundamental elements (safe product/process design and PRPs and HACCP) are appropriately administered, supervised and controlled.

This will include, as a minimum, the following:

- Management commitment,
- Roles and responsibilities,
- Training and education,
- Resource management,
- Documentation,
- Supplier-customer partnerships, and
- Continuous improvement.

It is likely that many of these practices will be under the framework of a structured (quality) management system that may be externally certified. We will discuss these essential management practices in further detail, with reference to food safety requirements, in Chapter 9.

8.4.2 Food Safety Culture

All systems and procedures of the world-class food safety programme rely on people working within the global food supply chain. Within the individual businesses that make up each supply chain link, the prevailing food safety culture is critical to the effective operation of food safety management programmes. There is no point in specifying excellent food safety programmes if the culture is such that these won't be accepted and applied within the business. The concept of food safety culture was introduced in Chapter 4 and this important topic will be further elaborated in Chapter 9, as well as in Chapter 15, where strategic activities to evaluate, map, and mature food safety culture will be considered.

8.5 World-Class Food Safety Programmes: Further Supporting Elements

In addition to the fundamental world-class food safety programme elements and essential management practices, it is likely that there will be further supporting elements in many businesses and in parts of the global food supply chain. These may include elements such as:

- *Quality Management Systems* – As the framework to manage the food safety programme, quality systems based on total quality management (TQM) principles are useful in ensuring ongoing effectiveness and continuous improvement of food safety programmes. Companies may wish to consider externally certified systems such as ISO 9001 (BSI, 2015), ISO 22000 (ISO, 2005a) and/or schemes meeting the requirements of the GFSI Guidance Document (GFSI, 2017).
- *Best practice programmes,* for example,
  - Good laboratory practice to provide confidence in laboratory results used in monitoring and verification of the food safety programmes.
  - Good distribution practice to maintain food safety in transit; this may also be considered as part of the prerequisite programmes.
- *Sustainability programmes*, both to assure supply chain sustainability through prevention of supply problems and to promote corporate responsibility in the way that the supply chain is managed.
- *Continuous improvement programmes* such as the 'Lean', Six Sigma, and TQM approaches where tools that emphasise employee engagement and teamwork, measurement, and systematising of processes can lead to standardised work and reduced variation and defects. Activities such as kaizen events, value stream mapping, and cause-and-effect analysis, can help us to understand our processes in much more

detail, seeing which activities are adding value in consumer terms, in this case to ensure consistent safe food production. This might also include specific programmes such as Total Productive Maintenance (TPM) to maximise the reliability and effectiveness of production equipment, and Focused Improvement activities, leading to business and product process levels as close to perfection as possible.

Although some of these might first seem more about the functioning of business rather than food safety, the complexities of operating in the global food supply chain mean that all business systems should be looked on as an integrated whole rather than as a collection of approaches that address different issues. This helps to ensure that we can progress away from the 'flavour-of-the-month' approach where new concepts and systems come in periodically to replace the old ways of operating, and the importance of food safety can become diluted where the new concept might initially seem targeted at a different area of business (e.g. TPM). Instead of working against each other, food safety management programmes need to be seen as core to all business operations and all approaches being used within each company should work together supporting this and other business objectives.

8.6 World-Class Food Safety Programmes in the Global Food Supply Chain

World-class food safety programmes should apply to the entire food supply chain (Figure 8.3). This means that all types of business, be they small or large and based in any link of the chain (i.e. agricultural, manufacturing/processing, foodservice/retail) need to apply and manage effective food safety programmes. It also requires that food products produced for any consumer (i.e. human or animal) should be subjected to the same stringent control mechanisms and that those handling and preparing food for any consumer, including in the home, should be aware of safe food handling procedures.

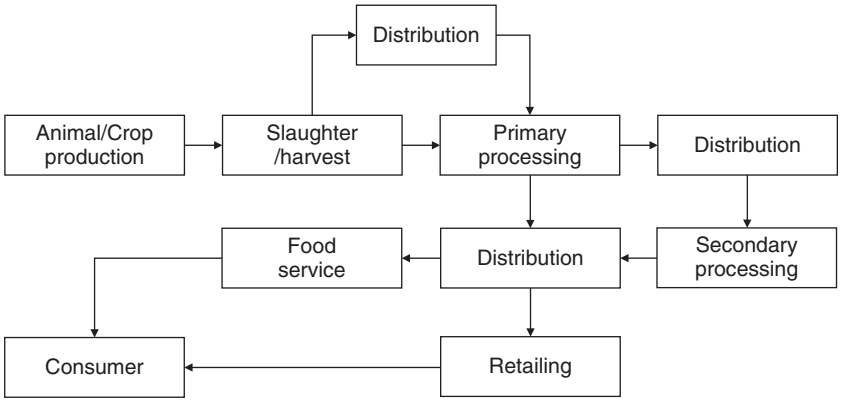

Figure 8.3 Supply chain model. Adapted from Sperber (2005a).

It is no accident that HACCP evolved in the middle of the food supply chain and for this reason many of the procedures are based on activities that can be performed in manufacturing. Although this gives much attention to the middle of the supply chain, particularly with historical experience of HACCP application, the importance in applying food safety programmes in all links must not be forgotten. However, from a practical point of view. it is likely that there will be more emphasis on PRP elements at the ends of the chain (i.e. in primary agriculture and in the home). The importance of animal health and welfare also must be recognised because primary agriculture forms the interface between animal health and public health. Food safety issues around animal health have already been discussed (Chapters 4 and 5), for example regarding concerns about antibiotics in the food chain and the ability for animals to become vectors for new human pathogens (zoonosis).

8.7 Continuous Improvement of the World-Class Food Safety Programme

A key aspect of the world-class food safety programme must be that it continually evolves to meet the requirements for food safety in the global food supply chain, and in doing so, continually improves and offers better protection for consumers and food businesses. This requires defined responsibilities and effective management of resources such that safe products meeting all food safety requirements result from the implementation of the world-class food safety programme. Through measurement and analysis of programme implementation, both monitoring and verification activities, areas where improvement is essential and/or possible will be identified and actions can be taken to continually strengthen the programmes (Figure 8.4).

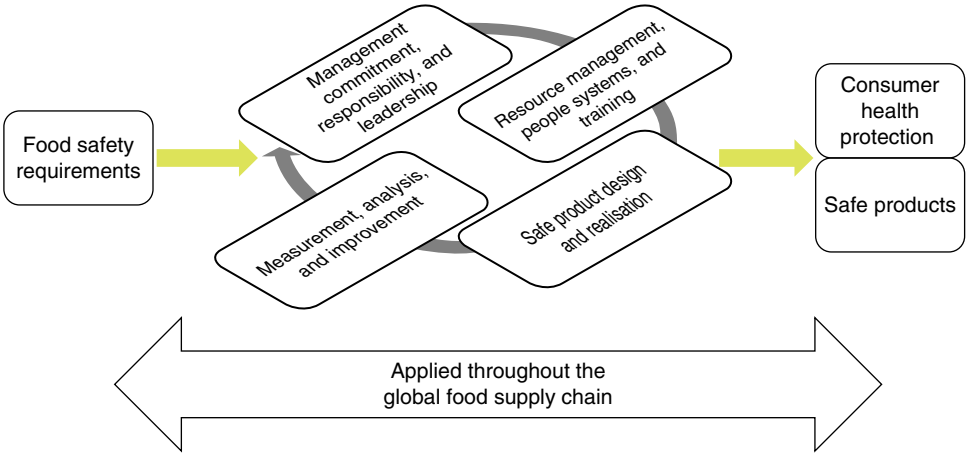

Figure 8.4 Process approach to food safety and continual improvement of the world-class food safety programme.

8.8 Conclusions

World-class food safety programmes are based on effective systems for safe product design, PRPs, HACCP and food defence, supported by essential management practices, and integrated into business management programmes. Applying a continuous improvement mindset towards achieving a world-class programme will enable food businesses to consistently meet both their obligations to consumers and their food safety regulatory requirements. This will result in a live and vibrant food safety culture operating 24/7 throughout the entire food supply chain.

9

Building the Foundations of a World-Class Food Safety Management Programme: Essential Steps and Practices

9.1 Introduction

'Prepare to fail if you fail to prepare' is a well-known saying. There is a lot of truth in this much used phrase, and yet there is very little written about the best practices in preparing to develop and implement a new or improved food safety programme. Perhaps this is because best practice is to regard it as a continuum – the cycle of continuous improvement as described in Deming's 'Plan, Do, Check, Act' (PDCA) cycle (Figure 9.1) (Cleary 1995).

This is complementary to the four key stages (Mortimore and Wallace 2001, 2013) of HACCP implementation where preparation and planning was highlighted as a separate and important factor for success:

Stage 1 – Preparation and planning
Stage 2 – HACCP study and plan development
Stage 3 – Implementation
Stage 4 – Verification and maintenance

A food safety programme that will be sustainable, i.e. one that will withstand changes in personnel and will strengthen and develop as new information becomes available, requires firm foundations. Sufficient time needs to be spent thoughtfully considering all aspects of the business units, with the goal of having an ongoing operational food safety programme that is a way of life and is world class.

The previous chapter described the elements of a world-class food safety programme (Figure 9.2). This chapter will start by focusing on one of these elements – essential management practices. These are important not just for planning a programme, but need to be in place on an ongoing basis in order to ensure that the system remains effective. The chapter will then go on to discuss the planning and preparation activities that are important whether starting to develop a new programme or reviewing and strengthening an existing programme.

Prerequisite programmes (PRPs) are discussed in detail in Chapter 10, but it should be remembered that PRP review and improvements are almost always one of the most time-consuming and costly elements when strengthening a food safety programme, and this is also a key component of the preparation process.

Food Safety for the 21st Century: Managing HACCP and Food Safety Throughout the Global Supply Chain, Second Edition. Carol A. Wallace, William H. Sperber, and Sara E. Mortimore.

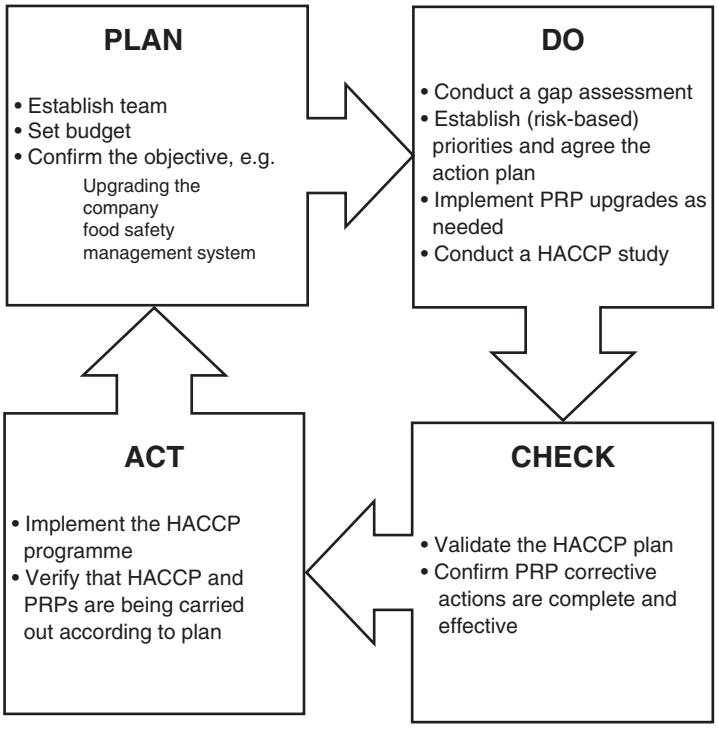

Figure 9.1 PDCA as a template for planning.

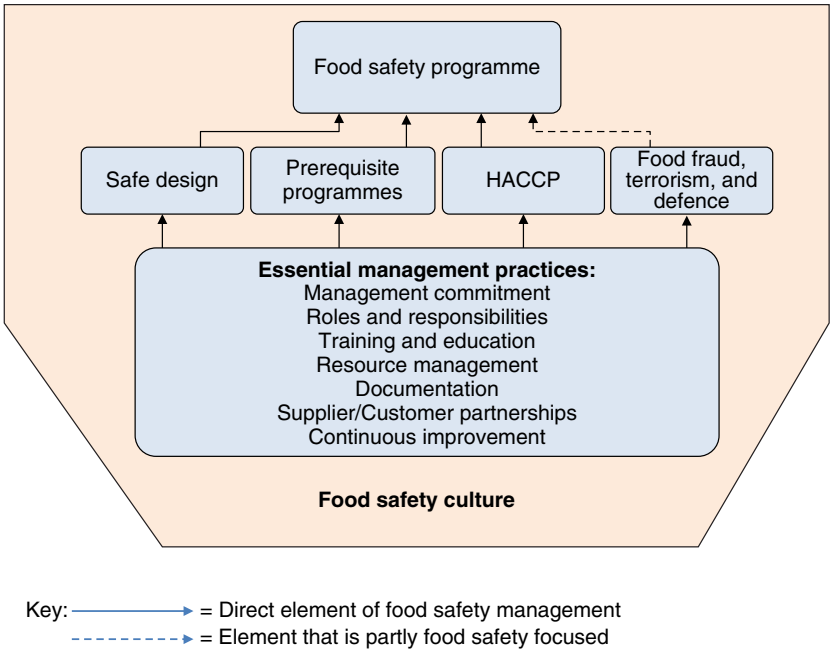

Figure 9.2 Fundamental elements of the world-class food safety programme.

9.2 Essential Management Practices

9.2.1 Management Commitment and its Role in Food Safety Culture

There is no point in doing anything without having real commitment from company senior management, which is why we are starting with it in this section. The senior management team needs to be involved early on, and, based on experience, we would contend that they need to stay involved and be visible often. For many, gaining real genuine commitment is a serious challenge and if not done well will be discussed at the water cooler or in the break room. Here is some guidance that will be helpful.

Start with the most senior managers in the organisation, those in the middle can follow later. Ensure that they are clear with regards to their responsibilities and the likely consequences (for them personally as well as the company) if there is a food safety incident. To do this, examples of failure within the industry and the consequences (both for individual leaders and for the companies they worked for) can be very impactful. Several examples are included in brief in Chapter 2, but the media can be used to search for recent, local and similar category examples to make it relevant and to get into more detail.

The senior team will need a clear and honest account of the status of food safety within their organisation. Many senior executives assume everything is perfect and mistakenly believe that nothing would ever go wrong in their own plants. Information shared should be fact-based and kept at a fairly high level. Often, the senior team has not really had to think about this before or has not had even this level of detail. Being able to include examples of the company's 'near misses' will be even more effective in gaining commitment, particularly if a cost of failure can be compiled.

When briefing the team, an overview of the gaps in the organisation together with a high level plan (with costs and timing) to close them will be needed in order to ensure alignment and full support to proceed. Whilst senior management commitment has long been believed to be important in HACCP and food safety success, recent research (Wallace 2009) has provided more information on what this means in practice. In particular, this has highlighted the importance to the workforce that they have 'promotional managers' (i.e. managers who demonstrate their commitment both through ongoing promotion of the food safety requirements and by being instrumental in providing necessary resources and support for its implementation). In some companies, this role is known as a food safety champion, and the senior team needs to understand the importance of this role as they commit to taking the project forward. We will discuss food safety culture a little later but this visible commitment at senior level is essential to having a positive and supportive culture.

The role and responsibility of the senior team will include:

- Showing visible signs of support and alignment, for example through vocal support at staff meetings or plant visits (i.e. acting as 'promotional managers' and champions).
- Involvement in regular updates and reviews on progress.
- Commitment to engaging other functional leaders to show uniformity in their support (Sales, Marketing, Research and Development, Operations, Information Technology, and Finance).
- Ensuring that required resources are made available.

Finally, some basic education can be provided on what a world-class food safety programme looks like. This will include:

- Food safety hazards–what are they, and how they get into food,
- Design for food safety,
- HACCP,
- PRPs,
- Culture and behaviour of people,
- Benefits, including the effect on the bottom line, and
- Driving external forces (customers, regulatory).

Senior managers need to understand that success or failure rests on their shoulders. Without their commitment, there is not a food safety programme, and without cross-functional alignment on what the gaps are and how they will be addressed, there will be no lasting progress. Gaps and gap assessments are presented in detail in Section 9.3.3.

9.2.2 Assignment of Roles and Responsibilities

The company needs to assign roles and responsibilities, but this may change once more detailed gap assessments have been done and the workload is clarified. That said, there are some obvious roles to assign at the beginning, and they may differ slightly depending on whether the company is large or small, has a corporate office or stands alone, whether this is an upgrade to the existing food safety programme or a brand new activity. We anticipate that more than 50 years on from the birth of HACCP and more than 20 years after the Codex (1993) principles were published, for most readers this will be an upgrade.

Whatever the circumstances, a *management steering group* will be needed to provide oversight. In a larger organisation, this should be a senior level team, but it may be a few key members of staff in a smaller company. The team should scope out its objectives but may need some additional education and training in order to be able to do this thoroughly.

A *food safety team* (could also be called the HACCP team) will also need to be appointed. This team will be cross-functional and be able to provide the more detailed technical knowledge that the company will need in order to be able to develop and maintain the programme. This team must be capable of using judgement and experience to aid risk-based decision making. They will also conduct training and awareness sessions within the rest of the organisation.

9.2.3 Training and Education

Training (for what needs to be done and how) and education (knowledge as to why it needs to be done) is increasingly being recognised as critical in food safety assurance. This is not really new thinking; more than a decade ago the question was asked, 'when HACCP appears to fail, is it the fault of the HACCP system itself or does the real failure lie with the people who are trying to implement it?' (Mitchell 1998). Unfortunately, it has taken more than a decade to shift thinking and recognise more widely that training and education has been inadequate, as evidenced by the number of foodborne illnesses that still occur each year. And, as can hardly be pointed out often enough, we have also

learned that many food safety failures are caused by inadequate attention to prerequisite programmes, possibly also due to lack of understanding of their importance through insufficient training and education. A few important questions need to be considered early on.

What are the desired outcomes of the training and education session?
This question needs to be answered not simply in terms of the knowledge content of the training (i.e. what the trainee will know how to do and why they are doing it), but what the actual business objectives are, for example, to implement a HACCP programme that will:

1) Reduce consumer complaints by X,
2) Reduce microbiological product testing by Y, and
3) Reduce product on hold/dispositional by Z.

A monetary value could be placed on these, also perhaps a productivity value. Doing this will help with the cost burden that often comes with the request for additional resources (refer back to the cost of quality model in Chapter 2).

Who needs training and education?
The simple answer is *everyone* but not all to the same degree.

Overview Sessions: Senior managers and hourly employees require an educational overview of HACCP, of PRPs, of the cause for change (i.e. what is wrong with what we have been doing so far), and some examples of companies who did not change and had a food safety incident. A reminder of the few essential rules that apply to everyone should be included (hand-washing, hygiene zone protocols, reporting signs of pest activity, cleaning up spillages, minimising use of water). Having both senior managers and hourly employees in the same sessions is an excellent way of emphasising the shared responsibility for food safety.
In-depth food safety knowledge: The food safety team needs in-depth training and education, both at the start of an implementation project and on an ongoing basis to ensure that they keep up to date. A detailed session on HACCP and food safety hazards lasting 2–3 days is a good introduction for this group, but they will not be experts even with this level of training. The more effective classes include content on both HACCP and food safety hazards and emphasise the connection between the theory (microbiological hazards, chemical hazards, and physical hazards) and practical application during hazard analysis. Since hazard analysis has been identified as an area of HACCP where teams have difficulty (Wallace 2009; Wallace et al. 2014), clear focus on how to apply this, along with the other HACCP Principles, is fundamental. Ideally, in larger companies, plant-based HACCP teams will have a headquarters assigned coach or mentor to help support their developing expertise. In some countries, an external university extension service or other type of third-party support system can be used to do the same thing in smaller companies.

The training and education suggestions described above are usually sufficient at this stage. Later, and during implementation, there will be a need for more training of critical control point (CCP) monitors, their supervisors, and PRP leaders.

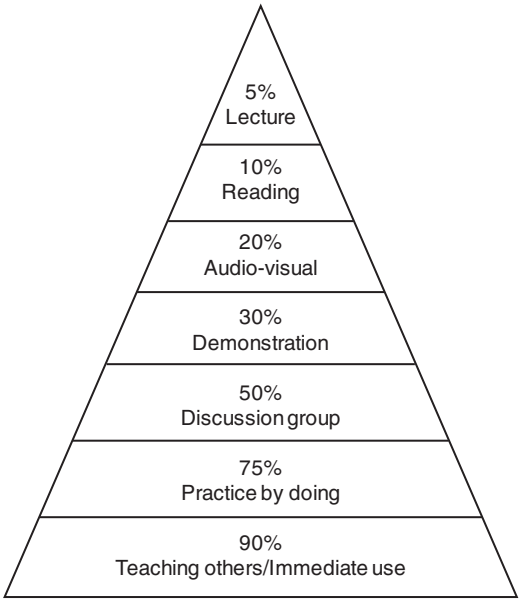

Figure 9.3 Learning pyramid. *Source*: Adapted from National Training Laboratories for Applied Behavioral Sciences, Alexandria, VA.

How should they be educated and trained?

Not through slide presentation alone is the simple answer. The Learning Pyramid, as proposed by the National Training Laboratories (Figure 9.3), indicates a mere 5% average retention rate of information by lecture alone. Combine that with the fact that the typical attention span for adults is 20 minutes and it starts to become clear that thought needs to go into how information will be delivered. Improved learning comes from using the knowledge in practice (average 75% retention rate), but that increases to 90% when having to teach others and by using the new knowledge immediately after the training session. This is really important to remember when providing new information on any subject and is a strong argument for a train the trainer approach. By training production supervisors and other functional managers (outside of the food safety team) to deliver food safety training, more of the knowledge will be retained and a sense of a shared responsibility is reinforced.

Research (Wick et al. 2006) suggests that there should be a new start and finish line where learning is concerned. We need to think of it as a process which does not start and end with the 2- or 3-day training session (which is traditionally the way HACCP training has been delivered), but to be more effective, the process begins much earlier and it continues for a period of time after the training session itself. This can be explained by means of six disciplines (Table 9.1). Using this training approach requires more effort on the part of the trainer and the trainees' supervisor, but experience shows that the additional time invested is very worthwhile.

Table 9.1 The six disciplines of breakthrough learning as applied to HACCP.

Discipline 1: Define outcomes in business terms
As discussed earlier, the team needs to think ahead of time about their objectives in doing the training. This includes deciding specifically what they really need to achieve in order to advance the business (e.g. completion of a HACCP plan, reduction in consumer complaints, reduced costs associated with internal or external company failure, reduced costs of testing). These and more can be utilised in setting improvement objectives. Each objective should also have a timeline attached to it.
Discipline 2: Design the complete experience
Involve the trainee's supervisor ahead of the session by having some discussions around training outcomes. This is where the training can be personalised to suit each individual. Poorly prepared trainees usually start any session by thinking 'what is in this for me'. Set some pre-work and assignments so that trainees come in eager to learn more and are already engaged in the subject matter, seeing it as a route to improved food safety performance.
Discipline 3: Deliver for application
This is the actual training event, so demonstrate food safety management and the HACCP concept in terms that are relevant to the trainee. Practical work and discussions should reflect processes being used in their actual workplace.
Discipline 4: Drive follow-through
By confirming food safety goals ahead of the training, it is easier to galvanise the trainees into action immediately following the training event. Regular milestones for review should be established and progress should be appropriately communicated within the organisation.
Discipline 5: Deploy active support
The more successful training programmes put a follow-through support plan in place at the start. This might involve prescheduled coaching and mentoring of the trainees as they work at applying the new knowledge. This can be achieved via support from a corporate team, a reputable consultant, or by the trainers themselves. It is also important that the trainees' immediate supervisor sees the work as important and stays actively engaged and supportive. This is important if HACCP is to be seen as the way of working on an ongoing basis and not just the latest activity until the next project comes along.
Discipline 6: Document results
Not simply in terms of *how* many people got trained, or what they learned, but in the sense of what they actually applied and how the company benefited as a result of the training. When training funds are reduced in companies, it is usually because there has been insufficient evidence of the return on the investment.

Source: Adapted from Wick et al. (2006).

Education and training for the food safety team needs to cover Codex Principles and guidelines and their application, plus information on hazards and their control (see 'In-depth food safety knowledge' above). When it comes to conducting PRP training, consideration of the approach outlined in Table 9.1 is also important; for example, essential practices such as hand-washing still need to be a learned behaviour for far too many people. Do not assume that this is happening 100% of the time. Table 9.2 shows possible HACCP training subject matter and learning objectives for different groups of personnel. This can be used to cross-check in-house training materials or those of a third-party consultant.

Table 9.2 Possible HACCP training subject matter and learning objectives for different groups of personnel.

Group	Learning Objective
Senior Management	1) Understand the critical need for effective food safety systems. 2) Understand the general principles of HACCP and how they relate to the food business. 3) Demonstrate an understanding of the training and knowledge requirements for food safety team members and the workforce as a whole. 4) Demonstrate an understanding of the links between HACCP and other quality management techniques and programmes and how a combined product management system can be developed. 5) Understand the need to plan the HACCP system and develop a practical timetable for HACCP application in the whole operation.
Food Safety Team Leaders	*HACCP system and its management* 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 programmes 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 programmes for verification and ongoing maintenance of HACCP systems. 7) Explain the methods to be used for the effective implementation of HACCP. *Additional topics* 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 programmes for CCP monitoring personnel. 6) Demonstrate an understanding of the links between HACCP and other quality management techniques, including PRPs, and how a combined product safety and quality management system can be developed and maintained.
Food Safety Team Members	*HACCP system* 1) Justify the need for a HACCP system. 2) Show how the legal obligations on food business proprietors to analyse 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 9.2 (Continued)

Group	Learning Objective
	5) Identify CCPs 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. *Additional topics* 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 programmes for CCP monitoring personnel.
CCP Monitors	1) Understand the general principles of HACCP and how they relate to the food handler's role. 2) Perform CCP monitoring tasks, record results and initiate appropriate actions.
Auditors of HACCP Systems	*HACCP and regulatory Auditing* 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. *Additional topics* 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	1) Understand why prevention of food safety failure is important and consequences of failure. 2) Understand the general principles of HACCP and how they relate to the food handler's role.

Source: Adapted from Wallace (2001).

Has the training and education delivered the required knowledge, skills, and ability?
Although implied by Disciplines 4 and 5 of Table 9.1 above, it is worth taking time out to consider the effectiveness of training in terms of the delivered knowledge, skills, and ability. In many cases, this will be possible to determine via supervision as suggested above; however, for effective HACCP development, it is important to establish if the HACCP team has the necessary knowledge of HACCP Principles to be able to apply them in practice. Research has confirmed that certain areas of HACCP knowledge are problematic following traditional style training (i.e. in a classroom for 2–3 days without pre-work or follow-up active support and mentoring) (Wallace et al. 2005), and this suggests that it is important both to consider appropriate training methods and to understand the levels of HACCP knowledge attained following the training intervention. This can be achieved via knowledge testing, possibly offered as part of externally certificated HACCP training or via published instruments (e.g. Wallace et al. 2005). Other research (Wallace 2009; Wallace et al. 2012) has shown some further interesting findings with regard to HACCP training, namely:

- HACCP team knowledge of HACCP Principles is not necessarily as good as the knowledge of individual team members.
- HACCP team knowledge of HACCP Principles can be used to predict the effectiveness of the HACCP plans that they develop.

This suggests that understanding of the HACCP knowledge both of the trained HACCP teams and of their individual members is important to delivering success in this area. From experience, it is rarely seen that a team or an individual has the level of expertise required to develop and maintain an effective HACCP programme, together with PRPs and preventive control measures, without considerable support following any training and education sessions.

9.2.4 Resource Management

Early in the process, and once the objectives have been established, the management steering group will need to review the base level of resources required. This could also be done by the food safety team once set up. Estimates need to be made concerning the food safety budget and resource requirements at this stage. Examples of budget considerations include:

- Training, which may include external trainer, room hire, travel time, test papers (if external certified training is used), and overtime costs for the hourly paid workforce.
- Administrative support if the team requires some short-term additional help.
- Additional education and/or consultant costs, where insufficient knowledge exists internally.
- Equipment and services costs where relevant. For example, analytical test equipment may be in need of an update, external testing laboratories may be needed, or an upgrade on the third-party sanitation or pest control contract.
- Plant infrastructure investment. This will be unknown until after the more detailed gap analysis, but experience shows this to be the key element of the cost associated with implementing a HACCP programme (i.e. the PRP upgrades as opposed to HACCP itself).

It is also a good time to review what activities are truly necessary via techniques such as value stream mapping. HACCP can provide the insights in terms of food safety value,

but an example of existing activities which add no value might be the receipt and filing of hundreds of unnecessary Certificates of Analysis (COAs). HACCP will help the organisation to focus on only getting in useful and actionable information on raw materials that are considered as introducing a significant hazard if uncontrolled. They then become part of the verification documents and have meaning.

9.2.5 Documentation

This tends to worry many smaller businesses, but whether the business is large or small there is a need for documentation as evidence of all the good work being done to protect consumer safety. It is important to think about 'measuring what matters', and this usually includes quality or regulatory compliance work as well as food safety.

Standard forms are provided in Codex (2009b) for the HACCP control chart. Those used as examples later in this book can also be used as a template. However, these are the formal elements of the HACCP plan, and the food safety team is encouraged to take additional notes or extend the forms to ensure they have a record of their thought process and the various actions that occurred. These additional working documents are unlikely to be shared with external assessors but, used internally, can be very helpful when updating a programme. Similar templates can be used to document PRPs.

Plan to control documents in terms of traceability and approval (via reference numbering, dates, and approval signatures), also think about where to store them and allocate responsibility to someone on the team for this role. In most companies, documentation tends to be more electronic than hard copy which makes it easier for tracking and retrieval, but online monitoring records can still be paper copy and need to be carefully collated and stored. Weaknesses in the archiving of documentation have been highlighted (Wallace 2009), where a study showed that some manufacturing plants had difficulty in retrieving key documents when their food safety systems were being assessed for effectiveness. If there is no documentary evidence that activities took place then, for many assessors (including customers and regulatory inspectors), the activity must be assumed to not have occurred. This is also a problem with systems using only exception reporting when problems occur. If nothing at all is written down or recorded in some other way, it is not possible to demonstrate without doubt that the systems have been under control.

9.2.6 Supplier/Customer Partnerships

Partnerships between customers and their suppliers are an important part of any food safety programme. Confidence in raw material safety and quality can be facilitated through partnerships based on trust between the parties that requirements will be met. This will take time to build up and will likely include visits to the supplier premises as well as audits and the monitoring of specifications (see Chapter 3). This can take considerable time, so a risk-based prioritisation approach will greatly help with the allocation of resources. Use of third-party private schemes (such as those benchmarked to the Global Food Safety Initiative [GFSI] guidance document) will also be helpful.

9.2.7 Continuous Improvement

An essential management role is to ensure that the company is constantly on the alert for improvement opportunities. Some companies fail because they get complacent and

feel that their programmes are effective, but the mindset should be one of continuous improvement. The team should be looking for new sources of information on food safety management, reviewing industry failures for root cause and assessing whether there are learnings that can be applied. Food safety management is a continuum – it is never 'done', so unlike many other projects this one does not have a real end point. Complacency is a real enemy in this sense. This is an excellent segue into our next topic, which is food safety culture, an emerging area in the food safety field and one that lends itself to real continuous improvement.

9.3 Food Safety Culture

Mentioned briefly in the first edition of this book, little more than 5 years ago, the concept of a food safety culture has made rapid strides in gaining acceptance by previously unconvinced food safety practitioners. Of course, food safety culture has always been there, perhaps under the guise of management commitment, employee engagement, hygienic behaviours, attitudinal assessment, operating climate, proactive mindset, and perhaps even within total quality management and continuous improvement methodologies. What has changed is the recognition that these areas can be brought together by working cross-functionally, food safety scientists with behavioural scientists, to pool their knowledge much in the same way that HACCP was devised by a microbiologist and an engineer. In laying out the criteria or dimensions of a food safety culture, we can begin to measure and improve upon it in a way that we could not previously – we can compare ourselves with others, we can share best practices, and we can build upon our current state.

A few pioneers were writing and advocating very early on, notably Griffith (2010, 2014) and Yiannas (2009, 2015). GFSI held its first conference on the topic in 2010, and Jespersen and others from Maple Leaf Foods started talking publicly about their learnings from a catastrophic *Listeria* event in 2008, later using them as a catalyst for further research and study.

There are several definitions now emerging for food safety culture. Here is one from Griffith (2014, p6), and a second one which has been adapted to better suit our interpretation:

Food safety culture means: *'The aggregation of the prevailing relatively constant, learned, shared attitudes, values and beliefs contributing to the hygiene behaviours used within a particular food handling environment'* (Griffith 2014).

Food safety culture means: *'The aggregation of the prevailing relatively constant, learned, shared attitudes, values and beliefs contributing to the* ***food safety*** *behaviours used within* ***an organisation****'.*

In the edited version, we have changed hygiene for food safety – seeing it as a broader scope and also as applying across the entire organisation (i.e. all functions, all levels, all locations, not just in the food handling environment). It is interesting to consider whether food safety culture stands alone or whether it is part of a broader organisational culture. Whether seen as a subset of the overall organisation culture or as a stand-alone area for development, what is important is that it does not compete for attention versus a sustainability or health and safety culture, for example.

In building the foundations for a world-class food safety programme, the need for a supportive food safety culture must be factored in early on. Senior management

commitment and communication of the overall vision will provide a good basis on which to build. We have reviewed training and education needs earlier, but it is important to note that these are essential for food safety culture as well as for scientific knowledge development. All functional leaders, middle managers, down to the lowest level administrator and operator have a role to play and need to be equipped with sufficient knowledge to engender the confidence to challenge existing practices and assumptions, ask questions, be curious, and to act as a champion. Training and education provision is an indicator of a food safety culture but not the only one:

- Resource provision in the way of human resources – both the number of people and their skill level
- Tools such as electronic systems and information technology, subscriptions to external organisations and trade associations, etc.
- Time, made available for meetings as well as training
- Regular senior level management reviews of progress
- Visible signs and artefacts:
  - Food safety questions being asked when headquarters personnel visit sites
  - Signs and posters
  - Regular status communications and stories via electronic postings
  - Reward and recognition schemes
  - Consequences of poor performance
- A mindset and evidence of self-driven continuous improvement

The GFSI has established a Technical Working Group who are currently actively engaged in developing a Food Safety Culture Guidance document. This should be very helpful for both industry and certification scheme owners to use as guidance and for benchmarking their own assessment mechanisms.

9.4 Preparation Activities for Food Safety Programmes

Project management techniques (e.g. Gantt charts) can be used very successfully to organise all the activities that need to occur and to ensure focus.

9.4.1 Preparing a Project Plan

At the start of the project and before starting the technical work, the team must do a few managerial things in terms of project management:

- *Confirm their objectives* (and also confirm whether third-party certification of the programme is one of them).
- *Confirm the deliverables* – what needs to get done in order to achieve the stated objectives. This can become a fairly detailed breakdown of tasks which can be organised into categories and assigned to individuals or teams. The deliverables will be fairly detailed and will almost certainly require that the team determine the structure of the HACCP programme, complete a gap assessment against PRP requirements, prioritise and complete any identified corrective actions.
- *Assign roles and responsibilities* – per the stated deliverables.
- *Confirm the scope of the project* –what does it include and what does it not include. For example, it might be limited to an update of an existing programme, or it might be that a new production line is being commissioned and a new HACCP plan is being prepared.

- *Determine the project milestones* and agree the project timeline.
- *Confirm assumptions and highlight any dependencies*, e.g. a product safety assessment see Chapter 11) may need to be completed ahead of doing a HACCP study. Some PRP improvements may also be incorporated, especially if they lead to food safety risk reduction.
- *Confirm the budget* – where capital expenditure is involved for PRP improvements, this may span over several years, so an intermediate and longer term improvement plan will have to be in place.
- *Set regular review dates* with senior management.
- *Agree a communication plan* so that everyone knows the status.
- *Agree the measures of success*, including celebration of key milestones.

Once the project plan is agreed, the team can get started on completing the assigned activities in terms of the deliverables. A few of the major ones are discussed in the remainder of this chapter.

9.4.2 Structure the HACCP Programme

The structure of the HACCP programme is important not just at the development stage but also for maintenance of the system. It can be modular with multiple smaller plans or one large all-encompassing plan. Usually this depends on the product and plant, and the company will need to evaluate options. As a guideline, a company making a single product line with few raw materials (e.g. canned fruit) may find that one process flow chart and HACCP plan is simple enough. A company with hundreds of ingredients and product lines (e.g. manufactured processed foods such as baked goods, confectionery, prepared meals) will typically use a modular approach. This involves breaking down the process into units or 'modules' which could be generically categorised as defined in the example given in Figure 9.4.

9.4.3 Carry out a Gap Assessment

There are several areas to review in terms of assessing the gap between where the organisation is at the start and where it needs to get to. The primary areas are:

World-class food safety programme

- Safe product design
- PRPs
  - Including risk evaluation at plants
- HACCP
- Food fraud and food defence

Management commitment (element of essential management practices) and food safety culture

- Organisation structure
- Knowledge and skills
- Provision of resources - human, IT systems, and other

We will look at each of these in turn.

World-Class Food Safety Programme Gap Assessment

Safe Product Design – the gap assessment consists of establishing whether any formal evaluations are being done and whether validation data exist, for example, through line

trials, challenge testing, and the compilation of literature references (see Chapters 6, 7, and 11). The organisation must know what is making its products safe and also what would cause them to be unsafe. Here, the team needs to factor in any likely unintended use as well.

PRP Gap Assessment – PRPs are described in Chapter 10, so detail of the specific PRP elements is not provided here. An on-site self-assessment should be conducted by the

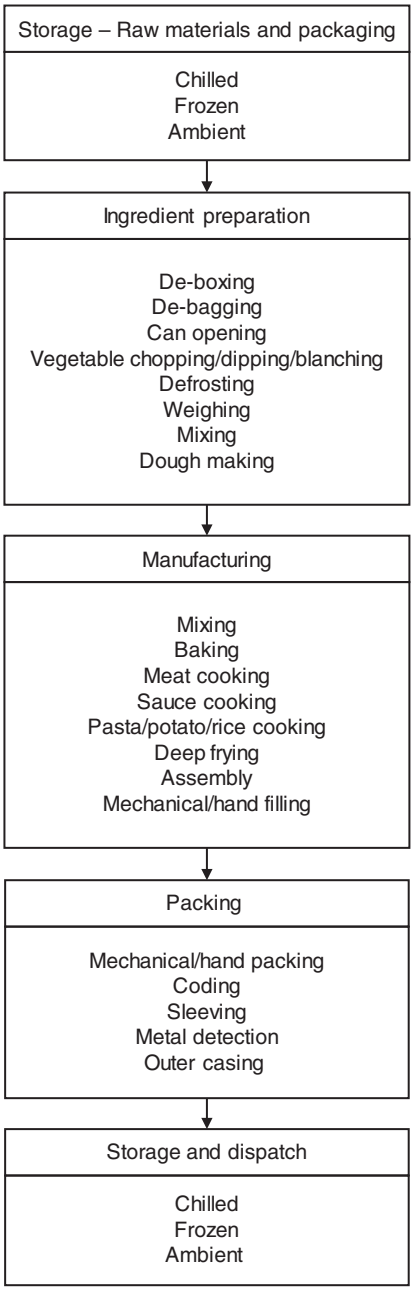

Figure 9.4 A process operation module. *Source*: Adapted from Mortimore and Wallace (1998).

food safety team against best practice standards. Alternatively, it could be helpful to hire a reputable third-party expert consultant or audit company with a good track record in auditing against best practice standards to carry out the assessment with the team. In conducting a gap assessment as opposed to formal audit, there will be more opportunity to make this a real team effort and to ensure that as much as possible gets reviewed. Engaging the workforce in this activity can help to reinforce that this is a shared commitment for improvement as opposed to it being seen as QA team 'police' work. The gap assessment should cover a review of compliance against all elements of a best practice PRP standard such as outlined in the next chapter.

The team should consider other inputs whilst going through this exercise, including:

- Previous gap assessments
- Previous audit reports (internal/external)
- Results of regulatory inspections
- Upcoming changes to existing regulations and private standards
- Consumer complaint data
- Any key performance indicators such as sanitation pre-operational inspections, first time quality, non-conforming product data, and environmental/product microbiological test data

Whilst all PRPs are important, there are two areas, sanitation and supplier quality assurance (SQA), that we want to use as examples to illustrate the gap assessment process and which will demonstrate the in-depth investigation required.

Example 1: Sanitation There is often real value in bringing in expert resources for this part of the assessment, as in-house resources rarely have sufficient expertise for evaluation of sanitary design and sanitation programme and practices assessment, or, alternatively, they may be too close to their internal programmes and unable to assess objectively. This programme is obviously essential for high risk foods, but all food manufacturers need solid programmes to ensure that products are both safe and wholesome for consumption.

Here are a few key areas to consider:

- *Sanitation risk evaluation*. The team will need to evaluate how the programme was developed. Was the plant sanitation programme developed as a result of a formal determination of *what* needed to be cleaned, *why*, *how*, and at what *frequency*? Risk factors will include potential microbiological contaminants (e.g. pathogenic and spoilage organisms), potential chemical contaminants (e.g. allergens, additives), and physical contaminants (pest infestation, foreign material).
- *Efficacy of the sanitation programme*. Many companies use a combination of measures on a routine basis including ATP bioluminescence and environmental *Salmonella* and *Listeria* species or indicator organisms monitoring plans via swabs. During an on-site assessment, there should be an opportunity to really take a closer look at the programme during active periods (Behling 2006):
  - Assessment of the manufacturing process – the equipment, the environment, the people – during and at the end of a production shift. This can be achieved via observation and by taking targeted environmental swabs from the equipment and environment.

- Observation of the clean-up process. This will involve talking with the operatives, observing what equipment is dismantled for cleaning and what is not. The assessment team will want to question people regarding the rationale. 'Too difficult to break apart' as a response is an excellent pointer for the team to do exactly that. They will watch whether the cleaning process itself can lead to cross-contamination (e.g. use of high-pressure hoses to clean the floors *after* the equipment is clean, or worse, when there is exposed product in the vicinity). The team will also be measuring flow rates, chemical concentrations, and will cross-check actual activities against documented work instructions – the aim is to be able to assess whether the company is doing what it said it would do in the procedures, and also to assess whether these are adequate.
- Post-cleaning sampling and pre-operational inspection. This is part visual inspection and part environmental sampling. Taking samples of first production off a newly cleaned line can also be used as an indicator through carrying out microbiological testing. However, if there are 'niches' such as cracks or crevices, poor welds, or dead ends somewhere in the system then contamination may not show up until later. In the case of pathogen testing, all production will need to be held until the test results of any product sampling are known. Allergen cleaning validation tests will also be important where the purpose of cleaning includes the requirement to remove allergens.
- Analyse pre-clean and post-clean data, draw conclusions from observations and make recommendations. The pest control programme can be reviewed at the same time given that sanitation is one of the preventative controls for this programme.

Example 2: Supplier Quality Assurance (SQA) Raw material quality is fundamentally important in ensuring that a safe, wholesome product gets to the consumer. There would be very few companies where the quality of their raw materials had little impact on finished goods. For a number of companies, this can actually be a critical control point CCP (i.e. where a high risk raw material is being purchased but receives no further kill step as it gets incorporated into the finished product). In this case, the reputation of the company relies on ability of their raw material supplier to consistently manufacture a safe product. It is therefore essential to have an effective SQA programme.

In doing a gap assessment of the SQA programme, consideration will be given to:

- Raw Material Specifications
  - Do they exist?
  - Are they current?
  - Are they agreed and signed by the supplier?
  - Do they include the hazards of concern (microbiological, chemical, physical)?
  - Is there a written guarantee of continuing supply to the agreed specification?
- Risk Evaluation
  - Do you know which raw materials are a high risk?
  - Are the hazards associated with raw materials included in the HACCP plan (via the hazard analysis)? This will be a gap in companies just starting to implement HACCP.

  - Have you confirmed which ingredients are classed as being sensitive from a food safety perspective and managed through a CCP or some form of preventive control (safety controlled by the supplier)?
- Product Safety Questionnaires (some form of document which questions the suppliers about their programmes)
  - Are they used?
  - Have they been reviewed?
  - Are there instances where potential hazards were missed (e.g. multiple allergens on the site but no action taken)?
  - Have third-party audits been done and are the reports on file?
  - How is the validity of test results assured?
- On-Site Supplier Audits
  - How is the need for an on-site audit determined?
  - Is there evidence that the auditor was suitably knowledgeable and experienced as well as trained and calibrated to do the types of audit being done?
  - Were any corrective actions required and is evidence on file that these were completed?
- Supplier Maintenance
  - Are COAs needed for verification of the food safety programme?
  - Are any microbiological tests ever done on samples of incoming deliveries and would this be useful?
  - Does the supplier inform you of issues?
  - Are all supplies formally approved?

In-Plant PRP Risk Evaluations – Experience has shown the benefit of doing this alongside a PRP gap assessment. It is an area that requires a certain amount of expertise and is often buried amongst all the other information gathered during generalised quality management system audits. Yet, it is *essential* to have this knowledge in order to upgrade or implement an effective food safety programme. The focus of this type of plant assessment is usually microbiological, but consideration should be given to chemical (particularly allergens), and physical hazards. This activity needs to be completed at the plant as the main aims are to:

a) identify the areas where cross-contamination can occur, and
b) identify the harbourage areas or niches where bacteria can get established and grow.

Starting with the layout map of the plant, track the flow of the product, people, and air. Include drains (and flow), garbage removal activities, raw materials, laundry, pallets, anything that comes in, goes out, or moves around the plant. Knowledge of the process and product is extremely important as the evaluation of risk if the product becomes contaminated cannot be done in isolation. However, bear in mind that just because the product does not support the growth of microorganisms, it does not mean that they will not survive. There are many examples of low water activity (dry) and frozen products that have caused foodborne illness. Peanut butter, chocolate, dry pet food, and ice cream unfortunately being good examples (see Chapter 2) of how cross-contamination within a process environment can result in major foodborne illness outbreaks.

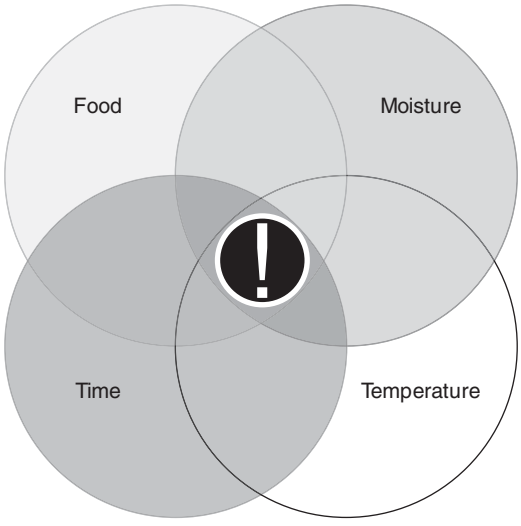

Figure 9.5 Microbial growth requirements. *Source*: Adapted from Kornacki (2009).

At the plant, assumptions made during a review of the layout can be confirmed and a closer look can be taken to identify harbourage and niche areas where a microbial source may be established.

As indicated in Figure 9.5, this comes back to basic microbiology (see also Chapter 4). Anywhere that moisture can get trapped, food (even minute particles transferred via dust) is available, and for a period of time at the right temperature can present a problem, as indicated on the diagram by the exclamation point (**!**).

Once the risk evaluation is completed, a list can be drawn up, corrective actions confirmed, and a timeline established for closing the gaps.

HACCP Programme Gap Assessment – This is only relevant if you are updating an existing programme. Some key areas to look at include:

- Process flow diagram:
  - When was it last validated on the production floor?
  - Is it complete – Does it include all process steps and process interventions?
  - Is it accurate?
- Was hazard analysis carried out at every process step?
  - Does the hazard analysis go into detail or is it at the 'biological hazard' level?
  - Have emerging pathogens been considered where relevant (for example, *Cronobacter sakazakii*)?
  - Do you know that sufficient control measures are in place, e.g. do you need to do a physical hazard control device (metal detectors, sifters, sieves, magnets etc.) audit?
- Is there sufficient data on the intrinsic product safety?
  - Does the current formula match that which was in place when the original product safety assessment was done? (This is a common weakness).
  - Are challenge tests needed?
  - Have mathematical models been used?

- Is the required validation data on file?
  - Literature references
  - Plant data
  - Was the validation sufficient?

These are just a few key questions. With training and experience, the food safety team should be able to compile a detailed list of areas to look at.

Food Fraud Prevention and Food Defence

As discussed in Chapters 8 and 13, food fraud could result in a food safety concern but not necessarily. A gap assessment can identify the degree of concern:

- Has an EMA risk level been assigned to raw material sourcing and likely vulnerability in the supply chain? There are electronic data mining tools now available in some parts of the world, so the team should be aware of those and accessing as needed.
- Has a food defence vulnerability assessment been used to develop a food defence plan?
- Are biosecurity concerns going to cause business disruption?

Management Commitment and Food Safety Culture

The ultimate responsibility for food safety resides with the senior management level in the company. This is why 'management commitment' or 'management responsibility' is increasingly being recognised as a critical success factor for any company's food safety programme, and food safety culture is now included as an optional addition within some of the GFSI benchmarked audit schemes. There are a few things which indicate how well this is implemented, such as whether the company has a food safety and quality policy and whether the roles and responsibilities for food safety are clearly defined in job descriptions. Within the plant itself, the assessment team should be looking for signs of whether short cuts are being taken, also look for evidence when procedures are not being followed and where there is an apparent lack of accountability for enforcement.

Attitudinal assessment is difficult, but the team could consider a discussion around productivity targets versus food safety and quality targets, as well as any employee engagement surveys that are carried out. How are they reviewed and seen as a food safety indicator? Are any external culture assessment tools used? (See also Chapter 15.) Also consider:

- How often are managers seen in the plant and are they interested in food safety when present?
- How much training are employees (supervisors and hourly) given per annum? How is this achieved?
- Is there evidence that any new behaviours are being reinforced (health and safety as well as PRPs are a good indicator)?

Are regular management reviews taking place? The agenda should include the following:

- Audit results (internal or third-party)
- Corrective action status
- Consumer/customer complaint data
- Key performance indicators such as HACCP compliance, sanitation metrics, first time quality, and environmental monitoring events.

Basically, does the management team take all necessary steps to ensure that product is produced under sanitary conditions, that specifications and HACCP standards are known and adhered to, and that adequate resources (trained and knowledgeable) are in place to deliver on commitments?

It is suggested that a gap assessment in this area is done after the world-class food safety programme gap assessment. The reason for this is that the outcomes of the food safety programme gap assessment will be a key indicator of whether there are organisational and cultural gaps that also need to be addressed. The human resources area of the gap analysis should be fairly straightforward, but here is some guidance:

Review organisation charts (include corporate teams where they exist as well as plant locations) and consider individuals on the basis of:

- Educational background - is it appropriate?
- Experience base (number of years, relevance)
- Proven leadership ability:
  - Being action oriented
  - Acting as a change agent (can motivate and lead others)
  - Holding people accountable
  - Being willing to speak up
  - Acting with high integrity

Obtain organisational benchmark data if available – from industry colleagues, suppliers, and customers. Then, collate the data in order to determine whether you have both the sufficient number of people and the appropriate knowledge base in terms of education and experience. Work with human resource colleagues to make recommendations where needed. This could include additional training, staff, and access to external resources.

The provision of other resources gap assessment should include assessment of:

- IT tools availability – are they sufficient for what the team needs to accomplish?
- Membership to external organisations
- How the team accesses new information in order to keep up to date
- How communications are organised
- Availability of posters and signage throughout the sites

Finally, reward and recognition schemes should be assessed as well as corrective and preventative action systems – are gaps being closed in a timely manner?

9.5 Prioritisation of Corrective Actions

Having completed all the required gap assessments, there will almost certainly be a long list of items requiring corrective actions. Whether starting a new programme or upgrading an existing one, the lists are likely to be extensive and it can feel overwhelming unless some prioritisation and planning occurs. Corrective actions should be prioritised on a risk basis. To refer to the start of this chapter, the PDCA cycle can be used to good effect or at least as a starting point (Figure 9.1).

Throughout the process, a communication plan needs to be included to keep the company apprised of progress and involved. Also responsibilities must be assigned to each

corrective action and timelines estimated and adhered to. Gantt charts can be helpful for tracking progress but a simple wall calendar will also work.

Setting timelines for corrective actions will need input and oversight from senior management as well as the food safety team and a risk evaluation of each of the issues identified can be used to assign priorities. The food safety concerns should be rated in terms of likelihood of occurrence versus severity of effect. For example, if in a cooked meats operation one of the issues identified was 'no physical separation of raw and processed product', then the food safety hazard associated with that gap needs to be specified. If procedures exist to manage this. then they need to be taken into account to determine the likelihood of a hazard occurring. A quadrant diagram can be used such as the one shown in Figure 9.6.

Severity of Effect:

Low = Minor injury
Med.= Serious injury or short-term illness, possible hospitalisation
High = Long term illness, chronic effects, or death

Likelihood of Occurrence:

Low = Unlikely to occur but might
Med. = Probably could occur (no history)
High = Highly probable (known history or it will happen at some time)

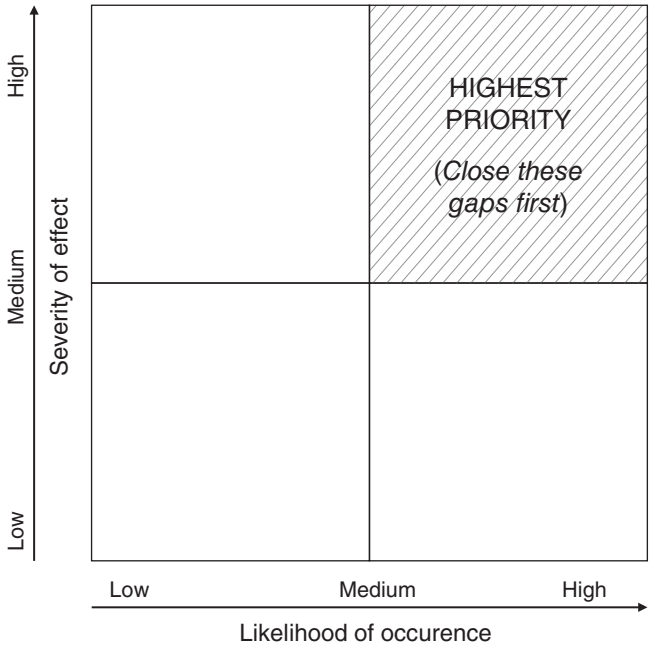

Figure 9.6 Prioritisation quadrant diagram. Adapted from Mortimore and Wallace (1998).

Any gap which is rated as being a HH should result in a closing of the plant until the actions are complete. Anything judged as a HM or a MH would be the next high priority, and the team should ensure that some immediate (short term) management of the identified issue is put in place whilst more permanent solutions are found. Anything with a MM would be next on the list followed by anything with an 'L'. Whilst the lower severity and likelihood issues can be done later, it is still important that they remain visible and on the list. If they are easy and low investment corrections then they should just be closed out.

Other factors to consider when prioritising by risk are the external factors – customer or regulatory obligations. This however should not be the main reason for making improvements.

9.6 Conclusions

A nice schematic to end on and which is adapted from the original (Panisello and Quantick 2001) is shown in Figure 9.7.

(A) is the sustainable model with a firm foundation of internal commitment, supported by training and education with appropriate resources and plant infrastructure and aligned to the external requirements. (B) shows how when the foundation for change is all external, there is instability and potentially the programme is not sustainable – when external priorities change. This knowledge can help build the action plan.

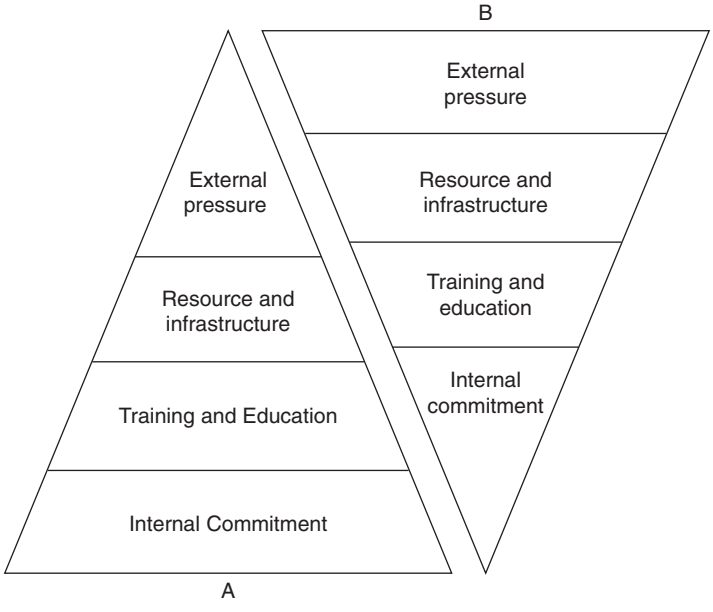

Figure 9.7 Panisello pyramids. Adapted from Panisello and Quanitick (2001).

External stimulus for change is healthy but should not the sole reason for doing it. The real prize is knowing that the right course of action is being taken and the peace of mind that comes with having a mind-set that is continually striving to do better. Also, the cost benefits (through future failure prevention) that come with it.

The final action plan resulting from these preparation activities should be reviewed and approved by senior management to confirm their ownership and support. Managers who have committed to the project will be keen to understand the size of the task and to monitor progress.

10

Formalised Prerequisite Programmes in Practice

10.1 Introduction

Prerequisite programmes (PRPs) provide the hygienic foundations for any food operation. The terms *prerequisite programmes*, *good manufacturing practice*, *good hygienic practice*, and *sanitary operating practices* are used interchangeably in different parts of the world but have the same general meaning. The term *prerequisite programmes* has evolved to be most frequently used for systems in support of HACCP (Wallace and Williams, 2001). Although PRPs are not yet as standardised as HACCP Principles, both in language and practice, the concept of supporting good practices is widely accepted. However, the lack of standardisation has led to different application approaches and practices around the world, and the lack of consistency in terminology within standards and guideline documents helps to promulgate misunderstanding about exactly what is required.

Whilst these differences currently exist with respect to PRP programme expectations, this does enable us to look around the world for best practice. As we further develop global standards and elaborate on detailed requirements needed to meet expectations, we have an opportunity to discuss and share best practices and bring all countries up to the same high level, raising the bar worldwide. Multinationals have accelerated some of this discussion because they increasingly shop around the world for raw materials and products and, increasingly, set up local manufacturing and retail facilities in developing countries.

PRPs are fundamental elements of the world-class food safety programme and have an important role to play in supporting the other fundamental elements. Traditionally thought of as support for HACCP, we can now see how PRPs play a role in food defence, food fraud prevention, and safe food design. They work *alongside* HACCP as a preventive control system. PRPs apply at all stages of the global food supply chain (see Figure 8.2) and thus include good practices for growing, harvesting, manufacturing, storage, distribution, retail, catering/foodservice, and home preparation. Whilst most PRP guidelines focus on the food industry. there is increasing understanding of the importance of the consumer in food hygiene and safety; further guidance on this is given in Chapter 18.

All PRPs are important for food safety assurance, and it is crucial that they are fully implemented in practice and kept up to date with best practice standards. In this chapter the requirements for PRPs as a cornerstone of the food safety management programme

Food Safety for the 21st Century: Managing HACCP and Food Safety Throughout the Global Supply Chain, Second Edition. Carol A. Wallace, William H. Sperber, and Sara E. Mortimore.

will be considered and examples of typical best practice expectations are provided for the formalisation and implementation of specific prerequisites.

10.2 Prerequisite Definitions and Standards

Several groups have suggested definitions for the term *prerequisites*, and the most commonly used are reproduced here.

Prerequisite Programmes:

> *Practices and conditions needed prior to and during the implementation of HACCP and which are essential to food safety* (World Health Organisation [WHO] 1999).
>
> *Universal steps or procedures that control the operating conditions within a food establishment, allowing for environmental conditions that are favourable for the production of safe food* (Canadian Food Inspection Agency [CFIA] 2015).
>
> *Procedures, including GMP, that address operational conditions, providing the foundation for the HACCP System* (National Advisory Committee for Microbiological Criteria for Foods [NACMCF] 1997).
>
> *(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* (International Organisation for Standardisation [ISO] 2015b).

A number of groups have published helpful material on PRPs; however, the internationally accepted requirements for prerequisites are defined in the Codex General Principles of Food Hygiene (Codex 2009a). The prerequisite programmes listed in this document are split down into groupings as follows:

- Primary Production
- Food Chain
  - Establishment: Design and Facilities
  - Control of Operation
  - Establishment: Maintenance and Sanitation
  - Establishment: Personal Hygiene
  - Transportation
  - Product Information and Consumer Awareness
  - Training.

These groupings form the essential areas where PRP elements must be developed, implemented, and maintained to provide environmental conditions that are favourable to the production of safe food and thus the foundations needed for effective HACCP systems.

The intended scope of the Codex guidelines is the provision of a baseline structure for application to the entire food chain. As such, the document offers guidance to governments on the essential elements they should encourage food businesses within

their jurisdiction to apply. For industry, it is intended that the elements of food-hygiene systems described should be applied as minimum standards in order to provide foods that are safe and suitable for consumption, and to maintain confidence in internationally traded food commodities. Other groups have produced PRP guidance at a more detailed level (e.g. IFST, 2013 and International Organisation for Standardisation [ISO] 2009); however. we will focus on the international requirements of Codex (2009a) in this chapter.

10.3 Prerequisite Programmes: The Essentials

Focussing on the headings given in Codex (2009a), the following paragraphs describe the general requirements for PRPs in each area. It should be noted that the Codex guidelines provide only brief, 'top-level' requirements, and so more detailed guidance will be needed to develop robust PRP elements for each area. Specific examples of how this might be achieved are given within the text for four PRP elements: Biosecurity, Cleaning and Sanitation, Pest Management and Allergen Control.

10.3.1 Primary Production

Figure 10.1 shows the four elements required of primary production PRPs. At this stage of the food chain, the intention is that food produced is safe and suitable for its intended use and primary production PRPs are, therefore, based on appropriate hygienic practices; control of contaminants, pests and diseases; and use of production areas where there are no environmental threats to the production of foods.

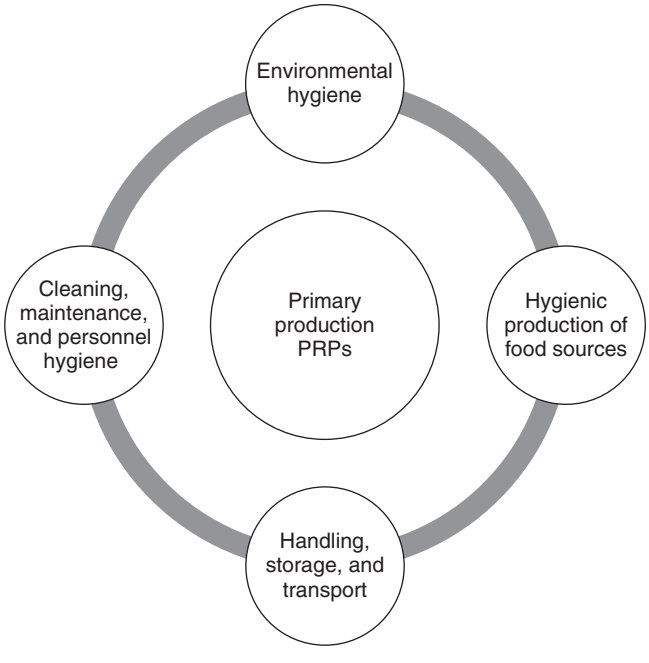

Figure 10.1 Primary production PRPs.

Environmental hygiene requires the consideration of likely contamination sources from the environment and prevention of use of areas that could cause the presence of unacceptable levels of potentially harmful substances in the food produced.

Hygienic production of food sources relates to the need to identify likely sources of contamination and implement controls to minimise the risk of contamination, including biosecurity measures to prevent contamination from air, soil, water, feedstuffs and other agricultural agents (e.g. fertilisers and pesticides); control animal and plant health, thus minimising threats to human health at consumption; protect food from faecal or other contamination; and manage wastes and harmful substances appropriately.

Handling, storage, and transport describes the protection, segregation, and disposal requirements needed to protect foodstuffs, preventing spoilage and deterioration where possible (e.g. through control of temperature, humidity, etc.).

Cleaning, maintenance, and personnel hygiene at primary production refers to the necessity for appropriate procedures and facilities for the maintenance of these essential practices. Although no details of the required standards of cleaning, maintenance, and personnel hygiene for primary production are provided, further useful information is available in the later sections of the Codex (2009a) document relating to secondary processing, and these may also be appropriate for primary production. A specific example of how the prerequisite elements supporting food biosecurity in primary production might be formalised is given in Box 10.1.

Box 10.1 PRP specific example: Biosecurity measures for poultry in primary production

Guidelines for maintaining poultry biosecurity (DEFRA 2017; USDA, 2011)

A) **General biosecurity measures for poultry growers (USDA, 2011):**

- *Keep your distance:* Restrict access to your property and birds at all times, separate clean and dirty areas with fences, and permit only bird caretakers to come into contact with birds.
- *Keep it clean:* Wear clean clothes and shoes, wash hands before entering bird areas. Provide clean food and water, remove manure and dead birds, and disinfect bird cages and implements that contact their droppings.
- *Don't bring disease home:* Cars, trucks, tires, cages and equipment can carry pathogens from areas with infected birds. New birds should be held separately from the flock for 30 days, as they may be infected. Do not mix species or birds from different sources.
- *Don't borrow disease from your neighbour:* Disinfect borrowed equipment before using. Do not use cardboard egg cartons or wooden pallets; their porous surface makes it impossible to keep them clean.
- *Know the warning signs of infectious bird disease:* Although it may be difficult, early detection of bird disease is crucial to prevent its spread. Look for sudden death, diarrhoea, reduced egg production, sneezing and coughing, lack of energy, swelling of tissue around the eyes, swollen heads, drooping wings, and incoordination or paralysis.
- *Report sick birds:* Call local veterinarians, agricultural extension agents, or the USDA Veterinary Services office.

B) **Specific requirements to be followed in Avian Influenza High Risk Areas**
Normally specific requirements would be announced in particular geographical zones during times of threat. This example is from the United Kingdom where, in 2016–2017, the Chief Veterinary Officer of England declared a Prevention Free Zone to prevent the spread of H5N8 from wild birds in central and northern Europe, where it was detected in November 2016. The following requirements were published and communicated to poultry keepers throughout England (DEFRA, 2017).

Minimum biosecurity requirements:

All keepers of poultry and other captive birds (irrespective of the number of birds or how they are kept) must adopt these biosecurity measures at all times.

Minimum biosecurity measures include:

- Reducing the movement of people, vehicles or equipment to and from areas where poultry are kept;
- Taking all reasonable precautions to avoid the transfer of contamination between premises, including cleansing and disinfection of equipment, vehicles, and footwear;
- Keeping domestic ducks and geese separated from other species (for example by keeping them in separate runs or sheds);
- Ensuring feed, water. and bedding has not been contaminated by or been in contact with wild birds and in particular gulls and waterfowl;
- Implementing effective vermin control where poultry or captive birds are kept;
- Records must be kept of all vehicles and people that enter the part of a premises where poultry are kept;
- Placing foot dips and boot brush containing a DEFRA-approved general poultry order disinfectant at the entry and exit of all houses and outdoor areas/range where birds are kept.

Requirement to report disease:

Any significant change in bird health (including increased mortality, decreased egg yield or growth rates, or changes in feed or water intake) should be discussed with a private veterinarian and if suspicion of avian influenza cannot be ruled out then it must be reported to DEFRA/APHA.

Additional biosecurity requirements:

All poultry keepers with 500 birds or more: The following measures must be implemented by all poultry keepers with more than 500 birds, although it is highly recommended that all poultry and captive bird keepers implement these measures where practicable.

The premises should be organised to minimise access to live birds by identifying and managing three discrete areas on the holding as outlined:

Poultry (live bird) area

- Access is limited to essential authorised personnel only;
- Full biosecurity practices must be adopted on entry and exit to the zone;

(Continued)

Box 10.1 (Continued)

- Keepers must operate effective barrier hygiene before entering a poultry house or the range (for example, coveralls and dedicated house boots);
- Only essential equipment and vehicles are permitted to be taken into the zone;
- The exterior of any vehicles (focussing on wheels and wheel arches) and equipment which enter or leave the area must be cleansed and disinfected on both entry and exit;
- Where possible use dedicated equipment/vehicles that only operate in this area;
- Thorough cleansing and disinfecting (based on industry best practice) of housing and equipment must be undertaken at the end of a production cycle and before new birds are introduced;
- Records must be kept of vehicles and personnel entering and leaving this discrete area.

Private (ancillary use) area

- Access is limited to essential personnel only and full biosecurity practices must be adopted on entry and exit to the area;
- This must be fully separated from the live bird area with a clear demarcation;
- Bedding and feed (if not stored in the live bird areas), must be stored in this area;
- The exterior of any vehicles (focussing on wheels and wheel arches) which enters or leaves the zone must be cleansed and disinfected on both entry and exit;

Restricted access (biosecure barrier) area

- Access to the public should be limited and only essential workers/contractors may enter this area subject to effective personal biosecurity;
- This area may include the farm office and areas of the premises used for general storage;
- Non-essential vehicles should not enter this zone.

Source: DEFRA 2017; USDA 2011.

10.3.2 Establishment: Design and Facilities

The first section on secondary processing is Establishment: Design and facilities and this has four main areas of prerequisite programme elements (Codex 2009a) as illustrated in Figure 10.2.

The *location* of food premises is important and care should be taken to identify and consider the risks of potential sources of contamination in the surrounding environment. In particular, environmentally polluted areas, areas of heavy industry which could pose contamination risks, areas prone to pest infestation, areas subject to flooding or where waste cannot be removed effectively should be avoided when planning food production facilities. Sporadic and seasonal contamination sources must also be considered, especially those related to air quality. For example, if there is a monthly cattle market, or annual county fair in the vicinity, an impact as a result of changes in weather conditions or agricultural activity. Suitable controls to anticipate and prevent contamination should be developed and implemented.

The design and layout of the *premises and rooms* should permit good hygiene and protect the products from cross-contamination during operation. Internal structures and equipment should be built of materials able to be easily cleaned, disinfected and

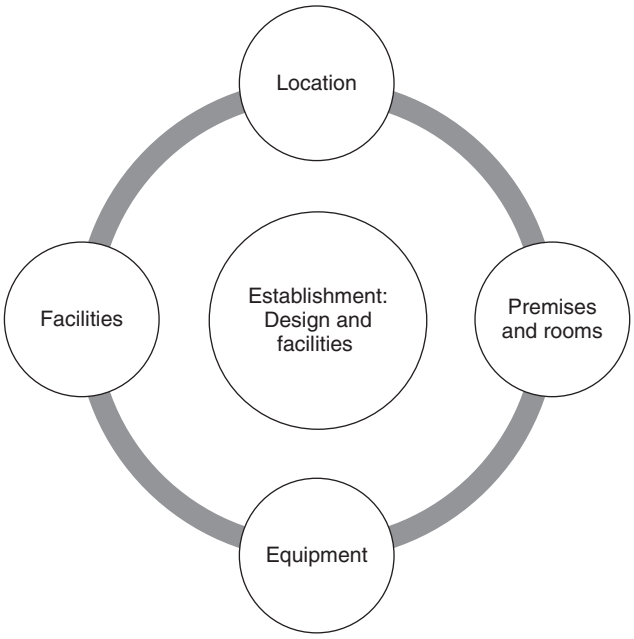

Figure 10.2 Establishment: Design and facilities – necessary prerequisite elements.

maintained. Surfaces should be smooth and non-pervious and able to withstand the normal conditions of the operation (e.g. withstand the normal moisture and temperature ranges and detergents/disinfectants in use) and be inert to the food being produced. Whilst this applies particularly to the direct food contact surfaces, other surfaces within the food processing area (i.e. walls, floors, partitions, ceilings and overhead fixtures, windows and doors) should similarly be designed to minimise the build-up of dirt, condensation, etc., and the shedding of particles or contaminants that might gain access to food products. Opinions vary globally as to the benefits of having false ceilings over production areas, just one example of the differing approaches to PRPs. They can be very effective in preventing ingress of foreign materials from dirty overhead pipes, wires, duct work, etc., but must be cleanable and the roof void must be managed to avoid it becoming a harbourage area for pests and debris. Similar standards should be applied to the design, construction, and siting of temporary/mobile premises and food-vending machines.

Equipment that will come into contact with food should be designed and constructed to facilitate cleaning and disinfection, including disassembly where necessary, and be made of materials which will have no toxic effects under the intended use. Food control and monitoring equipment should be suitable for the necessary use, for example, able to attain and maintain the required food temperatures to eradicate microorganisms and their toxins or reduce to safe levels or to monitor critical limits at critical control points (CCPs). Containers for by-products, waste, inedible and dangerous substances must be constructed to protect food from contamination and should be specifically identifiable, including appropriate security considerations (e.g. lockable) to prevent accidental discharge or malicious contamination.

Facilities should be provided to include adequate potable water supplies, suitable drainage and waste disposal, appropriate cleaning facilities, storage areas, lighting, ventilation, and temperature control. Suitable facilities should also be provided to promote personal hygiene for the workforce, including well-designed changing areas, lavatories, and hand-washing and drying facilities. All these facilities should be designed to minimise likelihood of product contamination, for example, protection of light fittings to retain any breakages and design of ventilation systems to prevent air flow from contaminated to clean areas.

10.3.3 Control of Operation

The rationale for operational control listed in Codex (2009a) is 'to reduce the risk of unsafe food by taking preventive measures to assure the safety and suitability of food at an appropriate stage in the operation by controlling food hazards'. This includes the need to control potential food hazards using a system such as HACCP. The required prerequisite elements for control of the operation are outlined in Figure 10.3.

Control of food hazards (Codex 2009a) requires the use of a system such as HACCP throughout the food chain to identify any steps in food operations which are critical to food safety; implement effective control procedures at those steps; monitor control

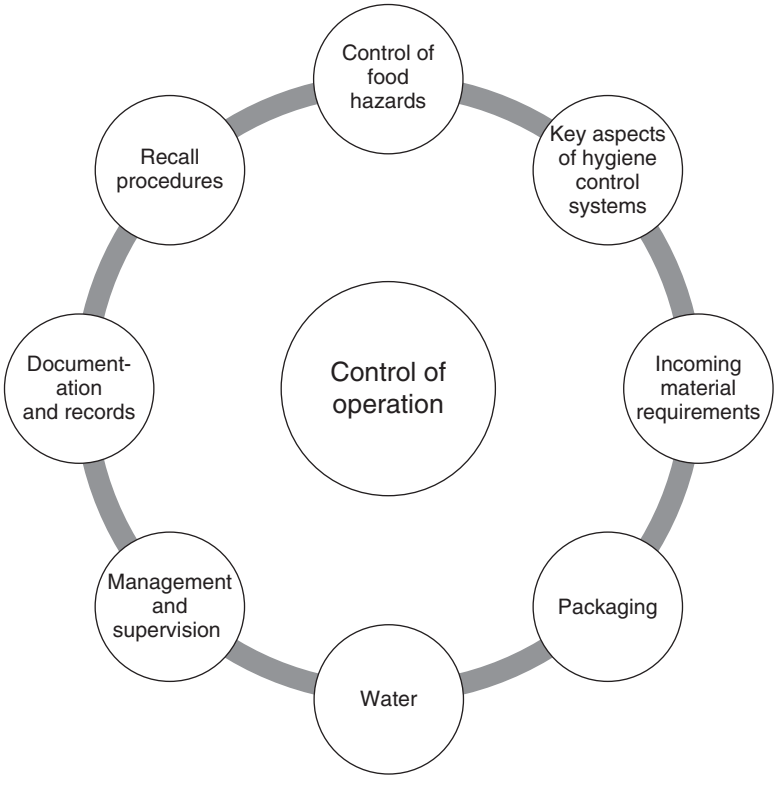

Figure 10.3 Control of operation – necessary prerequisite elements.

procedures to ensure their continuing effectiveness; and review control procedures periodically, and whenever the operations change. These requirements clearly signpost the need for application of the HACCP Principles to develop effective control plans (HACCP plans) for significant food safety hazards, as will be discussed in detail in Chapters 12 and 14. However, the obligation to enable control of food hygiene and safety throughout the shelf life of the product through proper product and process design is also acknowledged here.

Codex also describes *Key Aspects of Hygiene Control Systems*, including:

- Time and temperature control to prevent common causes of foodborne illness
- Use of specific process steps that can contribute to food hygiene (e.g. chilling or modified atmosphere packaging)
- Microbiological and other specifications based on sound scientific principles
- Management techniques to control microbiological cross-contamination risks (e.g. segregation of processes/parts of processes and restricted access procedures)
- Physical and chemical contamination prevention, including the use of suitable detection or screening devices where necessary.

Although not mentioned specifically in Codex (2009a), the requirements to prevent cross-contamination with allergenic materials on site should be considered as key aspects of the control system for chemical contamination. The best way of controlling allergens as with any food safety hazard is to design them out. However, this is not always reasonable so allergens must be controlled through:

- Avoidance of cross-contamination – where the risk comes from allergens which are inadvertently present and consequently not included on the label.
- Labelling – which can be used to manage allergens that are intentionally added to the formulation

Effective allergen management requires an integrated approach. Each stage of the product lifecycle should be considered, that is,

- **During product design**
  - Is the allergen required for functionality and would a nonallergenic alternative be available?
  - Is the allergen already in use in the plant?
  - Is the allergen already in use on the same process line?
- **Hidden sources – understanding supplier control programmes**
  - What allergens are used in the supplier's plant?
  - Has the supplier programme been verified during an on-site visit?
  - Can you be sure that the supplier will notify you if and when a new allergen is introduced to the plant?
- **During manufacture**, formalised allergen control programmes will be developed by conducting an allergen risk evaluation. This is the basis for the sequencing schedules and rework procedures which are used to prevent cross-contamination. Elements of this include:
  - Listing all allergenic materials which are on site. Accurate and detailed raw material specifications are needed to be able to identify hidden allergens within compound raw materials.

  - Listing all product manufactured together with the allergenic raw materials that go into them. This is commonly done as a matrix of products and ingredients.
  - Develop an allergen process flow diagram or use the HACCP documents. This, combined with a map of the plant, is used to document where allergenic materials are situated and where they could get added into the process.
- **Transportation and labelling**, includes the requirements to protect food from cross-contamination during transit and the need to ensure that all allergens are clearly and accurately labelled on the package. This is governed by legislation for specific allergens in some countries. For example, at the time of writing, in the European Commission there is a list of 14 allergen groups that must be labelled (Box 10.2) according to EU Regulation 1169/2011, Annex II.

Box 10.2 PRP-specific example of allergen labelling legal requirements

EC Allergen Labelling Requirements: Substances causing allergies or intolerances which must be labelled.

1) Cereals containing gluten, namely: wheat, rye, barley, oats, spelt, kamut or their hybridised strains, and products thereof, except:
   a) wheat-based glucose syrups including dextrose;
   b) wheat based maltodextrins;
   c) glucose syrups based on barley;
   d) cereals used for making alcoholic distillates including ethyl alcohol of agricultural origin;
2) Crustaceans and products thereof;
3) Eggs and products thereof;
4) Fish and products thereof, except:
   a) fish gelatine used as carrier for vitamin or carotenoid preparations;
   b) fish gelatine or Isinglass used as fining agent in beer and wine;
5) Peanuts and products thereof;
6) Soybeans and products thereof, except:
   a) fully refined soybean oil and fat;
   b) natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, and natural D-alpha tocopherol succinate from soybean sources;
   c) vegetable oils derived phytosterols and phytosterol esters from soybean sources;
   d) plant stanol ester produced from vegetable oil sterols from soybean sources;
7) Milk and products thereof (including lactose), except:
   a) whey used for making alcoholic distillates including ethyl alcohol of agricultural origin;
   b) lactitol;
8) Nuts, namely: almonds (*Amygdalus communis L.*), hazelnuts (*Corylus avellana*), walnuts (*Juglans regia*), cashews (*Anacardium occidentale*), pecan nuts (*Carya illinoinensis (Wangenh.) K. Koch*), Brazil nuts (*Bertholletia excelsa*), pistachio nuts (*Pistacia vera*), macadamia or Queensland nuts (*Macadamia ternifolia*), and products thereof, except

for nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin;
9) Celery and products thereof;
10) Mustard and products thereof;
11) Sesame seeds and products thereof;
12) Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/L in terms of the total SO_2 which are to be calculated for products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers;
13) Lupin and products thereof;
14) Molluscs and products thereof.

Source: European Parliament (2011), Regulation 1169/2011 Annex II.

Incoming material requirements and systems to ensure the safety of materials and ingredients at the start of processing are necessary to protect the operation and its products. This prerequisite element covers the need for appropriate specifications and acceptance procedures to prevent the acceptance of hazardous raw materials and ingredients that would not be controlled by the process, including the use of appropriate inspection and sorting procedures along with effective stock rotation.

Although only brief details are provided by Codex (2009a), these points underline the importance of effective supplier assurance programmes to control the safety of incoming goods. In practice, this will require the development of a detailed programme, including:

- Raw material hazard analysis and prioritisation (tying in with HACCP; see Chapter 12)
- Consideration of necessary human resources to manage supplier assurance and provision of adequate training
- Assessment of suppliers (e.g. via desktop assessment, on-site audit, or use of third-party audit)
- Ongoing evaluation of supplier performance and materials acceptability
- Use of approved supplier databases and integration with business ordering and materials acceptance procedures.
- Control and maintenance of documentation (e.g. specifications, presupply surveys, and questionnaires, conditions of supply, audit checklists, supplier performance data, etc.)

Suitable packaging design to provide the necessary protection to the product during its shelf life is also highlighted by Codex (2009a). This embraces the need to ensure that the chosen packaging system is itself safe and will not pose a threat to the food product, plus the requirement to ensure hygienic conditions of reusable packaging (e.g. refillable glass bottles).

Codex also lists the importance of hygienic control of *water*, in particular the use of potable water where water is a food ingredient and for all food handling and processing operations, with the exception of specific food processes where nonpotable water would not cause a contamination hazard to the food (e.g. using clean sea water for chilling in

some operations). The need to treat and monitor any water being recirculated for reuse is also described, as is the requirement to make ice only from potable water, and to assure the safety and suitability of steam for direct food contact. It is sometimes necessary to install in-plant water treatment systems such as in-plant chlorination systems to ensure a supply of potable water.

Appropriate *management and supervision*, reflecting the size of the operation and nature of its activities and processes is also highlighted, with the need to ensure personnel have enough knowledge of food hygiene principles to be able to form a judgement on likely risks and take necessary actions. The need to keep adequate *documentation and records* and to maintain these records for a period exceeding the shelf-life is also highlighted.

The development and testing of suitable incident management and *recall procedures* so that product can be withdrawn and recalled in the event of a food safety problem is highlighted. This includes the need for traceability and effective communication to enable efficient and effective product withdrawals, public warnings, and secure control of recalled products until destruction or other suitable disposition, i.e. not used for human consumption unless determined suitable or adequately reprocessed for safety.

10.3.4 Establishment: Maintenance and Sanitation

As shown in Figure 10.4, 'Establishment: Maintenance and Sanitation' is a broad-ranging prerequisite grouping, which includes the elements of cleaning and disinfection/sanitation, pest management, and waste management, plus the need to monitor the effectiveness of these elements in all cases.

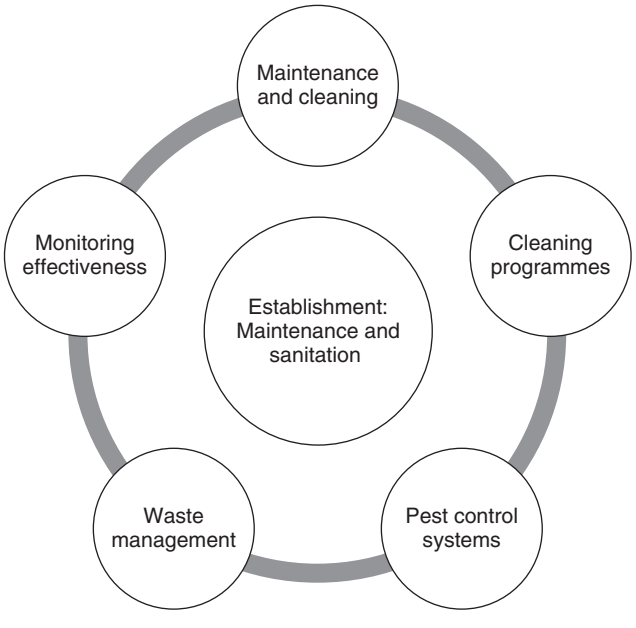

Figure 10.4 Establishment: Maintenance and sanitation – prerequisite requirements.

Maintenance and cleaning are both important to keep the processing environment, facilities, and equipment in a good state of repair where it can both function as intended and prevent cross-contamination with foreign material, food residues, and microorganisms that might otherwise build up. Facilities should operate preventative maintenance programmes as well as attending to breakdowns and faults without delay. Cleaning can be performed by the use of separate of combined physical methods, and will normally involve:

- Removing gross debris
- Applying detergent solution(s)
- Rinsing with potable water
- Disinfection/sanitation as necessary.

Dry cleaning or other appropriate methods may be used as appropriate to the specific situation, and all chemicals used should be handled and stored carefully, to prevent contamination of food products.

Cleaning programmes should be developed to encompass all equipment and facilities as well as general environmental cleaning, and this may require specialist expert advice. Cleaning methods need to be developed that are suitable for the item to be cleaned and should describe both the method and frequency of cleaning specific areas and items of equipment, and the responsibility for the tasks. Records of cleaning and monitoring should be kept.

A specific example of how the cleaning and disinfection/sanitation prerequisite elements might be formalised within a food business is given in Box 10.3.

Box 10.3 PRP-specific example: Cleaning

A formalised cleaning and sanitation programme is one which is risk based, is documented and is validated as being effective and routinely verified. What might each of these elements look like when properly implemented?

A) **Sanitary Design**
The facility and equipment will be designed and managed in a manner which enables them to:
   a) 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, dislodging of foreign materials (e.g. paint), development of condensation, mould or pathogenic bacteria, and avoidance of niche areas that are difficult to clean.
   b) Avoid cross-contamination of products through the ability to control employee traffic patterns, materials, and air flow. When a food business has both raw and cooked ready to eat microbiologically sensitive products on site this is critical.
   c) 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.
   d) Manage utilities to ensure they are not a source of cross-contamination (e.g. water and air supplies).

(Continued)

Box 10.3 (Continued)

B) **Risk Evaluation**
This is an evaluation of why to clean (the type of soil), what to clean, how to clean it and how often. Considerations will include potential microbiological risks (i.e. pathogenic and spoilage microorganisms) and potential chemical risks (i.e. allergens, pesticides, cleaning chemicals such as cyanuric acid in chlorine based manual cleaners) and additives; this last example being of particular concern in the feed industry where variability in species intolerance is a major hazard.
A documented evaluation should be done for each area of the plant, and each piece of equipment in the process.

C) **Determination of Appropriate Cleaning Methods**
Determination of the cleaning method is usually done together with the external sanitation services provider. Wet cleaning using chemical cleaners and sanitisers are usual for microbiological and allergen hazards. However dry cleaning has some significant benefits in terms of reducing the amount of water available to microorganisms and is increasingly recognised as a being a better option in certain circumstances. It is generally easier to prevent environmental micro growth in dry rather than wet conditions. If dry cleaning is used, a sanitiser (in countries where it is permitted) or alcohol wipe could follow 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 programme.

D) **Sanitation Schedules and Cleaning Procedures**
A Master Sanitation Schedule (MSS) will be in place for all areas outside the regular equipment and process area cleaning. It will include for example overheads and light fixtures, external perimeter, coolers and freezers. This could also be incorporated into one comprehensive schedule designed to indicate tasks which are daily, weekly, monthly, quarterly or annual. The cleaning procedures will state:
- The equipment/area to be cleaned.
- The frequency of cleaning.
- How it is to be cleaned
  - Via detailed work instructions or 'one-point' lesson plans
- The time (duration) allowed for the task
- Materials to be used, for example,
  - Chemicals
  - Tools
- Chemical concentration and contact times
  - Including any routine strength testing (e.g. with titration)
- Health and safety requirements, for example,
  - Safety glasses
  - Protective clothing
- Expected outcome, for example,
  - Visual standards
  - ATP

- Corrective action in the event of a problem, for example,
  - Actions required (e.g. re-clean)
  - Who to call
- Record requirements
  - Operator sign off
  - Reviewer sign off
- Verification/Preoperational inspections
  - Who is responsible
  - Method
  - Corrective actions

E) **Drain and Janitorial Cleaning**

A separate programme will be in place with similar procedures to those described above. It will include requirements for a current schematic of drains (with an indication of flow direction), dedicated colour-coded equipment (black is usually used for this purpose). The plant will recognise that this is a *major* cross-contamination risk if not properly controlled.

F) **Cleaning in Place (CIP) Programmes**

A plant operating a CIP system will usually have a separate documented programme. It will include:

- 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, no dead ends)
- Validation records

G) **Sanitation Equipment and Chemicals**

Tools and Equipment:

The plant will have a programme in place to ensure the integrity of its cleaning tools such that they are not a source of contamination.

- Stored clean and dry
- Be on a regular cleaning schedule
- Have designated containers
- Never use sanitation equipment for process operations (e.g. sanitation sinks for produce washing or former sanitation chemical buckets for work in progress food storage).

The design of sanitation tools is important. Products of an absorbent nature should be avoided as should designs that could be foreign material hazards. Avoid:

- Reusable cloths
- Reusable mops
- Wire bristle brushes (unless unavoidable and then should be controlled)
- Tools with wooden handles
- Abrasive scrub pads (can be single use and control issue)

(Continued)

Box 10.3 (Continued)

Chemicals:

- All chemicals used will be suitable for food use and approved by the appropriate authorities
- A Material Safety Data Sheet (MSDS) will be on file along with a supplier continuing guarantee (sometimes called a hazard data sheet).
- All chemicals will be properly labelled and *never* decanted into food containers.
- Chemicals will be stored securely and in accordance with the manufacturer's recommendations.

H) **Validation**

Validation of PRP programmes is the same as for HACCP. It is required to establish that the programmes will be effective. In a formal programme evidence of this will be documented. Many companies work with their sanitation provider on this area. Validation data will include:

a) Evidence that the chemicals and procedures are suitable for the tasks being carried out.
b) Evidence that the chemicals will be effective against pathogens of concern.
c) Evidence of suitability for food industry use.

I) **Verification** (including monitoring)

A number of monitoring and record review activities will be routinely carried out via the day-to-day measurements. This could include:

a) Wet Cleaning: Cleaner/Sanitiser concentrations
   - ATP swabs
   - Visual preoperational inspections (also post-cleaning if there is a time delay)
   - Microbiological or allergen residue checks of rinse water.

b) Dry Cleaning:
   - Usually entails preoperational visual inspections

c) CIP Cleaning:
   - Cleaner/Sanitiser concentration
   - Wash temperature
   - Wash contact time

   For COP (out of place cleaning), it might also be appropriate plus postcleaning ATP and visual inspection followed by a preoperational visual inspection.

d) Environmental Surveillance Programmes

   Microbiological surveillance programmes are an essential verification activity and all but very low risk operations will have them. The programme will have a risk-based sampling plan which takes account of the facility history, plant layout, product risk and includes identified sampling sites, frequencies, targeted microorganisms (often indicator organisms plus *Salmonella* and *Listeria* species), frequency, and method of testing. Testing of first product off the line after cleaning is sometimes done and this may include production being placed on HOLD status pending results.

e) Audit/Assessment
Regulator hygiene audits will form part of the verification programme. In a good programme this is supplemented by an in depth sanitation assessment occurring at least annually. It will include procedures and records review plus a considerable amount of time in the plant inspecting equipment (including tear down of, for example, pumps and gaskets), observation of the actual cleaning activities at whatever time of day, and environmental monitoring via swabbing. A review of the efficiency of the programme will occur as part of the annual assessment or separately and will include sanitation costs (chemicals/labour) and down time (planned or due to needed corrective actions).

J) **Training**
Left until last, but training is an essential factor for an effective programme. Verification activities should provide some useful indicators for ongoing training needs. Like any programme there will be training activities at a number of levels:
Sanitation Manager:
This is sometimes the quality or production manager's responsibility. Whoever has the responsibility for the programme will need a fairly in-depth level of training. They need sufficient knowledge of the types of soil and chemicals, 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.
Operators:
Hygiene and work instruction training
CIP Operators:
Require a higher level of training than other operators particularly on operation of the specific CIP programme.
All training will be validated through knowledge testing and documented.

Pest control systems are important to prevent the access of pests that might cause contamination to the product and good hygienic practices are necessary to prevent the creation of an environment conducive to pest infestation. Pest management is often contracted out to a professional pest control contractor. Buildings need to be made pest-proof and regularly inspected for potential ingress points. This will include sealing of holes, drains, and so on to prevent pest access and suitable screening (e.g. wire mesh on any opening windows, vents, and doors).

Interior and exterior areas need to be kept clean and tidy to minimise potential food and harbourage sources. All potential food sources (including refuse) should be kept in suitable containers off the ground and away from walls. Suitable interior traps and monitoring devices should also be considered and any pest infestations need to be dealt with promptly, without adversely affecting food safety. Regular monitoring and inspection should be performed to investigate for evidence of infestation and appropriate action taken where necessary.

Box 10.4 shows a specific example of how the pest control and management prerequisite elements might be formalised within a food business.

Box 10.4 PRP-specific example: Pest Management

A well implemented pest management programme will focus around two key objectives:

- Exclusion
- Elimination

Emphasis should be on the preventative approach (i.e. exclusion from entering the facility). As with sanitation, the programme will be based on a *risk evaluation*. Consideration will be given to the surrounding environment, likely ingress, 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.

A) Pest Control Procedures

Pest control procedures will be documented in a formal pest management plan. Practices (including those aimed at prevention) will match what the plant sees as requirements (e.g. keeping external vegetation short, managing the 'grave yard' of redundant equipment and pallets, spillages being cleaned up immediately). For most, the programme will involve the engagement of a pest control operator, a copy of his licence should be kept on file with the procedures, along with a copy of the contract and insurance details.

The preventative measures will include:

- Proofing of entrances and access points
- Insect screens
- Electronic insect killing devices
- Well maintained dry ingredients storage (sealed, no spillage)
- Controlled use of pesticides
- Use of traps

The facility will have a schematic of the premises with all the pest control devices clearly marked.

Pest Control Chemicals

Pest control chemicals will be stored securely and clearly labelled. A MSDS will be on file confirming suitability for food premises.

Bird Control

The plant will be designed to minimise bird activity through building construction, removal of food sources (garbage areas can be a problem if not well managed), and regular removal of roosting and nesting sites (drains and gutters will be fitted with screens and traps), doors will be fitted with air or strip curtains and kept closed, use of predator bird calls is often effective.

Rodent Control

- Bait stations will be tamper resistant, secured to the location and locked. Poison bait will be solid not granular and only used in areas external to the plant – bringing poison into food processing areas is not recommended.
- Mechanical traps will be used in areas around entryways and regularly maintained.
- Internal traps are placed around the walls according to risk (i.e. areas of frequent catches might require a higher number of traps). Usually they will be about 25 feet apart. All traps and bait stations will be numbered and cross marked on the plant schematic. Rodent activity will be marked to enable identification of hot spots. For monitoring purposes, nontoxic bait stations may be used which enables targeted and minimal use of poison.

All traps and bait stations will be regularly monitored, weekly for internal and external traps, monthly for external bait stations as a minimum.

Insect Control

- Screens will be in place if doors and windows are used for ventilation but this is discouraged. A well-designed facility will have positive air pressure in process areas where food is exposed. Air curtains are not effective for insects and should not be relied upon as a control device.
- Electric insect killers (EIKs) should be located outside of 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. The purpose of an EIK is to attract insects and that should always be remembered. 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 will be set up by a trained operator. Review of catch data should be included in the programme as previous.
- All EIKs and pheromone traps should be numbered and located on the schematic diagram.
- Any pesticides used on site should be recorded by name, percentage of active ingredient, target organism, method and rate of application, area treated, license number and name of applicator, date, and signature.
- The effectiveness of the pest control programme will be routinely (at least annually) reviewed and adjustments made.

Waste management should ensure that waste materials can be removed and stored safely so that they do not provide a cross-contamination risk or become a food or harbourage source for pests. In particular, waste must not be allowed to accumulate in food handling and storage areas and the adjoining environment and waste areas must be kept clean.

There is a need to *monitor effectiveness* of all maintenance and sanitation systems, and their effectiveness should be verified and reviewed periodically, with changes made to reflect operational changes. Audit, inspection, and other tools such as microbiological environmental sampling can be used to facilitate verification of these prerequisite elements.

10.3.5 Establishment: Personal Hygiene

The objectives for personal hygiene stated in Codex (2009a) 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.

Food companies should, therefore, have standards and procedures in place to define the requirements for personal hygiene and staff responsibility, and staff should be appropriately trained. Figure 10.5 shows the prerequisite elements for personal hygiene.

Establishment of *health status* is important where individuals may be carrying disease that can be transmitted through food. Anyone known or suspected to be carrying such a disease should not be permitted in food handling areas. Food handling personnel should be trained to report illness or symptoms to management and medical examinations should be done where necessary.

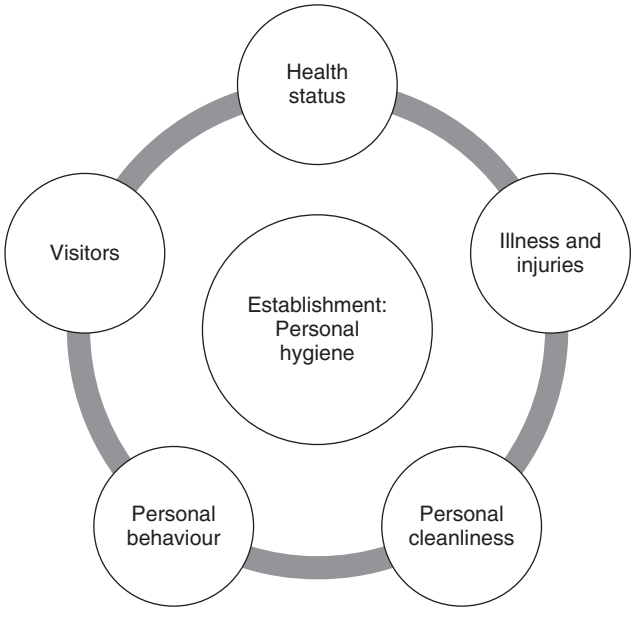

Figure 10.5 Establishment: Personal hygiene – prerequisite requirements.

Consideration of *illness and injuries* that may require affected staff members to be excluded or wear appropriate dressings should also be done. Codex (2009a) lists the following conditions that should be reported so that any need for medical examination or exclusion can be considered:

- Jaundice
- Diarrhoea
- Vomiting
- Fever or sore throat with fever
- Visibly infected skin lesions (boils, cuts, etc.)
- Discharges from the ear, eye or nose.

The need for good *personal cleanliness*, including effective hand-washing and wearing of adequate protective clothing and footwear is also highlighted. Similarly, the prevention of inappropriate *personal behaviour* such as smoking, vaping, eating, or chewing in food handling areas should be enforced and personal effects (e.g. jewellery, non-company cell phones, watches, etc.) should be prohibited in food handling areas. *Visitors* to processing and product handling areas should be adequately supervised and required to follow the same standards of personal hygiene as employees.

10.3.6 Transportation

To ensure continuation of food safety throughout transportation, transport facilities need to be designed and managed to protect food products from potential contamination and damage, and to prevent the growth of pathogens.

As illustrated in Figure 10.6, this includes *general* requirements on the need for protection of food during transit, plus further *requirements* for the design of containers and conveyances to facilitate this protection. This means construction so that the containers or conveyances do not contaminate the foods; permit effective segregation of different foods or foods from non-foods; protect foods from other contamination, such as from dust or fumes; and can be effectively cleaned and disinfected/sanitised.

Use and maintenance requirements for vehicles and containers include appropriate standards of cleanliness and cleaning and disinfection between loads as appropriate. Containers should be both marked, and used for, 'food use only' where appropriate and temperature control and monitoring devices should be used where necessary.

10.3.7 Product Information and Consumer Awareness

Product information is important both for following links in the food chain and for the final food preparer and consumer. Insufficient information or inadequate knowledge can lead to products being mishandled and, ultimately, to both foodborne illness and product wastage. Figure 10.7 illustrates the four essential prerequisite elements needed in this area: lot identification, product information, labelling, and consumer education.

It is important that sufficient *lot identification* information is easily identifiable on the products so that the lot or batch can be identified for recall purposes, the product can be handled correctly (e.g. stored at <5° C) and that stock rotation is facilitated.

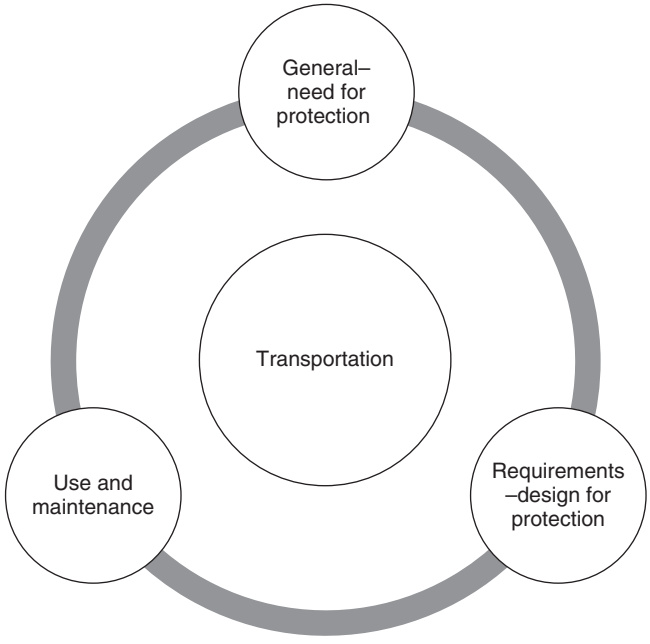

Figure 10.6 Transportation –– prerequisite requirements.

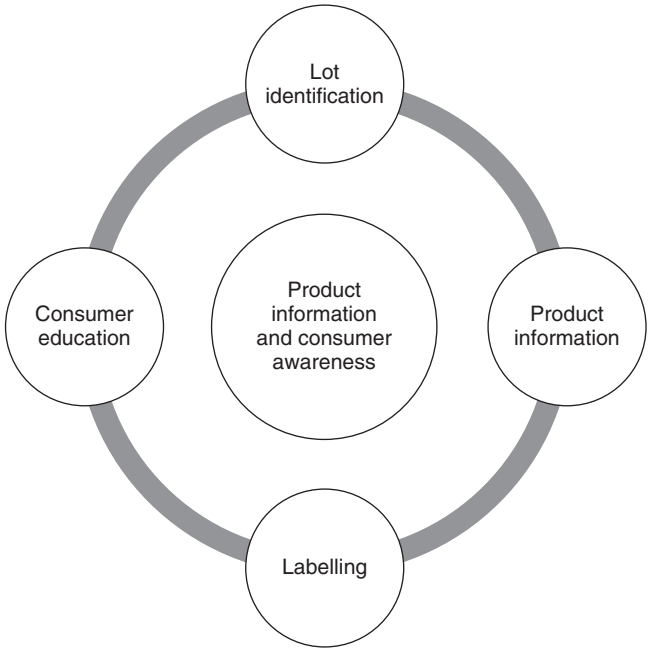

Figure 10.7 Product information and consumer awareness.

This will include permanent marking to identify the producer and the lot. Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985) applies here.

Product information and *labelling* should be clear and sufficient such that it facilitates the correct handling, storage, preparation, and use of the food by the next person in the food chain. This might include considerations both for the control of microbiological hazards (e.g. use of temperature control) and for the provision of information about potential allergens, such as might be required by local legislation (see example in Box 10.2). For example, for allergen information, considerations may include:

- Use of simple and straightforward language so as to provide the essential information without confusing consumers.
- Use of precautionary labelling (e.g. 'may contain' certain allergens in some cases). This is not a preferred option but is sometimes used where there is a risk that cross-contamination may occur which cannot be adequately contained.
- Copy approval for packaging and artwork early in the development process to ensure satisfactory information is accurately listed.
- Use of bar code scanners during production to monitor whether correct packaging is being used. This is particularly useful in allergen management as a more effective alternative to periodic visual checks of packaging during production.
- Understanding of the label production process at the packaging manufacturers to assess likelihood of mix up during printing.

Codex (2009a) also highlights the importance of *consumer education*, particularly the importance of following handling instructions and the link between time and temperature and foodborne illness.

10.3.8 Training

The final prerequisite element described by Codex (2009a) is training, which is highlighted as 'fundamentally important to any food-hygiene system', since inadequate training, instruction, and/or supervision can pose threats to food safety. In fact training is an overarching requirement that impacts the success of all PRPs, the HACCP system and management requirements as well as the operation of day-to-day business procedures, and lack of or inadequate training has been implicated in food incidents (Chapter 2). Figure 10.8 shows the four essential elements of training for food hygiene described by Codex (2009a).

Food-hygiene training is essential to promote *awareness* in food handling personnel of their roles and *responsibilities* for food control. Food handlers need the knowledge and skills to handle food hygienically and personnel need an appreciation of the requirement to protect food from contamination (e.g. when handling cleaning or pest control chemicals).

Companies should develop and implement appropriate *training programmes* including a training needs assessment such that adequate training is developed and implemented. Training is likely to include details on the type(s) of food handled and produced

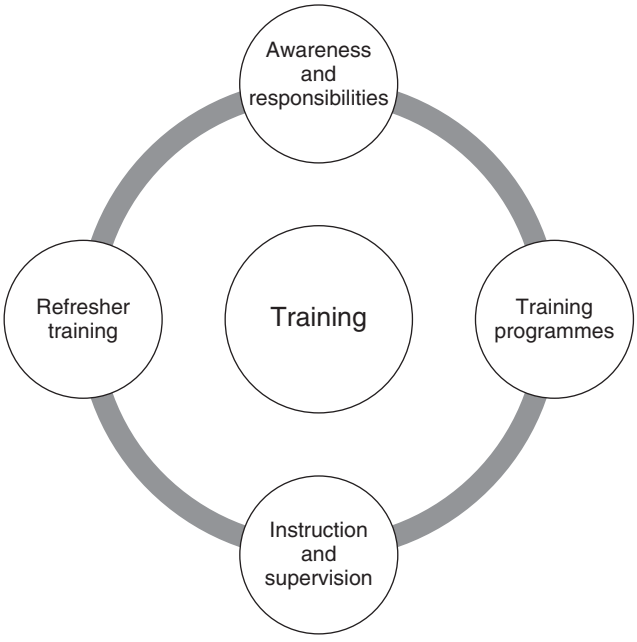

Figure 10.8 Training – prerequisite requirements.

and their ability to support the growth of food pathogens, plus control and monitoring procedures, such as:

- Process activities,
- Packaging systems,
- Handling and storage requirements,
- Labelling and shelf-life, and
- Specific requirements (e.g. monitoring CCPs under HACCP plans).

There should be adequate *instruction and supervision* of personnel and ongoing monitoring of food hygiene behaviour. Managers and supervisors should have levels of food hygiene knowledge that will allow them to judge potential food safety risks and take appropriate action.

Training should be evaluated and reviewed with *refresher training* or update training implemented as necessary.

10.4 Prerequisite Programmes and Operational Prerequisites

Based on the *Codex General Principles of Food Hygiene* (Codex 2009a), the preceding sections describe the generally accepted hygiene requirements in any food business to provide the general environmental conditions that are favourable to the production of safe food and thus the foundations needed for effective HACCP systems. Although Codex (2009a) does not currently use the term *prerequisite programmes*, these requirements are generally accepted as key PRP elements around the world. Other prerequisite terms have been introduced in recent years, which also needs discussion here, first, *Operational Prerequisite Programmes (OPRPs)*.

Operational prerequisites has been introduced under ISO 22000:2005 (ISO 2005). It is defined as:

> ***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.*

This operational PRP (OPRP) definition is different from the PRP definitions listed at the start of Section 10.2, and it refers specifically to the control of food safety hazards. This was initially seen as controversial in some circles because in HACCP (Codex 2009b); (see also Chapter 12) significant food safety hazards are expected to be controlled by CCPs. Although PRPs have always been considered important as a foundation for HACCP and therefore need to be established as formal programmes that are validated, monitored, and verified, ISO 22000 suggests that operational PRPs are as necessary as CCPs for the control of food safety hazards.

More recently for companies operating under the FDA FSMA Preventive Control rules for human and animal food (FDA 2016a), the term *preventive controls (PCs)* has become common place. These are 'measures required to ensure that hazards are significantly minimised or prevented' and include:

- Process controls,
- Food-allergen controls,
- Sanitation controls,
- Supply-chain controls, and
- Recall plan.

They include not only the controls at CCPs, if determined to be present, but also controls other than those at CCPs that are appropriate for food safety (i.e. certain PRP-specific control measures).

The idea for OPRPs and PCs stems from the fact that the manifestation of some hazards, in particular cross-contamination risks, might require elements of control that are generally thought to be part of PRPs. For example, the potential allergen contamination of a shared production line that is used to make both products containing and not containing certain allergens is likely to need specific targeted cleaning procedures as part of the management of this issue. A traditional way of dealing with this was to elevate that specific cleaning procedure to the status of a CCP, ensuring that it was validated in the same way as all other CCPs and then monitored and verified as effective. In this example the general cleaning of all other aspects of the operation would have remained part of PRPs. Using the same example but taking the ISO 22000 definition (ISO 2005) into account, it is likely that the specific targeted cleaning of the line to remove the likelihood of allergen contamination would now be thought of as an OPRP or a PC under the FDA rule.

Since the previous version of this book was published, the use of OPRPs has become more widespread. However, the focus on this concept still seems to be with businesses and areas of the world where ISO 22000:2005 is the standard of choice. Some groups have proposed decision trees to help determine if the prerequisite elements required are PRPs or OPRPs, for example the Prerequisite Decision Tree developed by Campden

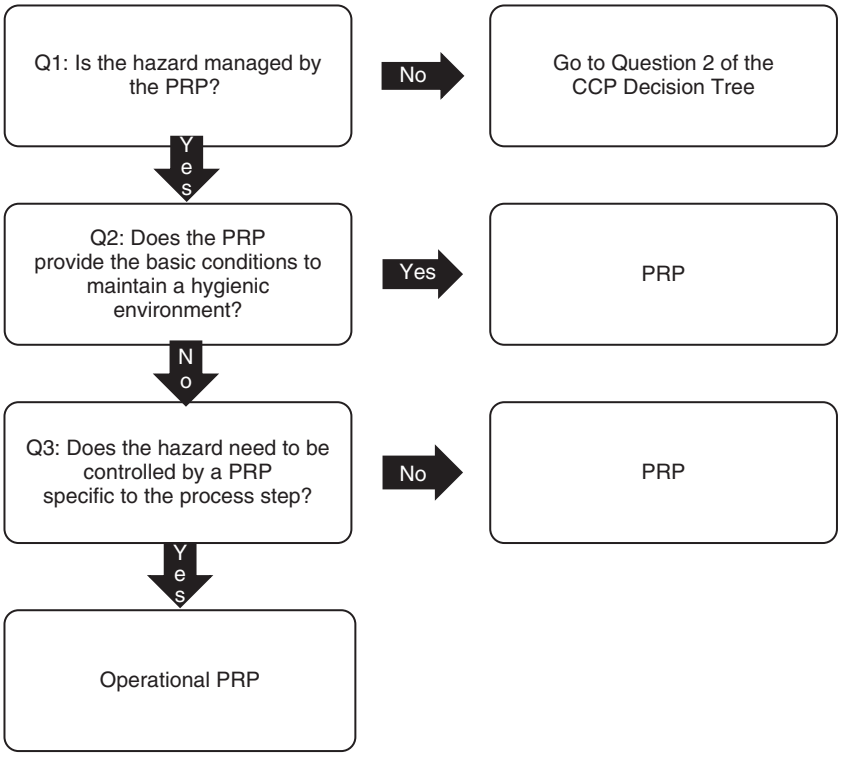

Figure 10.9 Prerequisite decision tree. *Source*: Gaze (2009) .

BRI (Gaze 2009) and the Operational PRP decision tree proposed by Mortimore and Wallace (2013), reproduced in Figures 10.9 and 10.10, respectively. Tools such as these may help to clarify some of the confusion regarding differentiation between CCPs, PRPs, and OPRPs. The concept may gain further traction if it were to be adopted into the Codex HACCP system and general principles of food hygiene, which are under review at the time of writing. Otherwise, more acceptance is only likely to come as more companies get exposed to the concept through the adoption of ISO 22000 (ISO 2005). Many US companies who had adopted the OPRP term because they found it useful (as opposed to doing it for certification to ISO 22000) have now converted their OPRPs into PCs to meet the FDA rule.

10.5 Validation and Verification of Prerequisite Programmes

PRPs are the basic standards for the food facility, in which the safely designed product can be manufactured. They form the hygiene foundations on which the HACCP system and other elements of the world-class food safety programme are built to control food safety every day of operation. As such, it is essential that PRPs are working effectively at all times, and it is therefore necessary that each prerequisite element is validated to establish that it will be effective and that an ongoing programme of monitoring and

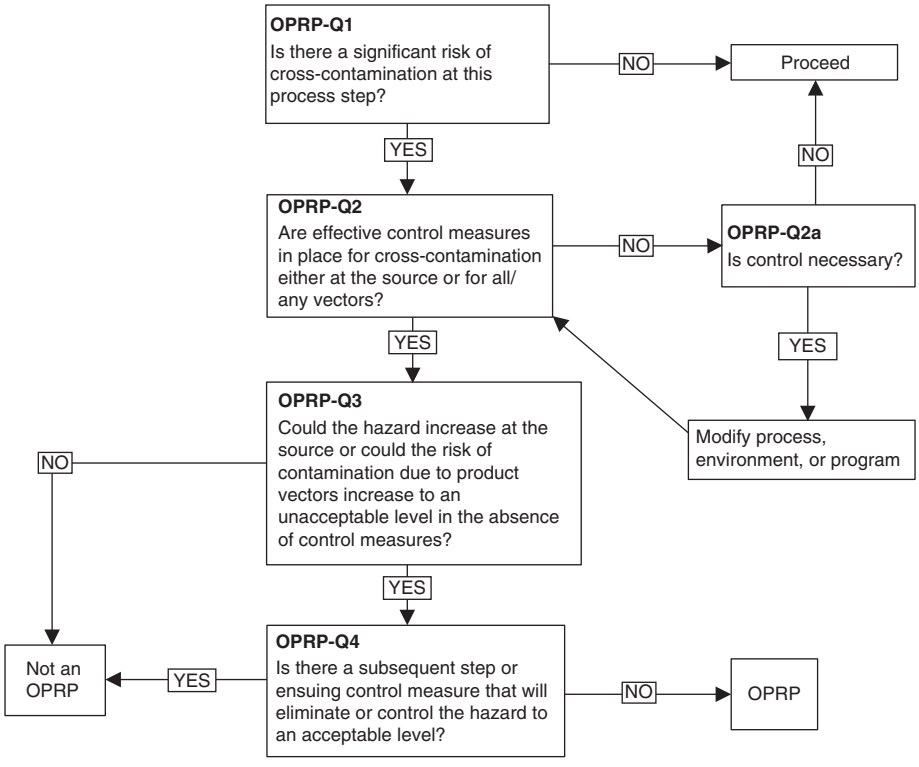

Figure 10.10 Operational PRP decision tree; *Source*: Mortimore and Wallace (2013) .

verification is developed and implemented. Formal challenge of proposed and existing PRPs is therefore a key part of assuring effectiveness of the world-class food safety programme and further guidance on this can be found in Chapter 14.

10.6 Further Reading on Prerequisite Programmes

Whilst not an exhaustive list of PRP guidance documents, the following publications may be helpful to readers wishing to find more detailed PRP suggestions than given in the Codex general principles of food hygiene (Codex 2009a) that have been discussed.

British Standards Institution (BSI). (2013). Prerequisite programmes for food safety in food retail. Specification, PAS 221:2013.

IFST. (2013). *Food and Drink—Good Manufacturing Practice: A Guide to its Responsible Management (GMP6)*, 6th edn. Oxford: Wiley Blackwell.

International Organisation for Standardisation (ISO). (2009). Technical Specification, Prerequisite programmes on food safety—Part 1: Food manufacturing, ISO/TS 22002-1:2009.

International Organisation for Standardisation (ISO). (2011). Technical Specification, Prerequisite programmes on food safety—Part 3: Farming, ISO/TS 22002-3:2011.

International Organisation for Standardisation (ISO). (2013a) Technical Specification, Prerequisite programmes on food safety—Part 2: Catering, ISO/TS 22002-2:2013.
International Organisation for Standardisation (ISO). (2013b). Technical Specification, Prerequisite programmes on food safety—Part 4: Food packaging manufacturing, ISO/TS 22002-4:2013.

10.7 Conclusions

PRPs are necessary to provide the foundations of good hygienic practices necessary in every food operation and act in tandem with the HACCP system. As such, they are essential to the production of safe food and form a cornerstone of world-class food safety programmes. The internationally accepted minimum prerequisite standards are defined in the Codex General Principles of Food Hygiene (Codex 2009a); however, this document lists 'top-level' information and companies also need to seek further guidance to establish detailed PRPs, as illustrated in the case study examples in this chapter. All PRP elements need to be fully implemented in the facility and subjected to routine, ongoing maintenance and review procedures. Only then can they be said to be 'formalised' such that they deliver their essential role in the management of food safety.

11

Conducting a Product Safety Assessment

11.1 Introduction

A formal and regular product safety assessment process is essential to be sure that all critical elements for the safe production of high-quality foods have been considered, researched, and adopted, as necessary, for all products produced. Of course, a safety review and assessment process should be a required element for commercial developments in all types of businesses. For example, around the world we have learned that improperly designed highway bridges and buildings can collapse and that banking corporations can fail by engaging in unsound business practices. The global food industry bears greater responsibility than most types of business for adequate product safety assessment processes. Its products are consumed daily by billions of people and designed to provide nourishment as opposed to being hazardous to health. Product safety assessment forms the bridge between controlling the safety of the individual product designs (Chapters 6 and 7) and controlling the safety of manufacturing processes, the latter being governed by HACCP-based food safety management systems (Chapter 12).

11.1.1 Who Is Involved in Product Safety Assessments?

It will be important to involve a range of different job roles in product safety assessments and so a team approach is most effective. This team forms the link between product development teams and the HACCP team who will assess the safety of processes and develop preventative controls for hazards during production. The precise make-up of the product assessment team may vary depending on the structure of each individual company; however, it is likely that this will include, as a minimum, research and development (R & D), food safety/technical (ideally with microbiology and toxicology know how), and supplier quality assurance staff.

It is in the best interest of a food company that its R & D staff be aware of the fundamental food safety requirements that need to be considered in product development. Such awareness can be effective in preventing food safety and quality problems after product commercialisation. Internal or external experts can provide appropriate food safety training; however, it is important to note that research and development staff should not be expected to perform a product safety assessment in isolation and, instead, will most likely be working alongside technical, more specialist, colleagues in assessing the food safety requirements for new product developments.

Food Safety for the 21st Century: Managing HACCP and Food Safety Throughout the Global Supply Chain, Second Edition. Carol A. Wallace, William H. Sperber, and Sara E. Mortimore.

To promote safe product design, research staff should understand the potential hazards inherent to raw materials and finished products (Chapter 5), as well as the practical measures that can be used to control intrinsic (Chapter 6) and extrinsic (Chapter 7) hazards. The staff must also be capable to identify the needs for and to coordinate all laboratory tests and sensory evaluations during the course of product development.

Many food manufacturers have learned that it is practical to have two teams within their R & D organisations that are involved in the development and commercialisation of a food product: a product development team and a product safety assessment team. The latter team will perform the initial recipe/product concept safety assessment and will hand over to the HACCP team so that the new development can be taken in to the manufacturing site HACCP plans.

A *product development team* should be formed to manage each new product development project. This team will include personnel who are broadly experienced in the types of products being sold by the company. The individuals on a product development team will vary depending on the type of project but are likely to include food scientists, process engineers, packaging engineers, and financial and transportation personnel as necessary. Various technical functions are also part of the product development team, including chemists, microbiologists, regulatory personnel, and lawyers as necessary. This latter group of individuals would likely support many product development teams. It is often useful to include a person who is expert in experimental design, analysis, and mathematical modelling.

A *product safety assessment team* is used by many companies as the authoritative body to review and verify that all necessary control elements are in place to assure the product's safety, quality, and regulatory compliance. The individuals, who typically serve on the product safety assessment team permanently, are lead scientists or managers in the company who have the expertise and responsibility to serve in this capacity. They are typically selected from the following functional areas:

- food safety/technical and quality,
- raw material supplier assurance,
- packaging technology, and
- regulatory affairs.

In large corporations there can be a substantial physical gap between the product development team and the several or many food manufacturing plants that can be located over large regions or even globally. Therefore, it is vital that a seamless product safety assessment process is established and required for every product, so that information about the product and its safety is accurately documented and transferred from the R & D staff to the product safety assessment team and, following approval, to the HACCP teams and manufacturing staff. Large corporations typically have sufficient internal resources to ensure that this requirement is met and maintained.

In small corporations or very small companies, the physical gap between the product development team and the manufacturing locations is much smaller than it is for larger corporations. In fact, in small companies, the research, technical, product safety, and manufacturing functions might be located together and involve the same small number of people. Smaller companies, however, often do not have sufficient internal resources

to conduct R & D activities, much less ensure an effective product safety assessment and transfer process. The management of such companies must recognise this limitation and provide the necessary external resources to complement its internal resources in order to ensure the production of safe food.

11.1.2 Timing of the Product Safety Assessment Process

The product safety assessment process begins during product conceptualisation and is carried forward by the product development team during its development activities, including sensory and consumer testing. The process must be completed before commercial launch of the product. As will be elaborated in following chapters, the product safety assessment process is the key link in the transfer of food safety knowledge from the research and development team to the operations team that will manufacture the product. The product's HACCP team resides in plant operations. The product safety assessment that is approved at the R & D stage contains essential information that must be considered and used in the hazard analysis that is conducted by the plant HACCP team.

11.1.3 Product Safety Assessment Process

During the course of a project, the product development team should organise all essential information related to the formulation and production of a food, whether a new product or a reformulated commercial product is being developed. The information should include the following:

- the type of food and its intended and unintended (where known) use;
- the food ingredients and their sources;
- the product formulation and its intrinsic control factors;
- the product process and its extrinsic control factors;
- the product package and its safety features;
- the product label and consumer use instructions;
- the product distribution from production plant to point of consumption; and
- the product handling by foodservice personnel or the consumer.

This information is likely to be contained in a range of documentation sources, which must be collated by the product development team to provide sufficient detail for evaluation by the product safety assessment team. Typical documentation includes:

- supplier evaluations and approval forms;
- ingredient specifications;
- product specifications, including complete formulation;
- package specifications, including tamper-evident features;
- process requirements related to food safety;
- label information and consumer use instructions; and
- literature references of potential hazards and control measures, also documented consideration of likely cross-contamination points in the process and where this might pose a hazard.

The product safety assessment team should hold regularly scheduled meetings so that it is available to consult with product development teams during product conceptualisation and development. Regular communications with the product safety assessment team will facilitate the development process and will help ensure that unanticipated barriers are not detected during the final review and approval by the product safety assessment team. After final review and approval, the product specifications and product safety assessment must be signed by each functional expert member of the product safety assessment team.

11.2 Training for Research and Development Personnel

As The Pillsbury Company began in 1972 to apply its novel system of food safety management, HACCP, to the production of its consumer foods (Chapter 1), it conducted training of all of its R & D personnel in the critical elements to develop and document the necessary product safety control features. Remarkably, in addition to its comprehensive nature and its immediate availability, most elements of this original product safety training programme would be found in modern product safety training programmes. We have pointed out several times the 'timeless essence' of HACCP features. The same timeless essence obviously can be found in effective training and education programmes. It is the responsibility of all food processors to operate at this high level of performance in their product development, documentation, and product safety assessment activities. Of course, even timeless training programmes evolve; some features can be improved and expanded, whereas others might need to be minimised or eliminated. This is continuous improvement.

Training and education will be necessary for personnel involved in R & D processes, including both those involved in product development teams and those involved in product safety assessment. It is essential that these personnel be knowledgeable about the microbiological, chemical, and physical hazards in food ingredients and products; and in the intrinsic and extrinsic measures that can be applied to control identified hazards. Further elements of the initial training should include the development of ingredient and product specifications that encompass relevant physico-chemical data related to water activity, moisture content, pH, storage temperature, chemical preservatives, and headspace environment.

Training for product safety assessment personnel must also include a consideration of the hazards and potential control measures that need to be in place during product processing. Consideration of these measures during product development can later assist the plant HACCP teams in their determination of critical control points. For example, time and temperature controls are often necessary in processing steps and product storage; magnets and metal detectors may be required to detect potential product contamination with metal; and sifters and screens may be required to detect and remove physical contaminants from dry ingredients and products. R & D personnel should be trained to keep accurate process flow diagrams as processes are developed. Additionally, the responsible personnel must be trained and competent in the administrative features related to product and process development, including specifications,

testing procedures, approval procedures, and so on. These features will be demonstrated in the following example.

11.3 Example of a Product Safety Assessment

This fictional example has been created to illustrate the features of a product safety assessment. Across a particular company, standardised forms and procedures should be developed to facilitate the assessment and documentation process. The first page(s) of the assessment include a general description of the product and its intended use and specific descriptions of the production site, product formulation, physico-chemical features of the product, processing steps, and process flow diagram.

Product Safety Assessment

Date November 2, 2016
PSA Number 173-2009
Company Riviera Risottos
Plant Hendek, Turkey
Product Name Himalayan Nut Pilaf

Product Description and Intended Use

Himalayan Nut Pilaf is a ready-to-eat, cold-prepared vegetarian meal. It is manufactured from fresh and dried ingredients that are sourced globally. After manufacture, it is blast chilled, stored, and distributed chilled. The package label includes a declaration of the ingredients, nutritional information, allergen information, and information for product storage, handling, and shelf life. It is intended for consumption by the general population, which may include high risk groups.

Physico-chemical features	Range
Moisture (%)	56.0–59.5
Water activity	0.975–0.99
pH	6.6–6.9
Chemical preservatives	None
Headspace environment	Air
Storage temperature (° C)	1–4
Maximum shelf life (days)	10

Ingredient	%	Ingredient specification number	Potential hazard(s)
Cooked basmati rice	69.19	27.342	*Bacillus cereus*
Sunflower oil	1.72	28.06	None identified
Fresh white onions, chopped	6.88	23.01	None identified
Fresh garlic cloves, crushed	0.86	23.24	None identified
Fresh carrots, diced	8.61	23.17	None identified
Cumin seed	0.43	29.27	Foreign material *Salmonella* spp.
Ground coriander	0.86	29.18	Foreign material *Salmonella* spp. Potential economically motivated adulteration risk
Sodium chloride	0.43	29.01	Foreign material
Black pepper	0.26	29.02	Foreign material *Salmonella* spp.
Groundnuts, unsalted	10.76	24.16	*Salmonella* spp., aflatoxin, allergen
	100.00		

Process Description	
Rice Cooking	Cook one part rice in two parts (v/v) water. The cooked rice is drained and quickly cooled to ambient temperature. If not used in production within 2 hours, the rice is put into chilled storage at 1–4°C for a period not longer than 2 days.
Herb/Spice Blending	The cumin, coriander, salt, and black pepper are blended, measured into batch-sized quantities, and stored at ambient temperature not longer than 1 week.
Vegetable Blending	The sunflower oil, chopped onion, crushed garlic, and diced carrots are blended with herb/spice mixes and used within 4 hours.
Product Blending	The cooked rice is blended with the oil and vegetable/herb/spice mixture. Then the groundnuts are blended in.
Packaging	The Himalayan Nut Pilaf is packaged into plastic trays (CPET) in 250 g or 500 g portions. The containers are lidded with an oxygen-impermeable film. The product labelling information is contained on the cardboard sleeve, to which coding information is applied during manufacture. All packages are visually inspected for seal integrity and passed through a metal detector.
Storage	The packaged product is cased, palletised, and put into chilled storage at 0–4°C.
Retail	The Himalayan Nut Pilaf has a maximum chilled shelf life at 4°C or less of 10 days. It is distributed to retail outlets within 3 days of its manufacturing date.

11.3.1 Process Flow Diagram

The product will be produced within the remit of the Riviera Risottos modular HACCP system for Risotto and Pasta Meals. A diagram indicating the specific process activities for this product from the HACCP modules is reproduced in Figure 11.1. More detail on the HACCP plan for this operation, including the other process steps that make up these modules but are not involved in this product, can be found as a case study in Appendix 1.

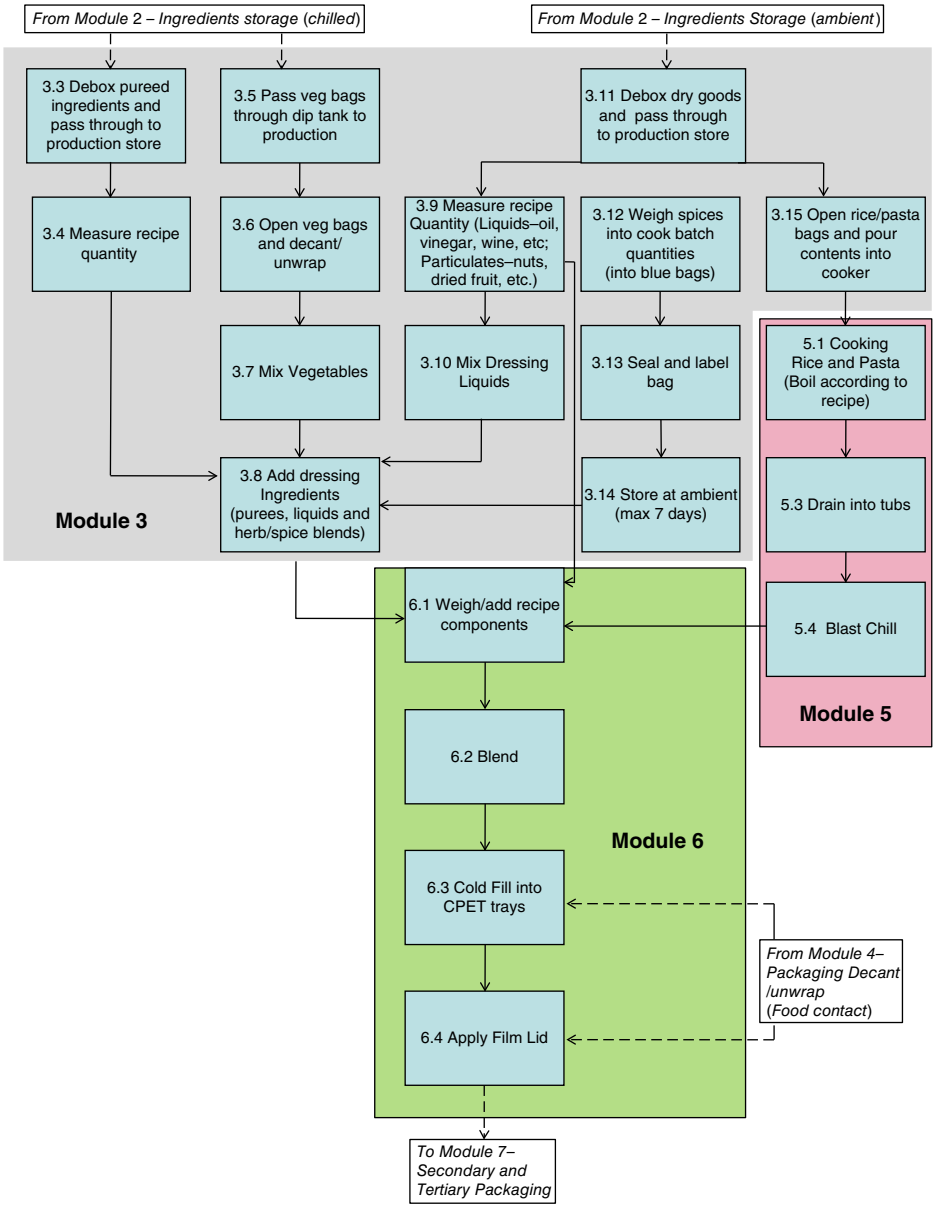

Figure 11.1 Process flow diagram for Himalayan Nut Pilaf.

The last pages of the assessment include supporting references, the product label, and a summary of the assessment team's deliberations, its decisions, and approval.

Supporting studies

Riviera Risottos research notebook	Volume 169; Jan. 1 to June 15, 2016
Research report number 74-2, May 2016.	Validates product shelf life
Riviera Risottos engineering notebook	Volume 37; Feb. 1 to July 15, 2016
Research report 162-1, June, 2016.	Validates process flow and controls, and quality of finished product

Product Label

Riviera Risottos
Himalayan Nut Pilaf

Net Weight 250 g

INGREDIENTS: COOKED BASMATI RICE, UNSALTED GROUNDNUTS, DICED CARROTS, CHOPPED ONIONS, SUNFLOWER OIL, CRUSHED GARLIC, GROUND CORIANDER, CUMIN SEED, SALT, BLACK PEPPER

Nutrition Facts		**%DV ***
Serving Size	1 cup (125 g)	
Servings per container	2	
Calories	224	11
Fat Calories	72	
Total Fat	8g	11
Saturated	0	
Trans fat	0	
Protein	12g	
Total Carbohydrates	26 g	10
Fibre	<1 g	
Sugars	<1 g	
Cholesterol	0	
Sodium	200 mg	8

***Percent Daily Values, based on a 2000-calorie diet.**

CONTAINS GROUNDNUTS

Keep refrigerated: Use by expiration date.

No preparation necessary. Add diced cooked meat, poultry or seafood as desired.

Product Safety Assessment

The PSA team has reviewed the submitted information and supporting studies. This information is consistent with our previous experience and with published expert opinions on the control of potential foodborne hazards. When produced and handled under the specified conditions, Himalayan Nut Pilaf is highly unlikely to present a food safety hazard.

- The potential threat of *Listeria monocytogenes* infections is controlled by the washing and peeling of fresh vegetables, sanitary production conditions, temperature control, and the short product shelf life.
- The potential threat of *Salmonella* in spices is controlled by irradiation by the vendor.
- The potential threat of *Bacillus cereus* intoxication is controlled by the short-term storage of cooked rice, which is permitted only under chilled conditions.
- The potential hazard of foreign material contamination in spices is minimised by visual inspection, metal detection, and vendor control requirements.
- The use of groundnuts in this product presents several potential hazards, all of which can be readily controlled by good practices. The potential hazards of *Salmonella* and aflatoxin contamination can be greatly minimised by vendor control programmes, with at least monthly verification by testing in Riviera Risottos facilities. The potential allergen hazard of groundnuts is controlled by product labelling and by thorough cleaning of all process equipment before products not containing groundnuts can be produced. Full supplier traceability of spices and ongoing market surveillance is used to reduce likelihood of economically motivated adulteration.

Approval Signatures	**November 2, 2016**
Responsible Person or Alternate	**Corporate Functional Responsibility**
R. Deville	Research and Development
C. Basmati	Engineering and Quality Assurance
S. Wrappe	Packaging
B. Canu	Procurement
L. Advokat	Legal and Regulatory Affairs
W. Bowman	Food Safety

11.4 Conclusions and Principles for Effective Product Safety Assessment

Several important principles should be at the forefront of awareness and serve to guide the decisions of research and manufacturing personnel who are responsible for product safety.

1) All food prototypes must be safe for consumption. This principle pertains to R & D or pilot plant-produced samples tasted in the test kitchen or evaluated by internal sensory panels and during external central location consumer tests, home-use tests, and market trials before product commercialisation. It is vital that the research team coordinate its development activities with the product safety assessment team so that the safety of all analysts is assured.

2) It is essential that a thorough product safety assessment is conducted and approved by the responsible personnel. This assessment is one of the important means to transmit important knowledge from the R & D team to the plant team, which in turn must transfer pertinent information from the product safety assessment into the plant's HACCP plan.
3) No consumer testing or consumption of 'sales samples' can be done before having an approved product safety assessment.
4) No commercial production of new or reformulated food products can be permitted until the product safety assessment is completed and approved by the product safety assessment team and the product's HACCP plan has been approved and implemented by the plant HACCP team.
5) Members of product safety assessment teams must have appropriate training and knowledge to be able to assess effectively the safety of each new product, product variant, or ingredients or process changes.

12

Developing and Implementing a HACCP Plan

12.1 Introduction

Developing a HACCP plan is a key part of the development of any food safety management programme, and HACCP plans, developed by HACCP teams and unique to each production facility, are essential to the production of safe food throughout the global food supply chain. Implementation of the HACCP plan is an equally crucial part of food safety system effectiveness. It is important to get implementation right so that the critical control points (CCPs) identified at the HACCP plan development stage will work every day to protect the consumer.

As discussed in the introduction to this book, the HACCP concept has been public knowledge for several decades, and this means that many companies already have HACCP systems in place. So, whilst some people might be starting at the beginning to develop a HACCP plan for the first time, others will be reviewing and upgrading existing systems that may have been in place within their companies for many years. It is therefore important to discuss the steps of HACCP plan development and bring together the authors' experiences of HACCP over the last 40 years, both to share best practices and to outline common pitfalls. As we have discussed in previous chapters, there have been many limitations in the way that HACCP has been applied, and few companies have used it to best effect, particularly when considering it as part of the integrated food safety management system supported by strong prerequisite programmes (PRPs). For effective food safety management in the 21st century we need to get back to basics and use the established HACCP Principles (Codex 2009b) to best effect, such that we produce valid HACCP plans that will work to control all relevant food safety hazards when working alongside their supporting prerequisites.

There is limited advice on HACCP implementation in the literature. and it is often assumed that if companies can develop HACCP plans then effective implementation will follow. This is not true because implementation is an easy place to go wrong, and weaknesses in HACCP plan implementation feature strongly on the list of reasons for HACCP failure (Chapter 2). It is important to note that many people see having a HACCP plan as the end point of their HACCP endeavours; it is actually only the beginning. Understanding these issues is fundamental to success in 21st century HACCP (i.e. the full application of HACCP principles along with implementation and maintenance of the resulting management systems).

Food Safety for the 21st Century: Managing HACCP and Food Safety Throughout the Global Supply Chain, Second Edition. Carol A. Wallace, William H. Sperber, and Sara E. Mortimore.

The implementation of a HACCP plan requires the input of a range of different personnel within the operation. The HACCP team members who have developed the plan will have key roles, as will the wider food safety team, and in particular, the line operators, supervisors, and managers who will be involved in the day-to-day running of HACCP in practice. The process of HACCP implementation involves the handover of responsibility and ownership of HACCP from its developers to its operators, and thus the HACCP plan documents are activated as a working system.

In this chapter the processes of HACCP plan development and implementation will be discussed in a step-by-step fashion. For those who are new to HACCP, working through the chapter will build an understanding of the necessary tasks and procedures that need to be undertaken. For those reviewing their existing programmes to assure continued system effectiveness, this chapter could be viewed as a checklist of points to consider in strengthening the HACCP elements of food safety management practices. Only by taking the time to work through these steps methodically, using the necessary combination of expertise, knowledge, and experience, can an effective HACCP plan be developed. Referring back to Chapter 2 and the misconception that 'HACCP has been done already' (Section 2.3), experience tells us that this statement is far from true. It is therefore essential that food businesses are not complacent about their control procedures but are open to the possibility that existing systems can be improved, and this chapter aims to build on experiences and learnings, to deliver tips for success and to help avoid the common pitfalls that may result in HACCP system weaknesses.

12.2 Preliminary Concepts

12.2.1 HACCP Principles

As mentioned in Chapters 1 and 8, the HACCP plan is established by applying the seven HACCP Principles (Codex 2009b). Before examining in detail how to develop a HACCP plan, it is useful to consider briefly the requirements of each Principle (Table 12.1).

12.2.2 The HACCP Plan and Documentation Approaches

The HACCP Plan is defined as follows:

> *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).

Put simply, the HACCP plan is the documentation produced that shows how significant hazards will be controlled. The HACCP plan is a formal document holding all details of areas critical to food safety management for a product or process. It normally consists of the core plan, support documentation, and documenting the plan study and development.

- Core Plan
  - Valid process flow diagram
  - Documented CCP management details: this is usually captured in a table known as a HACCP Control Chart (Mortimore and Wallace, 2013), HACCP Worksheet (Codex 2009b), or CCP Management Table

Table 12.1 The HACCP Principles explained.

HACCP Principle		Clarification
PRINCIPLE 1	Conduct a hazard analysis.	This requires the team to look at each process step one at a time, consider which hazards might occur, evaluate their significance, and establish how best to control them.
PRINCIPLE 2	Determine the Critical Control Points (CCPs).	At this stage the points that are critical to product safety are identified. This can be done through judgement and experience or using a structured tool, the Codex Decision Tree
PRINCIPLE 3	Establish critical limit(s).	Critical limits are the safety limits that form the boundary between safe and potentially unsafe food. These need to be established to manage all CCPs.
PRINCIPLE 4	Establish a system to monitor control of the CCP.	The monitoring system needs to demonstrate that the CCP is under control on a day-to-day basis and must be capable of detecting loss of control.
PRINCIPLE 5	Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.	If the CCP is not working, action needs to be taken to protect the consumer and to put right the cause of the deviation.
PRINCIPLE 6	Establish procedures for verification to confirm that the HACCP system is working effectively.	This requires checking that the system is capable of controlling relevant hazards, is working in practice, and is up-to-date on an ongoing basis.
PRINCIPLE 7	Establish documentation concerning all procedures and records appropriate to these principles and their application.	Documentation will include the process flow diagrams and tables created during the HACCP study (HACCP plans and development records) as well as monitoring and corrective action records.

Note: At the time of writing this second edition, the Codex General Principles of Food Hygiene, including the HACCP Principles and guidelines (Codex 2009a, b) are open for review and update. This means that we can expect to see updated documents over the next few years and, although the number of HACCP principles is expected to stay the same, it is likely that there may be some changes to wording as well as to definitions. Certainly, it is expected that there will be additional and more detailed application guidance and, therefore, readers are encouraged to look out for future Codex publications.

- Support Documentation
  This comprises the preparatory documentation that has been used in developing the HACCP plan as well as details of the verification requirements, including:
  - HACCP team details
  - Product/process description (including terms of reference, consumer target group, and intended use of product)
  - Hazard analysis details (details of approach and justification)
  - CCP identification (details of approach and justification)
  - HACCP verification plan
  - HACCP audit and review data

- Documenting the HACCP Study and HACCP Plan Development
  A key requirement when developing HACCP plans is to understand what needs to be documented not only to help the HACCP team in their deliberations during the HACCP study, but also to ensure that all food safety hazards are identified, evaluated, and effectively controlled and to provide evidence of an effective food safety system (e.g. when being assessed by external auditors). Codex (2009b) guidance on document organisation (the HACCP Worksheet) is widely used as a basis for HACCP study records, but there is no prescribed format and most companies use their own adaptations of recommended tables. A variety of templates are available in text books (e.g. Mortimore and Wallace 2013) and in HACCP plan examples published on the Internet. Suggested documentation formats are built into this chapter to illustrate the HACCP application process and may be adapted to suit any food operation.

12.2.3 HACCP Application Process

The process of HACCP plan development and implementation, through the application of the Codex HACCP Principles, involves a number of interlinked stages (Figure 12.1). Application of the HACCP Principles is done using a logical, step-by-step approach such that each step builds on the work done in applying the previous step. As can be seen in the diagram, the HACCP Principles are involved not only in development of the HACCP plan but also in HACCP implementation and maintenance. This is a simplified schematic to illustrate the key process steps where HACCP Principles are applied, and it should be noted that there will be some further overlap of where individual HACCP Principles apply (e.g. it is possible that validation requirements of Principle 6 might be considered during HACCP plan development, when considering suitability of control measures).

12.2.4 Codex Logic Sequence

Before applying the HACCP Principles, there are a number of preparatory steps that must be completed. These are described in the Codex logic sequence for the application of HACCP, as shown in Table 12.2.

Steps 1 to 5 are also known as the Codex preliminary steps to HACCP application, and these are applied as part of the preparatory process before use of the HACCP principles. As previously discussed, HACCP is normally applied by a multidisciplinary team so that personnel from all aspects of the operation are included. The first preliminary step includes identifying and training the team and assembly of the team to carry out the study. A product (or process) description is developed as background information for the team, and the intended use for the final product is also considered. The team then prepares and confirms a process flow diagram that describes all the steps in the process being studied. Only when these steps have been completed is the team ready to apply the first of the HACCP Principles at step 6.

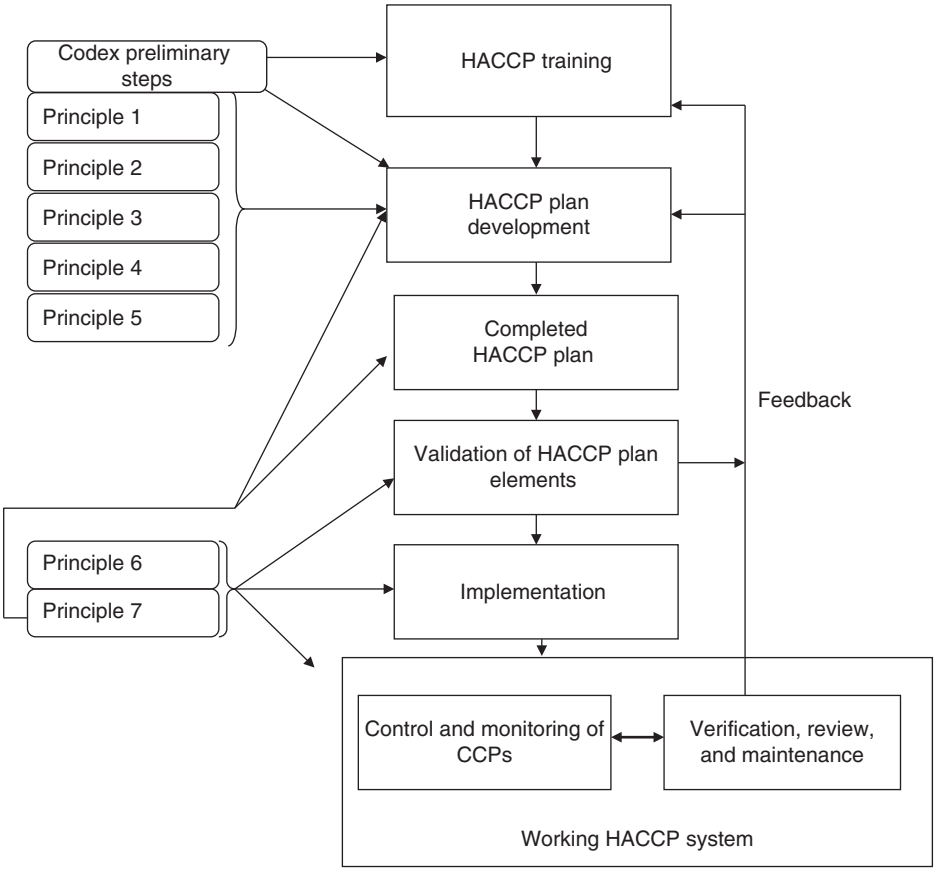

Figure 12.1 HACCP application process. Adapted from Wallace et al. (2005).

Table 12.2 Logic sequence for application of the Codex HACCP Principles.

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

(Codex 2009b)

12.3 Applying the Codex Logic Sequence to Develop a HACCP Plan

In this section the stepwise development of a HACCP plan will be discussed, according to the requirements of Codex (2009b). To illustrate this process, elements of a case study HACCP plan are included to show the application of the steps. This is for a fictional manufacturer of chilled prepared meals known as *Riviera Risottos,* one of whose products was introduced in Chapter 11. The full case study can be found in Appendix 1. Application of the Codex logic sequence is normally done by the HACCP team, which will be discussed in detail at Step 1 (Section 12.3.2).

12.3.1 HACCP Study Terms of Reference and Scope

Although not listed as a step in the Codex logic sequence, it is standard practice to establish the scope or terms of reference at the start of any HACCP study. This should include the types of hazards to be studied, and normally this will be microbiological, chemical, and physical hazards. However, although all relevant hazards need to be covered in the operation, they do not need to be studied at the same time, and so a particular study could focus on a specific hazard group, such as when a specialist (e.g. microbiologist) needs to be brought into the team. Most experienced HACCP teams will cover all hazard types together, but new HACCP teams may also find it easier to focus on one group of hazards at a time.

Another important part of the terms of reference or scope is to identify exactly which part of the operation is to be covered by the HACCP study. This involves considering where the start and end points need to be and whether the HACCP study covers one product, a process involving several products, or a process module as outlined in Chapter 9 (Section 9.4.2). Modular (or process-led) systems are practical to develop and are used in most manufacturing businesses, particularly those with complex processing operations, as well as in many foodservice operations. This is where the operation is split into a number of process sections and HACCP is applied to each section rather than to each individual product (the individual product approach is referred to as linear or product-led HACCP). With modular HACCP, a key point is to ensure that the modules add up to the entire operation and that no processes are missed out, so it is important to identify the start and end points accurately for each HACCP study, and this is defined as part of setting the terms of reference and scope.

These details may be listed as an introduction to the HACCP plan, but they are also commonly included in the product/process description (see Codex logic sequence step 2). For the case study company, the terms of reference and scope for HACCP plan development are listed in Table 12.3.

12.3.2 Codex Logic Sequence Step 1: HACCP Teams

This step tells us to 'Assemble HACCP team'; however, before a HACCP team can be assembled, the correct people need to be identified and trained. The HACCP team is a specific group of individuals who work together to apply the HACCP principles and will have different, but likely overlapping, membership from the food safety team discussed in previous chapters. The multidisciplinary HACCP team is believed to be one of the

Table 12.3 Riviera Risottos HACCP plan terms of reference and scope.

SCOPE	The manufacture of chilled ready-to-eat prepared meals, which may be consumed hot or cold, including products relating to special dietary needs requirements for the following brands: • Riviera Risottos branded products • Retailer private label products
TERMS OF REFERENCE	• The HACCP plan for risotto and pasta meals products will cover all relevant microbiological, physical, and chemical hazards to include allergens and compounds that cause intolerance reactions. • This HACCP plan covers all processes for risotto and pasta meals products, from raw material intake to chilled storage of finished products prior to dispatch.

most powerful strengths of HACCP. It ensures that HACCP plans are developed by a group of people who, collectively, have the knowledge and experience to take decisions about food safety. It is important that the HACCP team includes personnel who understand not only the HACCP principles, but also the food products and their ingredients, the production processes and packaging systems, the manufacturing and handling environments, and the likely hazards associated with all of these aspects.

The essential expertise within the HACCP team, therefore, includes:

- Personnel who understand the process operations, ingredients, and products on site.
- Personnel who have knowledge and experience of the equipment, how it works to achieve process conditions, and the likely failure modes.
- Personnel who understand the likely hazards and appropriate control mechanisms, including how to validate process controls, including the necessary validation requirements.

and this expertise is most likely to be gained by including personnel from manufacturing/operations alongside quality, technical, and engineering disciplines. Additional specialists may also be required to provide knowledge and experience of specific aspects (e.g. microbiologists, toxicologists, supplier/vendor quality assurance personnel, storage and distribution personnel, or product developers). Within the HACCP team, a leader needs to be appointed and a scribe or team administrator identified. These are two crucial roles to the success of HACCP, ensuring that the HACCP development programme is coordinated and kept on track and that accurate records of all team discussions are maintained.

The total size of a HACCP team is normally kept to a maximum of four to six personnel for ease of management, although this core team may not include the additional specialists who may be called in for specific tasks. In small operations, and even in some larger ones, it may be difficult to achieve a multidisciplinary HACCP team of this nature because of the limited number of appropriate personnel on site. Although it is likely that the fewer members of staff will have wider job responsibilities and, therefore, an understanding of the whole operation, allowing them to contribute the same way as a multidisciplinary team, it is also likely that personnel in small businesses will have less knowledge of food safety hazards, and this will need to be compensated for by bringing in external support.

The multidisciplinary approach to HACCP works well and ensures that the system does not rely on the knowledge and experience of one individual. However, it is important that a balance of individuals is found and a 'sharing' environment promoted where job roles are left outside the door. This helps to overcome any difficulties from existing group norms such as inability to challenge more senior or dominant staff when necessary (Wallace et al. 2012).

For a HACCP team to work effectively, all team members need to understand the application of HACCP Principles. For best results, the whole team should be trained using a practical training intervention that covers both theory and practical application of HACCP. Whilst the multidisciplinary aspect of the team is essential to cover all necessary aspects of the operation, it is unlikely that all team members will have the same level of HACCP principle knowledge, even after the same training intervention. Wallace et al. (2012) found that there is a 'levelling out' of HACCP knowledge within HACCP teams, such that the team knowledge is not necessarily better than, and in fact, is sometimes worse, than that of the individual team members. It is therefore important to understand the balance of HACCP knowledge within the team such that the HACCP study process is guided by the team members with the best knowledge of HACCP Principles. This might mean that one or two people with good HACCP knowledge are given the task of ensuring that HACCP plan development proceeds effectively, whilst the remaining team members focus on their functional input to the team deliberations (Wallace et al. 2012). Published knowledge testing formats are available to help determine HACCP knowledge levels (e.g. Wallace et al. 2005).

Table 12.4 shows details of the Riviera Risottos HACCP Team.

12.3.3 Codex Logic Sequence Step 2: Product/Process Descriptions

This Codex preliminary step tells us to 'Describe Product'. In practice, this step considers both the product(s) and the process. The reason for the product/process description is that it is important for all members of the HACCP team to understand the background to the operations that they are about to study. This is achieved by discussing the operation and noting key information. Although some HACCP teams prefer just to have the familiarisation discussion, it is most useful if the information is recorded formally as a 'product description' or 'process description'. This document then becomes a historical point of reference to the situation when the HACCP plan was developed. It will be useful at later stages as a training tool for new personnel and briefing aid for internal or external auditors or regulatory personnel who need to gain an understanding of the food safety management approach.

Table 12.4 Riviera Risottos HACCP team.

R. Arborio, Quality Manager (HACCP Team Leader)
L. Grain, Production Manager
C. Basmati, Engineering Supervisor
M. Wild, Production Supervisor
T. Jasmine, Technical Consultant

Topics normally included in the team's discussions are:

- Main ingredient groups to be used or 'work-in-progress' (WIP) inputs to process modules,
- Main processes and how materials are prepared/handled,
- Production environment and equipment layout,
- Hazard types to be considered, if known,
- Key control measures available through processes and prerequisites, and
- Packaging/wrapping if appropriate to scope of study.

Much of this information will have been collected at the product safety assessment stage (Chapter 11) and should be transferred to the HACCP team by the product development or product safety assessment team. As an example, the case study HACCP team constructed a process description as shown in Table 12.5.

When applying HACCP in foodservice operations, in addition to the general product description information such as the example in Table 12.5, it is normal practice to group all the different menu or food items into like process groups. This can also be included as part of the product/process description step as per the example in Table 12.6.

12.3.4 Codex Logic Sequence Step 3: Identify Intended Use

It is important to identify the intended use of the product, including the intended consumer target group. Different consumer groups may have varying susceptibilities to the potential hazards (e.g. the elderly, young children, or immunocompromised individuals). However, it must be emphasised that all products should be safe for all consumers.

Intended use considerations need to be examined throughout the products supply chain, including further manufacturers/processors, foodservice, retailers, and through to handling and use by the final food preparer and consumer. Different uses of the food items may also need to involve different hazard considerations, for example, food items that may be cooked or used without any further heat process. The HACCP team needs to think about any ways that the product could be abused or used other than that intended. Where there is a *known common use* (that differs from the intended use), the HACCP team needs to consider ways to design out or to control hazards that may arise. An example of this is low-calorie powdered drink mixes (e.g. hot chocolate) that are intended to be made up with boiling water. In some cases, diet/weight loss groups have recommended to their members the use of these products to flavour desserts such

Table 12.5 Descriptions of product.

Ready-to-eat 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 used on site are strictly controlled, and prerequisite programmes include instructions on handling, segregation, and labelling requirements. Ingredients are sourced through approved suppliers globally.
All prepared meals are cooked to pasteurisation temperatures, then blast chilled, and stored and distributed chilled. The shelf life of the products is determined by prescribed storage and usage conditions and is verified during production trials and confirmed microbiologically.
Fit-for-purpose food-grade packaging is used. All packaging carries full ingredient listing, nutritional information, allergen information, heating and storage instructions, and shelf life information.

Table 12.6 Catering process groupings.

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:	Example foods:	Example foods:
• Salad greens • Fresh vegetables • Coleslaw/dressed salads • Fish for raw consumption (sushi) • Sliced sandwich meats • Sliced/grated cheese • Meat salads (made with precooked meats)	• Fried chicken • Grilled or fried fish • Hamburgers, sausages, etc. • Roasted, fried, or grilled meats • Hot vegetables • Cooked eggs	• Soups • Gravies • Sauces • Rice dishes • Prepared meals (e.g. chilli, rice and pasta dishes) • Meat salads (made with meats that require pre-cooking)

Adapted from FDA 2006a.

as low-calorie yogurts. If the drink mix was relying on boiling water to make it safe then this secondary use as a dessert additive could be potentially unsafe. Other good examples include refrigerated cookie dough products that are intended to be baked but are frequently consumed raw, particularly in the United States, and soup mixes being blended with sour cream to make salad dressings. Where the use is known to be other than intended, additional controls need to be in place (e.g., in the case of cookie dough, by using heat-treated flour in the formulation).

Intended use and consumer group information is usually included as part of the process description record (from Step 2). In many cases it will be important to provide information to the consumer about how to handle, store, and prepare (including cooking as appropriate) the food item safely, and this can be derived once the intended use and potential misuse of the product is established. Table 12.7 shows the intended use and misuse considerations from the case study company.

12.3.5 Codex Logic Sequence Step 4: Construct Process Flow Diagram(s)

A process flow diagram, outlining all the process activities in the operation being studied, needs to be constructed. This should list all the individual activities in a stepwise

Table 12.7 Riviera Risottos intended consumer use and potential misuse.

INTENDED CONSUMER USE	• The products are intended for the general population which may include high risk groups. • Some products may contain allergens, so are not suitable for the whole population. • All allergens are stated on pack and all packs carry the relevant warnings • Products may be consumed cold or reheated as per instructions. • All products may be held under refrigerated or frozen storage prior to use.
ENVISAGED CONSUMER MISUSE	• Temperature abuse • Consumed after 'Use By' date

manner and should show the interactions of the different activities. The purpose of the process flow diagram is to document the process and provide a foundation for the hazard analysis (Step 5).

To produce a flow diagram, it is necessary to separate the process into a series of steps. In the context of HACCP the word *step* refers not only to obvious processing operations but also to all stages that the product goes through, for example, incoming raw materials, storage, etc. The diagram should progress logically and relate to how the product is actually produced and should contain enough detail to allow an understanding of the process. The steps should be listed as 'activities' (i.e. what is happening at this step) and time and temperature information should be included where relevant. Equipment design features such as mesh sizes on sieves and filters used in sieving/filtration steps can be included to provide additional information to the HACCP team. A common error in HACCP is to list the names of the process equipment rather than the process activity and to miss out transfer steps, as in the example of milk-processing in Figure 12.2. This often results in an incomplete process flow diagram, which makes the process difficult to follow.

Incorrect labelling of equipment as process steps in this way can be a problem because there are some cases where more than one process step takes place in one piece of equipment, and these may have different hazards. If only the equipment name is recorded,

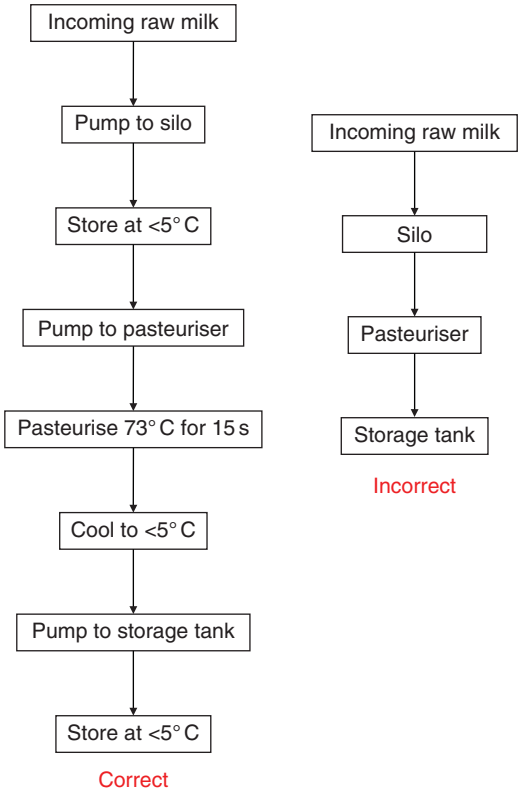

Figure 12.2 Common errors with process flow diagrams: Milk processing example.

then there is a chance that a process step and its associated hazards may be missed. Figure 12.2 shows a classic example of this: the pasteuriser used in milk processing. In this case both the pasteurisation heat process and the cooling process take place in the pasteuriser, and the raw milk heating up and pasteurised milk cooling down are separated only by a thin metal plate. Hazards associated with the heat process would include survival of vegetative pathogens while in the cooling process, a different hazard of cross-contamination with pathogens as a result of a leak in the pasteuriser plate pack may occur.

The most commonly used type of flow diagram for use in HACCP studies shows ingredients or groups of ingredients and how they are stored and handled until they are combined. This gives a realistic interpretation of what actually happens from the starting point of listing ingredients along the top of the page through to the end point with the finished product(s) at the bottom. The style of process flow diagram will also depend on how the HACCP system is structured for the operation and the terms of reference/scope of the HACCP study. In most manufacturing operations, unless the process is very simple, the modular approach to HACCP will be used (as discussed in Section 12.3.1). This means that there will be a series of process flow diagrams comprising the different process modules, and they should fit together to cover the whole operation. Only the initial modules will show the handling of ingredients but later modules should show the incoming inputs from the previous module (e.g. work-in-progress (WIP) or part-produced items). In foodservice operations, current thinking is to group all recipe items into a set of common processes as shown in Table 12.6. This means that, similar to modular HACCP in manufacturing, foodservice process flow diagrams will be generalised and will cover the processes but will not show individual ingredients or specific menu items. It will also be important to identify and analyse hazards that are associated with the individual ingredients.

Full detail of all process activities, storage, and transfer steps are needed in the HACCP study to allow a thorough hazard analysis to take place. This requires a detailed layout to be prepared; however, many companies also use briefer outline process flow diagrams (e.g. to gain an oversight of the operations or for sharing with customers). These may be at the level of showing how the HACCP modules fit together or somewhere in between; thus, there may be three levels of process flow diagrams in operation:

- Level 1 – Top Level: normally shows how HACCP modules fit together
- Level 2 – Intermediate Level: overview of main operations suitable for discussion with customers, general familiarisation, etc.
- Level 3 – Detailed Level: full detail on all process activities and steps allowing hazard analysis to be performed.

Tips for Constructing process flow diagrams

There are a number of conventions for flow diagrams.

- All ingredients or inputs to process modules are listed along the top of the page.
- The final product or output from the process module is placed at the bottom.
- The diagram is made up of a series of text boxes connected by arrows that denote the direction of process flow.

- Process steps are described as activities and not confused with equipment names.
- All variations on processing activities are included (e.g. when things are done differently on different shifts).
- If water, air, steam, and so on are used in processes (e.g. washing, cooking or drying), they are not listed as ingredients, but the place they enter the process is indicated. However, water as an ingredient should be included.
- Layout should be designed such that lines do not have to cross wherever possible.
- Reworking or backward flow must also be identified on the flow diagram. This common practice is an area that is easily forgotten but it is essential to include here for the hazard analysis.
- Normally all steps are numbered to allow ease of transfer of data onto the HACCP plan.

Example process flow diagrams developed by the HACCP team at Riviera Risottos are shown in Figures 12.3 through to 12.5. Note that diagram 12.3 shows how the modules fit together; Figure 12.4 has been developed as an overview flow diagram to show the linkage of the different processes used to make risottos and pasta meals, including both hot meals and cold rice and pasta-based salads. This diagram would need to have further detail added to understand exactly how the different subprocesses are conducted, and this has been achieved at Riviera Risottos by developing a series of flow diagrams covering the subprocesses, an example of which is shown in Figure 12.5 (Module 5 Cooking and Cooling Activities).

12.3.6 Codex Logic Sequence Step 5: On-Site Confirmation of Flow Diagram

Since the process flow diagram will usually be developed in the office away from the processing activities and it will be used as a tool to structure the hazard analysis, it is important to check and confirm that it is correct. This is done simply by going into the process area and comparing the documented diagram with the actual process activities, noting any changes necessary, and making sure that all variations (e.g. on different shifts) are covered. This exercise is normally done by members of the HACCP team or production personnel, but it is good to have someone independent to confirm the process flow because the on-site HACCP/production team may be too close to the processes and either miss points out or make assumptions. The completed process flow diagram should then be signed off and dated as valid. It is important to make sure that this is done before the hazard analysis commences.

Common problems with flow diagrams

- Insufficient detail is recorded for the process to be understood.
- Grouping together of process steps or ingredients results in omission of necessary steps/ingredients.
- Diagram is too complex and not easy to understand. This often occurs where engineering detail is included (e.g. technical outline of the process equipment).
- Inclusion of too much non-product/process information (e.g. quality checks such as weight control).
- Diagram does not include all possible permutations of product flow (e.g. additional holding stages or rework).

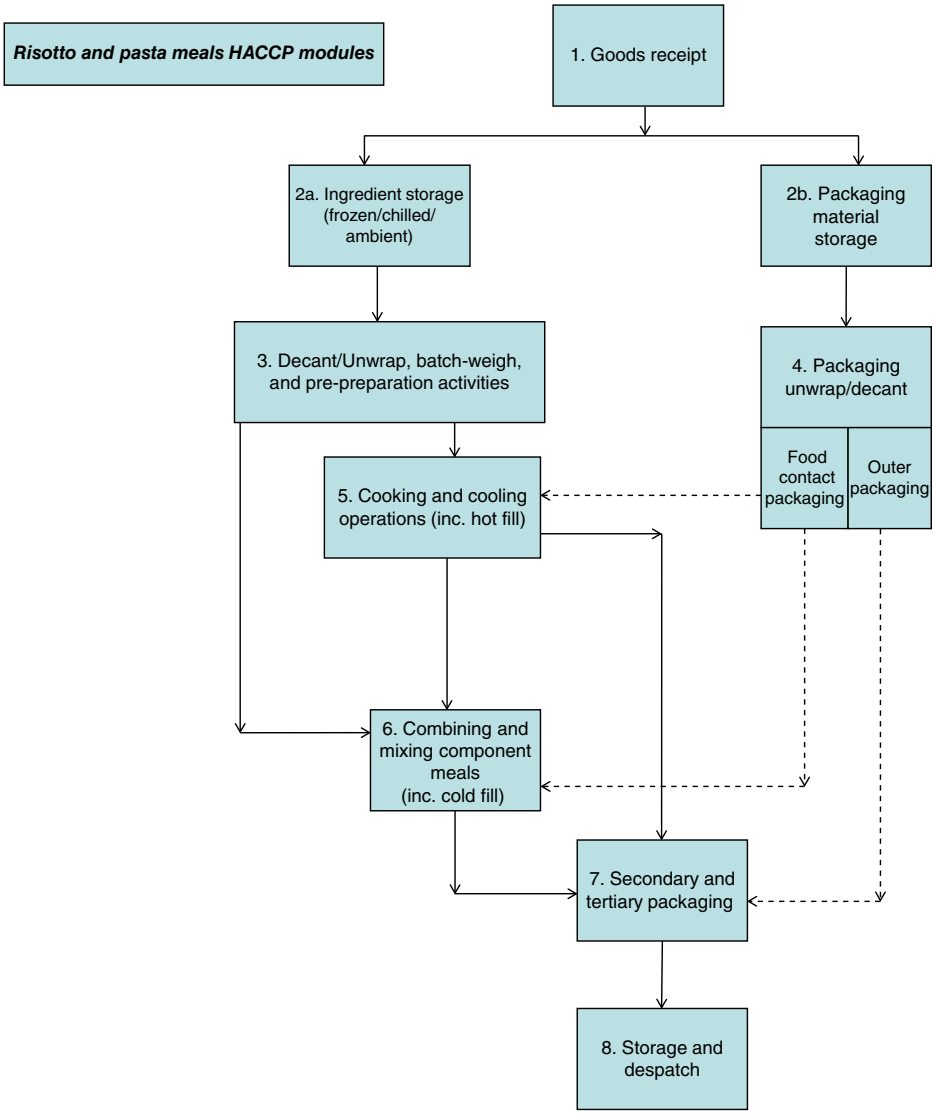

Figure 12.3 Riviera Risottos: HACCP Modules for risotto and pasta meals.

- Diagram is not representative of what really happens. This usually means that
  - it has not been verified and
  - the HACCP team do not have realistic site specific knowledge or have made assumptions because they are too close to the process.

12.3.7 Codex Logic Sequence Step 6: List All Potential Hazards, Conduct a Hazard Analysis, and Consider Control Measures (Apply HACCP Principle 1)

Using the process flow diagram(s), the HACCP team now needs to consider each process activity in turn and list any potential hazards that might occur. They should then carry

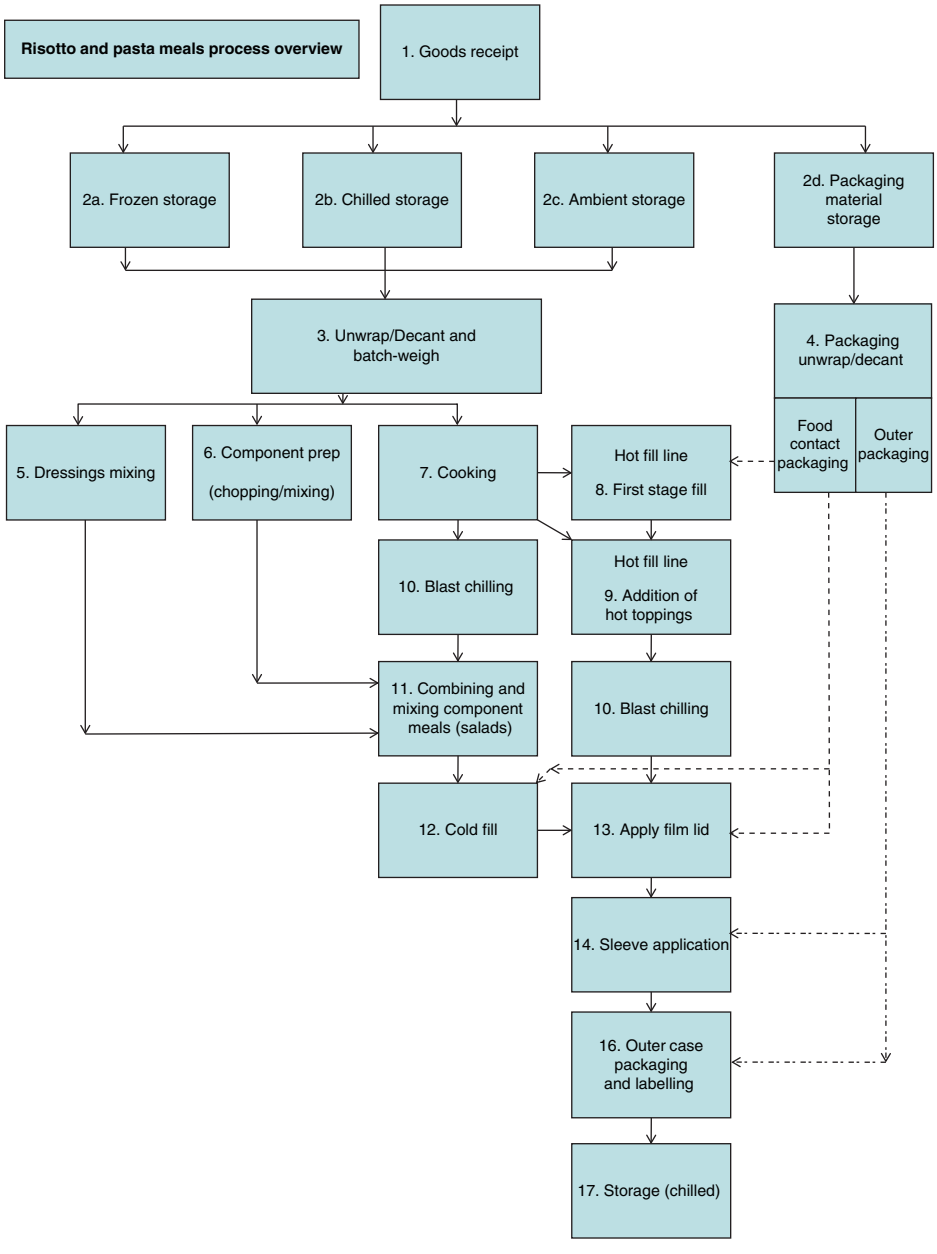

Figure 12.4 Riviera Risottos: Case study overview process flow diagram.

out an analysis to identify the significant hazards and identify suitable control measures. These terms are defined by Codex (2009b) as follows:

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

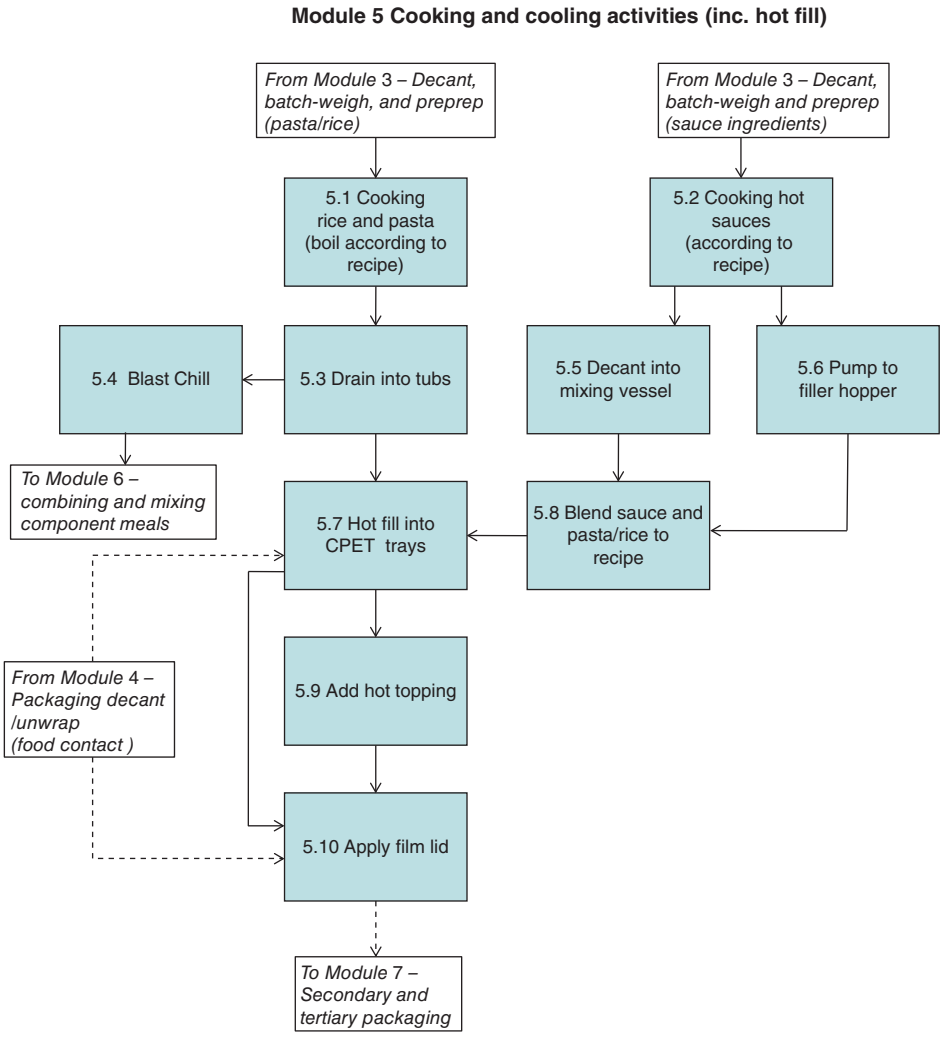

Figure 12.5 Riviera Risottos: Detailed process flow diagram HACCP Module 5.

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.*

Control Measure: *An action or activity that can be used to prevent, eliminate or reduce a hazard to an acceptable level.*

The NACMCF HACCP Guidelines (1997) very similar wordings to the Codex (2009b) definitions given, illustrating the agreement that exists at international levels. However, the NACMCF (1997) definition of a hazard differs slightly:

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

This provides a useful reminder of the need to evaluate risk to consumer health, which will be done alongside consideration of likelihood of occurrence during the hazard analysis, and to ensure that effective control systems are developed.

Hazard analysis is a key element of HACCP and will determine the strength of the resulting HACCP plan. The hazard analysis needs to be accurate and specific, including detail about the type of hazard and its source or cause, as well how the significance of specific hazards was determined and justified. If the hazard analysis is too brief or general, then the following steps in the HACCP study will be more difficult, and the HACCP plan is likely to be weak.

For *microbiological hazards* it is possible to generalise to a certain extent, but consideration should be given to specific pathogens. Microbial hazards are normally listed as specific organisms or using the collective terms, vegetative pathogens and spore-forming pathogens. A third term, toxin-forming pathogens, is also sometimes used, but organisms in this group could be either vegetative organisms or spore formers. The cause or source of the hazard needs to be established along with how the hazard is manifested in the process, that is,

- *Presence* of the hazard in a raw material,
- *Contamination* with the hazard during processing and handling,
- *Growth* of microorganisms during production, and
- *Survival* of microorganisms through a failure in a process designed to destroy them.

For *physical hazards* it is important to consider whether the item would genuinely cause physical harm to the consumer. Physical hazards are:

- Items which are sharp and may cause injury,
- Items which are hard and may cause dental damage, and
- Items which could block airways and cause choking.

For *chemical hazards* the hazard analysis will consider the likelihood or presence of toxic chemicals in the raw materials and contamination by chemicals during processing which may raise the toxicity to an unacceptable level. Further detailed information about hazards can be found in Chapter 5.

The process of hazard analysis includes:

- *Hazard Identification*: identifying which hazards may occur and where,
- *Assessment of Significance*: establishing which hazards are likely to occur and cause an adverse health effect, and
- *Identification of Control Measures*: establishing an effective mechanism for ongoing control of the hazard.

The hazard identification step is often approached by team brainstorming. This is a technique used to pool together ideas from members of the group. All team ideas need to be captured and recorded for evaluation of significance. A common approach to documentation of the hazard analysis is the use of Hazard Analysis Charts (Mortimore and Wallace 2013). Hazard analysis charts (Table 12.8) are used to help structure the hazard analysis, allowing HACCP teams to document the important aspects with respect to potential hazard identification, reasoning and decision making regarding significance and determination of appropriate control actions. This level of detail is important to the production of the HACCP plan.

Table 12.8 Hazard analysis chart headings.

Process step	Hazard: source, cause, and manifestation	Likelihood of occurrence (high/low)	Severity of outcome (high/low)	Significant? (yes/no)	Justification of significance decision	Control measure(s)	Justification of control measures

The process of hazard analysis requires the team to transcribe each process activity from the process flow diagram to the hazard analysis chart, consider any potential hazards along with their sources or causes, and then evaluate their significance. The source, cause, and manifestation information is useful because this helps in identifying an appropriate control measure and the inclusion of justification columns provides useful information for any future challenges of the HACCP plan (e.g. through external audit).

Determination of hazard significance

Codex (2009b) requires 'control of hazards that are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food' and states that the process of hazard analysis is intended to 'identify those hazards that are significant for food safety and therefore should be addressed in the HACCP plan'. Although the term *significant hazard* is not defined by Codex, the International Life Sciences Institute (ILSI 1999) offers a useful definition:

> ***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.*

To identify the significant hazards, it is necessary to consider the likelihood of occurrence of the hazard in the type of operation being studied as well as the severity of the potential adverse effect. A significant hazard, therefore, is one that is *both* likely to occur *and* cause harm to the consumer (Figure 12.6). Many companies will assess significance of hazards using judgement and experience but structured risk-evaluation methods, where different degrees of likelihood and severity are weighted, are often used to help with the significance decision. Currently, there are no definitive rules on this and no tools provided within Codex HACCP Principles and guidelines (Codex 2009b), although a historical approach to HACCP (NACMCF 1992) did include this kind of structured system. Because of the difficulties experienced by HACCP teams in ranking hazards (Wallace et al. 2014), there has been a resurgence in the use of these risk evaluation tools in recent years. This may be partly linked to uptake of the ISO 22000 audit standard, *Food safety management systems – Requirements for any organisation in the food chain* (ISO 2005), which requires formal records of hazard assessment to be maintained, although there is no specific requirement in the standard for any particular tool to be used; however, it is likely that general increases in

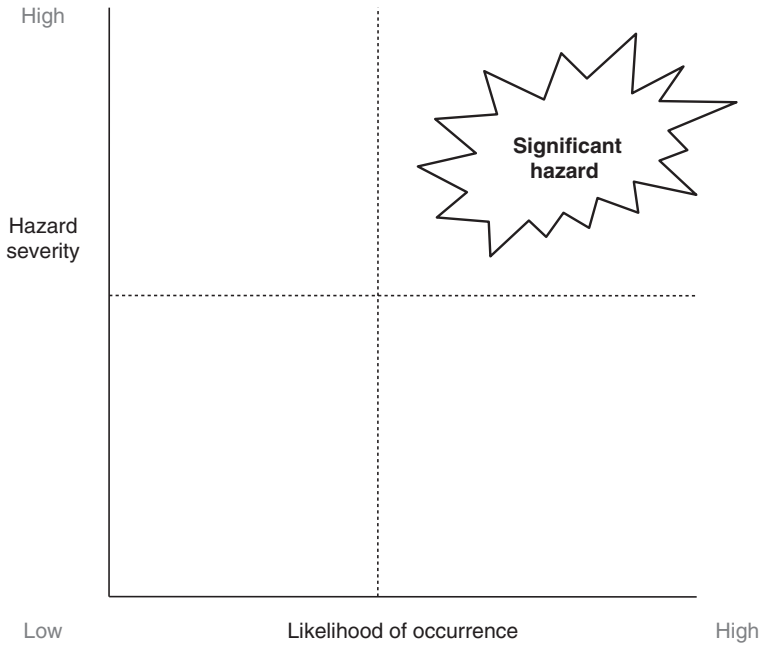

Figure 12.6 Significance assessment.

pressure for robust evidence of effective hazard analysis (e.g. for supplier/customer and third-party audits) may also have played a role.

Structured risk-evaluation methods often involve significance assessment tables which aim to consider the degree of likelihood and the severity of effect by rating these as, for example, 'high', 'medium', or 'low' (Table 12.9). This is similar to the concept shown in Figure 12.6 but aims to put individual hazards in boxes to assist with the significance decision.

Although these tools are generally believed to make significance assessment more straightforward by the companies using them, they do still require training in their application and use of judgement to position the identified hazards in the correct subcategories, i.e., a tool such as Table 12.9 is only useful if there is also guidance on which boxes are equivalent to significant hazards. An example of how this works is shown in Box 12.1. This example is provided in the *EU Commission Notice on the implementation of food safety management systems covering prerequisite programs (PRPs) and procedures based on the HACCP Principles, including the facilitation/flexibility of the implementation in certain food businesses*, 2016/C 278/01 (European Commission 2016).

Table 12.9 Example significance assessment table.

	Likelihood of occurrence			
		High	**Medium**	**Low**
Severity of effect	High			
	Medium			
	Low			

Box 12.1 Example of a hazard analysis – (semi-quantitative) risk-evaluation procedure

P = Probability; the probability that the hazard is occurring in the end product, if the considered specific control measures are not present or are failing – taking into consideration the next steps in the process where an elimination or reduction to an acceptable level is possible and taking into consideration the already correctly implemented PRPs.

E = Effect; the effect or the severity of the hazard related to human health.

RISK LEVEL: SCALE 1 TO 7

Probability (likelihood)						
	High	4	4	5	6	7
	Real	3	3	4	5	6
	Small	2	2	3	4	5
	Very small	1	1	2	3	4
			1	2	3	4
			Limited	Moderate	Serious	Very serious
			Effect (Severity)			

PROBABILITY

1 = very small	• Theoretical chance – the hazard never occurred before; • There is a next step in the production process which will eliminate or reduce the hazard to an acceptable level (e.g. pasteurisation, fermentation); • The control measure or the hazard are of such a nature that when the control measure is failing, no production is possible any more or no useful end products are produced (e.g. too high a concentration of colourants as additives); • It is a very limited and/or local contamination.
2 = small	• The probability that as a result of the failing or absence of the PRPs, the hazard will occur in the end product is very limited; • The control measures for the hazard are of a general nature (PRPs) and these are well implemented in practice;
3 = real	• Failing or lacking of the specific control measure does not result in the systematic presence of the hazard in the end product, but the hazard can be present in a certain percentage of the end product in the associated batch.
4 = high	• Failure or absence of the specific control measure will result in a systematic error, there is a high probability that the hazard is present in all end products of the associated batch.

(*Continued*)

EFFECT (or severity)	
1 = limited	• There is no problem for the consumer related to food safety (nature of hazard, for example, paper, soft plastic, large size foreign materials); • The hazard can never reach a dangerous concentration (e.g. colourants, *S. aureus* in a frozen food where multiplication to higher counts is highly unlikely or cannot happen because of storage conditions and cooking).
2 = moderate	• No serious injuries and/or symptoms or only when exposed to an extremely high concentration during a long period of time • A temporary but clear effect on health (e.g. small pieces).
3 = serious	• A clear effect on health with short-term or long-term symptoms which results rarely in mortality (e.g. gastro-enteritis); • The hazard has a long-term effect; the maximal dose is not known (e.g. dioxins, residues of pesticides, mycotoxins, …).
4 = very serious	• The consumer group belongs to a risk category and the hazard can result in mortality; • The hazard results in serious symptoms from which mortality may result; • Permanent injuries.

Determination of controls - CCPs and OPRPs when considered relevant

Risk levels 1 and 2: no specific actions, control covered by PRPs.

Risk levels 3 and 4: possible OPRPs. Additional question to be answered by the HACCP team: Is the general control measure(s) as described in the PRPs enough as monitoring for the identified risk? — If YES: PRP; — If NO: OPRP

Risk levels 5, 6, and 7: CCP or if no measurable critical limit exists this may be an OPRP (e.g. controlling an allergen).

Source: Adapted from European Commission 2016

Further assistance to consider when carrying out the hazard analysis is provided by Codex (2009b), which lists some brief points (Table 12.10) and NACMCF (1997), which lists a series of questions to help the HACCP team discuss different hazard issues (Table 12.11).

The series of questions in Table 12.11 is designed to be used as part of hazard analysis, as appropriate to the process under consideration (NACMCF 1997). The purpose of the questions is to assist in identifying potential hazards. Whilst some of these questions may help HACCP teams during the hazard analysis, many are more general questions about hygiene conditions at the facility and might prove more useful when evaluating the PRP requirements (see Chapters 9 and 10). In addition, there may be further questions to ask with the experience gained from more recent food incidents, such as when products are used for different means than intended (e.g. consumed raw rather than baked/cooked).

Further focus on the importance of PRPs in analysis and control of hazards is seen in guidance on flexibility of HACCP application for certain types of businesses, often

Table 12.10 Codex guidance on application of HACCP Principle 1.

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

The HACCP team should list all of the hazards that may be reasonably expected to occur at each step according to the scope from primary production, processing, manufacture, and distribution until the point of consumption. The HACCP team should next conduct a hazard analysis to identify for the HACCP plan which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food.

In conducting the hazard analysis, wherever possible the following should be included:

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

Consideration should be given to what control measures, if any exist, can be applied for each hazard.

More than one control measure may be required to control a specific hazard(s), and more than one hazard may be controlled by a specified control measure.

Source: (Codex 2009b).

Table 12.11 Examples of questions to be considered when conducting a hazard analysis.

1. Ingredients

- Does the food contain any sensitive ingredients that may present microbiological hazards (e.g. *Salmonella, Staphylococcus aureus*); chemical hazards (e.g. aflatoxin, antibiotic or pesticide residues); or physical hazards (stones, glass, metal)?
- Are potable water, ice, and steam used in formulating or in handling the food?
- What are the sources (e.g. geographical region, specific supplier)

2. Intrinsic factors: Physical characteristics and composition (e.g. pH, type of acidulants, fermentable carbohydrate, water activity, preservatives) of the food during and after processing.

- What hazards may result if the food composition is not controlled?
- Does the food permit survival or multiplication of pathogens and/or toxin formation in the food during processing?
- Will the food permit survival or multiplication of pathogens and/or toxin formation during subsequent steps in the food chain?
- Are there other similar products in the market place? What has been the safety record for these products? What hazards have been associated with the products?

3. Procedures used for processing

- Does the process include a controllable processing step that destroys pathogens? If so, which pathogens? Consider both vegetative cells and spores.
- If the product is subject to recontamination between processing (e.g. cooking, pasteurising) and packaging which biological, chemical or physical hazards are likely to occur?

4. Microbial content of the food

- What is the normal microbial content of the food?
- Does the microbial population change during the normal time the food is stored prior to consumption?
- Does the subsequent change in microbial population alter the safety of the food?
- Do the answers to the above questions indicate a high likelihood of certain biological hazards?

(Continued)

Table 12.11 (Continued)

5. Facility design

- Does the layout of the facility provide an adequate separation of raw materials from ready-to-eat (RTE) foods if this is important to food safety? If not, what hazards should be considered as possible contaminants of the RTE products?
- Is positive air pressure maintained in product packaging areas? Is this essential for product safety?
- Is the traffic pattern for people and moving equipment a significant source of contamination?

6. Equipment design and use

- Will the equipment provide the time-temperature control that is necessary for safe food?
- Is the equipment properly sized for the volume of food that will be processed?
- Can the equipment be sufficiently controlled so that the variation in performance will be within the tolerances required to produce a safe food?
- Is the equipment reliable or is it prone to frequent breakdowns?
- Is the equipment designed so that it can be easily cleaned and sanitised?
- Is there a chance for product contamination with hazardous substances (e.g. glass)?
- What product safety devices are used to enhance consumer safety?
  - metal detectors
  - magnets
  - sifters
  - filters
  - screens
  - thermometers
  - bone removal devices
  - dud detectors
- To what degree will normal equipment wear affect the likely occurrence of a physical hazard (e.g. metal) in the product?
- Are allergen protocols needed in using equipment for different products?

7. Packaging

- Does the method of packaging affect the multiplication of microbial pathogens and/or the formation of toxins?
- Is the package clearly labelled 'Keep Refrigerated' if this is required for safety?
- Does the package include instructions for the safe handling and preparation of the food by the end user?
- Is the packaging material resistant to damage thereby preventing the entrance of microbial contamination?
- Are tamper-evident packaging features used?
- Is each package and case legibly and accurately coded?
- Does each package contain the proper label?
- Are potential allergens in the ingredients included in the list of ingredients on the label?

8. Sanitation

- Can sanitation have an impact upon the safety of the food that is being processed?
- Can the facility and equipment be easily cleaned and sanitised to permit the safe handling of food?
- Is it possible to provide sanitary conditions consistently and adequately to assure safe foods?

9. Employee health, hygiene, and education

- Can employee health or personal hygiene practices impact upon the safety of the food being processed?
- Do the employees understand the process and the factors they must control to assure the preparation of safe foods?
- Will the employees inform management of a problem which could impact upon safety of food?

(Continued)

Table 12.11 (Continued)

10. Conditions of storage between packaging and the end user

- What is the likelihood that the food will be improperly stored at the wrong temperature?
- Would an error in improper storage lead to a microbiologically unsafe food?

11. Intended use

- Will the food be heated by the consumer?
- Will there likely be leftovers?

12. Intended consumer

- Is the food intended for the general public?
- Is the food intended for consumption by a population with increased susceptibility to illness (e.g. infants, the aged, the infirmed, immunocompromised individuals)?
- Is the food to be used for institutional feeding or the home?

Source: NACMCF 1997.

small retail and foodservice businesses. An example of this is the recent European Food Safety Authority (EFSA) Scientific Opinion on *Hazard analysis approaches for certain small retail establishments in view of the application of their food safety management systems* (Ricci et al. 2017).

In summary, whilst working through the hazard analysis, most experienced HACCP practitioners would weigh up the likelihood and severity to make a judgement on significance. We need to remember that risk is the probability or likelihood that an adverse effect will be realised. Risk evaluation decisions should be taken from a sensible viewpoint based on knowledge, experience, and data. Risk evaluation tools need expert knowledge in their application but can offer a structured framework for significance assessment in the right hands. However, in the wrong hands, errors in application of risk evaluation tools can lead to both inappropriate identification of extra hazards as significant or, more dangerously, non-identification of significant hazards (Wallace et al. 2014). Flexibility of approach will still be needed for many smaller businesses with limited technical resource, but this should be based on strong, science-based guidelines, such as from industry guides (Ricci et al. 2017).

Control Measures

Once the significant hazards have been established, effective control measures need to be identified for each significant hazard. As defined previously, control measures are the actions that can be used to prevent, eliminate, or reduce a hazard to an acceptable level. Control for each significant hazard is essential, but there may be more than one control measure for any hazard. There will also be control measures operating for PRPs.

Control measure options include:

- Process steps (e.g. cooking, sieving, metal detection),
- Product intrinsic factors,
- Use of approved suppliers,
- Temperature controlled storage or holding,
- Handling procedures, and
- Controlled segregation.

An important point about control measures is to make sure that they are capable of ongoing control of the hazard at all times. Often HACCP teams mistakenly identify

monitoring checks rather than controls – the measure must be control **not** monitoring, and effective control measures must:

- Relate to the hazard and source,
- Be comprehensive and appropriate, and
- Be validated (i.e. will it really control the hazard?).

When deciding on control measures it is important to consider the different options that may be available to control the particular hazard in order to establish the best method for control. This can include an evaluation of the measures currently in place, but it is important to decide whether these are strong enough or if additional control is necessary. Chapter 6 provides further detailed information on designing control options.

12.3.8 Codex Logic Sequence Step 7: Determine CCPs (HACCP Principle 2)

CCPs are the points in the process where the significant hazards must be controlled and are defined by Codex (2009b) as follows:

> ***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.*

CCPs can be identified using HACCP team knowledge or experience and by using tools such as the Codex CCP decision tree (Figure 12.7). The Codex CCP decision tree is a

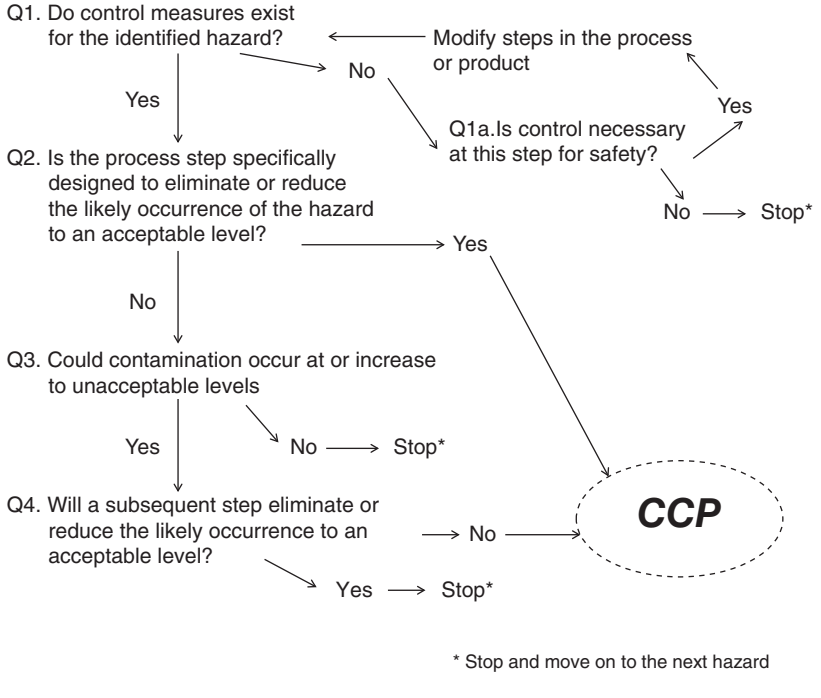

Figure 12.7 CCP decision tree. *Source*: Adapted from Codex 2009b.

useful tool and, although it may seem daunting to use at first, it does become easier with practice. In some cases, CCPs are specified by legislation (e.g. milk pasteurisation).

To use the decision tree, the questions are asked in sequence for each significant hazard that has been identified for each process activity as follows.

Q1 Do control measures exist for the identified hazard?

In most cases, when conducting the hazard analysis (Step 6), control measures will have been identified for the significant hazards. Therefore, it is most common to answer 'yes' to Q1. However, if the HACCP team could not identify a control measure then it is necessary to answer 'no' and move on to the subquestion, Q1a.

Q1a Is control at this step necessary for safety?

Perhaps control is not necessary at this process step for safety (e.g. there might be a control measure later in the process). In this the answer 'no' results in the decision that this step is not a CCP for that particular hazard and the instruction to stop/proceed (move on to the next hazard). However, if the HACCP team considers that control is necessary at this step for safety (perhaps there is no control later), then the answer 'yes' results in the decision tree instruction to 'Modify step, process or product', that is, carry out some modification to allow a control measure to be built in.

For example, if you were concerned about metal hazards entering a process but had no control measure later on that could remove them, it would be possible to carry out a modification to build in control through a suitable metal hazard removal system such as magnets or metal detection later on in the process.

Once a modification has been determined, the team needs to go back and ask Q1 again. Now they will be able to answer 'yes' and move on to Q2. A key point to remember, though is that **if you cannot establish a CCP for a significant hazard, then you cannot make the product** because it would always be potentially unsafe for consumption.

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

This is a key question in the Codex decision tree and one that people often have difficulty with. The question provides, in effect, a short-cut to a CCP decision for those process steps that are designed to control hazards (e.g. most cooking processes). The important thing to remember is that the question is asking about the process step and not the control measure. This is because control measures are always designed to control hazards so would always result in the answer 'yes'. Because you are asking the question about control measures, and a CCP is identified every time you answer 'yes', the result could be many more CCPs than are actually required. To make matters slightly more confusing some process steps are also control measures; these are the ones that this question is designed to find.

Where cooking processes are not specifically designed to control hazards then the team should answer 'no' rather than 'yes'. Not all cooking steps are CCPs; some are at such high heat processes, designed to change the physical structure of the product rather than for safety (e.g. some baking processes), that a significant hazard such as vegetative pathogens simply could not survive. In other words, the likelihood of occurrence should have been established as 'low' during the hazard analysis and it will not

be a significant hazard. Although this should have been identified at the hazard analysis stage, and therefore not be an issue during CCP decisions, some companies find in practice that customers or regulators insist on such steps being CCPs, even when there is clear justification that this is not required.
If the team believes the answer to this question is 'no', they should progress onto Q3.

Q3 Could contamination with identified hazard(s) occur in excess of acceptable level(s) or could these increase to unacceptable levels?
Note: Acceptable levels are safe for consumption and unacceptable levels may cause harm to the consumer.
If a significant hazard has been identified, then this is really already saying that something unacceptable could occur. Therefore, in most cases the answer to this question will be 'yes'. However, the question does give the chance to just think again and confirm whether it is unacceptable or acceptable. Sometimes use of the loop at Q1a resulting in a process modification might mean that the hazard(s) are no longer considered unacceptable (perhaps they have been designed out of the process completely), and so the answer would be 'no' in this case. Where you have answered 'yes' to this question, move onto Q4; otherwise stop and proceed with the decision tree for the next hazard.

Q4 Will a subsequent step eliminate the identified hazard(s) or reduce their occurrence to acceptable levels?
This last question allows the presence of a hazard at one process step if it is going to be effectively controlled at a later process step. It is helpful in keeping the CCPs to a manageable number, whilst making sure that the essential ones are identified. If there is a subsequent step in the process where the hazard will be controlled ('yes' answer), then the current process step is not the CCP but the later step will be. It is important to check that the later process step is properly identified as a CCP when the team gets to the end of the study. If there is no subsequent process that will control the hazard, then the current step needs to be made a CCP and managed accordingly.

In the same way as for hazard analysis, when working with the decision tree it is useful to keep a record of the team's discussions and justification of the decisions for future reference. This is normally done using a CCP Decision Record Sheet such as the one in Table 12.12. Even if the team is not using the decision tree, it will be important to keep a record of the decisions so that full evidence of the HACCP process is available to show regulators and auditors.

Once the HACCP team has worked through the processes for all the hazards, a list of CCPs will be available. These are the points in the processes that must be carefully managed to make sure that the food produced is safe. For each of the CCPs it is now important to define how they will be controlled and managed on a day-to-day

Table 12.12 CCP decision record.

Process step (Hazard)	Control measure	Q1	Q1a	Q2	Q3	Q4	CCP Y/N?	HACCP team notes (justification)

Table 12.13 Example HACCP Control Chart.

CCP no.	Process step	Hazard	Control measure	Critical limit	Monitoring			Corrective action	
					Procedure	Frequency	Responsibility	Procedure	Responsibility

basis. HACCP Principles 3, 4, and 5 are applied to set these standards, and normally this information is recorded in a HACCP Control Chart or Table such as the one in Table 12.13.

12.3.9 Codex Logic Sequence Step 8: Establish Critical Limits for each CCP (HACCP Principle 3)

Critical limits are the safety limits that must be achieved for each CCP to ensure that the food is safe. If the process operates beyond the critical limits, then products made will be potentially unsafe. Critical limits are defined by Codex (2009b) as follows:

Critical Limit: *A criterion that separates acceptability from unacceptability.*

Critical limits are expressed as absolute values (never a range) and often involve criteria such as temperature and time, pH and acidity, moisture, etc. Critical limits must be measurable and must be established for all CCPs. The choice of critical limit can be based on scientific and experimental data, industry or legislative standards, and historical evidence.

Critical limits are rarely the same as existing control parameters. For example, in cooking boiled eggs, one hazard might be identified as presence of *Salmonella* spp. in the raw egg, and this should be controlled by the cooking process. The critical limit to kill salmonella will be the equivalent of 70° C for 2 minutes in the centre of the egg. However, it would be unusual to cook eggs using these parameters; instead, the egg would be boiled in water at 100° C for, say, 6 minutes. It is important to know that these everyday process parameters would achieve the critical limit, along with what the margin of error is, and this is done by validating the process, which will be discussed in more detail later (Section 12.3.10).

As mentioned, critical limits never involve a range because they are the absolute value that defines the barrier between 'safe' and 'potentially unsafe'. Therefore, another measure that is often used for practical purposes in food operations is the 'target level' or 'operational limit'. The difference between critical limits and operational limits is illustrated in Figure 12.8. Operational limits provide a buffer zone for process management and indicate if a CCP is going out of control.

12.3.10 Codex Logic Sequence Step 9: Establish a Monitoring System for each CCP (HACCP Principle 4)

Once the critical limits, and operational limits, have been established, the next step in HACCP involves developing a monitoring system for ongoing measurement,

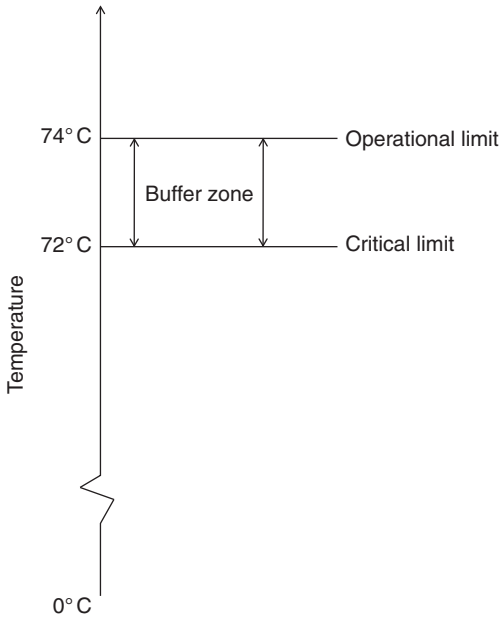

Figure 12.8 Critical limits and operational limits.

which will demonstrate that the CCPs are working effectively. Codex (2009b) defines monitoring as:

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

Monitoring is necessary to demonstrate that the CCPs are being controlled within the appropriate critical limits and monitoring requirements need to be specified by the HACCP team during the HACCP study. Each monitoring activity should have a person who is allocated to carry it out (CCP monitor) and record the results and take any necessary actions. In manufacturing, monitoring is usually done by production line personnel who are involved in operating the processes where the CCPs are located. The frequency of monitoring should also be defined and this will relate to the throughput of product in the particular process, i.e. in a fast-moving process that produces large amounts of product in a short time, the monitoring occasions may need to be closer together than in a slower process with a smaller throughput. This relates to the ability to handle the amount of product that is produced between monitoring checks if a CCP is found to be out of control (e.g. if monitoring checks are done every 30 minutes, then there will be less potentially unsafe product to handle than if the checks are done every 4 hours). The ideal is to have continuous monitoring systems linked to alarm and action systems. For example, metal detection is frequently used as a CCP in food manufacturing, and traditionally, metal detection effectiveness has been monitored manually via the use of test sticks at a given frequency. More recently, continuous monitoring of metal detectors by online computer systems has become possible and is used in some companies. In this case, the computer system does the monitoring, and this can be verified as effective by manual checks on the system (e.g. every 4 hours) as illustrated in Table 12.14.

Table 12.14 Comparison of regular and continuous CCP monitoring.

CCP Metal detection	Process step	Hazard	Control measure	Critical limit	Monitoring			Verification
					Procedure	Frequency	Responsibility	
Example 1 Manual Monitoring	Metal Detection	Metal in product	Effective metal detection and removal system in place	2-mm ferrous; 3-mm non-ferrous; 4-mm stainless steel	Check operation of detector and rejection mechanism with metal test pieces	Every 30 minutes	Line operator	Check and sign-off line records by supervisor every shift
Example 2 Online monitoring	Metal Detection	Metal in product	Effective metal detection and removal system in place	2-mm ferrous; 3-mm non-ferrous; 4-mm stainless steel	Online monitoring and recording by computer system.	Continuous	Line supervisor	Check operation of detector and rejection mechanism with metal test pieces every 4 hours

12.3.11 Codex Logic Sequence Step 10: Establish Corrective Actions (HACCP Principle 5)

Corrective action needs to be taken where monitoring shows that there is a deviation from a defined critical limit. Corrective actions must deal **both** with the product produced while the process is out of control (it may need to be destroyed or reprocessed) **and** with the process fault that has caused the CCP deviation in order to bring the process back under control. Codex (2009b) defines corrective action as follows:

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

As for monitoring, the corrective action procedures and responsibility need to be identified by the HACCP team during the HACCP study but will be implemented by the appropriate operations personnel if deviation occurs. Corrective action is not 'contact the Quality Manager' for every event. The multidisciplinary team should use their collective knowledge to brainstorm the likely failure modes and identify appropriate specific corrective actions for each eventuality. The effectiveness of the proposed corrective action plan needs to be verified and challenged because this is the last defence mechanism protecting the consumer from receiving potentially unsafe product should a CCP fail.

12.3.12 Codex Logic Sequence Step 11: Establish Verification Procedures (HACCP Principle 6)

Verification requires that procedures are developed to confirm that the HACCP system can and is working effectively. There are two different types of confirmation required:

1) It is important to check that the HACCP plans developed by the HACCP team will work effectively to control all the relevant hazards. This is done once the HACCP control charts have been completed, before implementation of the HACCP plan in the operation, and is known as **validation**. Validation is also done periodically after the HACCP plan has been implemented to check that the HACCP plan is still appropriate for the control of all relevant hazards, taking into account any changes that have occurred in the operations, processes, products, and ingredients, as well as any updates to knowledge on hazards.
2) The HACCP team needs to consider how to determine if the HACCP system is working effectively over time, once it has been implemented. This is known as **verification** and involves various procedures and methods that will be used to demonstrate compliance with food safety requirements.

Many people find the terms *validation* and *verification* confusing, partly because the words sound similar and partly because they are both part of the verification principle. They are actually two separate and different activities and would benefit from being separated out into two HACCP Principles (see Chapter 4). However, although they are both part of Principle 6, it is helpful to consider the definitions in more detail to help understand the difference (Table 12.15).

Table 12.15 Defining validation and verification.

Term	Codex Definition	Clarification
Validation	Obtaining evidence that the elements of the HACCP plan are effective	• Is the HACCP plan capable of controlling all relevant hazards if correctly implemented? **OR** • Will it work?
Verification	The application of methods, procedures, tests, and other evaluations, in addition to monitoring, to determine compliance with the HACCP plan.	• Is there compliance with food safety requirements defined in the HACCP plan **OR** • Is it working in practice?

Validation will include:

- Cross-checking through the HACCP plan to make sure that all the principles have been correctly applied.
- Checking that the hazards will be controlled, that is,
  - The control measures are suitable.
  - Correct CCPs have been identified.
  - Critical limits are set correctly for the hazard (e.g. using literature values, challenge testing, etc.).
  - Process will achieve the critical limit(s) (e.g. the process is capable of always achieving this limit within normal process variation).
  - Monitoring will detect loss of control if it happens.
  - Corrective action will prevent the potentially unsafe food being consumed.

Validation can be done by HACCP team members working with other managers within the business. As with preparing the HACCP plan, it will be better to involve more than one person if possible and, like hazard analysis, this will be an area where many companies will need to use expert resource from outside the company to assist in validation.

Commonly used **Verification** procedures include:

- HACCP audits,
- Review of CCP monitoring records,
- Product testing (microbiological and chemical tests),
- Review of deviations, including corrective action and product disposition, and
- Review of customer and consumer complaints.

Verification can also be done by HACCP team members or other personnel within the business (e.g. supervisory staff). It is important to have independence from the system to audit effectively so consideration can be given to using external resource or other personnel who were not involved in developing or in the day-to-day running of HACCP. Auditors should be competent because studies have shown that weaknesses exist in HACCP systems, even when audited by professional third-party auditors (see Chapter 2); therefore, it is recommended that food companies question the competency and experience of external HACCP auditors before their engagement.

12.3.13 Codex Logic Sequence Step 12: Establish Documentation and Record Keeping (HACCP Principle 7)

It is important to document the HACCP system and to keep adequate records. The HACCP plan will form a key part of the documentation, outlining the CCPs and their management procedures (critical limits, monitoring and corrective action). It is also good practice to keep documentation showing how the HACCP Plan was developed, i.e. the hazard analysis, CCP determination, and critical limit identification processes.

When the HACCP plan is implemented in the operation, records will be kept on an ongoing basis. Essential records include:

- CCP monitoring records,
- Records of corrective actions associated with critical limit deviation,
- Records of verification activities, and
- Records of modifications to processes and the HACCP plans.

In Europe, the legal requirements for food safety management include documentation commensurate with the size of the business, so smaller businesses would not be expected to keep the same level of documentation as larger ones. However, the key consideration for all businesses should be to have sufficient documentation to demonstrate the effective working of the HACCP system. Maintenance and archiving of HACCP records is therefore an important element of effective food safety management systems and will be discussed further in Chapter 14. Records may be kept as paper archives; however increasingly companies are turning towards computerised record keeping systems. This may involve simple scanning of paperwork for storage purposes or integrated systems where monitoring is done through handheld computer terminals, perhaps accessed by the CCP monitor using a swipe card, and the data are archived within the site computer systems.

12.4 Implementing a HACCP Plan

The implementation stage is where the HACCP plans are handed over from the HACCP team that has worked on the development process to the operations personnel who will manage the CCPs on a day-to-day basis. Training is therefore a key requirement, and this will include training for the personnel who will monitor CCPs and take corrective action, along with HACCP awareness training for the wider operations workforce. Implementation needs to be carefully planned, with responsibility for the various actions given to the appropriate people. It is not simply a case of handing the HACCP plan documentation over to the operations personnel; rather, there is a need for detailed and careful planning such that all the required activities for successful implementation can be identified and progressed.

12.4.1 Activities for Implementation of a HACCP Plan

When implementing a new HACCP plan, this is best achieved by breaking the necessary activities down into steps as in Figure 12.9. When implementing updates to existing HACCP plans, this will be more straightforward and may be done via a less formal

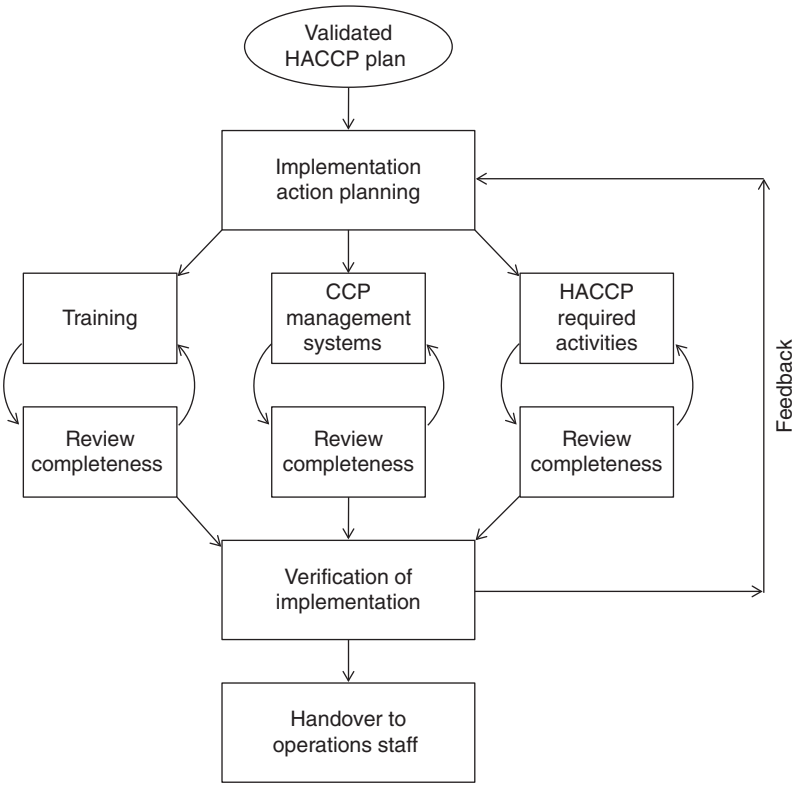

Figure 12.9 Steps to HACCP implementation. Adapted from Mortimore and Wallace (2001). Note that these steps of HACCP plan implementation do not have to occur in a set order as several activities could be going on at the same time involving different personnel.

approach; however, the importance of reviewing the completeness of each amendment and verifying that effective HACCP plan implementation has been achieved cannot be understated in either case.

Most companies choose a phased approach to implementation of HACCP plans, implementing a bit at a time to make sure each part works smoothly before moving on to the next. Implementation planning is, therefore, crucial to make sure that each piece of the 'puzzle' is completed and links with the others. Implementation always starts with the validated HACCP plan.

12.4.2 The Validated HACCP Plan

The requirements for validation of HACCP plan elements were discussed in Section 12.3.10. It is important to make sure that new HACCP plans have been validated and signed off as correct and suitable for control of all likely hazards in the operation before the implementation process commences. This is equally true for any amendments to existing HACCP plans and, in this case, validation will make sure that the amendments enhance and strengthen the existing food safety systems. It would be a great shame to implement a poorly thought out HACCP plan amendment that actually weakens food

safety control. Ensuring that the HACCP plan (or amendment) has been validated before implementation will prevent the need to go back to this step should deficiencies be identified during implementation, as this will result in loss of focus and credibility.

12.4.3 Implementation Action Planning

The main HACCP plan implementation activities will involve setting up CCP management systems, including monitoring and corrective action, alongside training of personnel and completion of any other initiatives required to support HACCP (e.g. PRP improvements from the gap analysis (see Chapter 9) or modifications to the processes or equipment, often issues which came through the decision tree loop at Q1a (Section 12.3.8). It is important to construct a detailed activity list for all implementation activities, which can be checked off as each task is completed. This should include details of who is responsible and also the deadlines for action, i.e. an implementation timetable. Project planning techniques, as discussed in Chapter 9, including use of Gantt Charts (Figure 12.10) are useful to keep the implementation plan on track. These form a pictorial representation of the timetable and capture a list of all the main and subactivities plus their priorities; however, a simple listing of what needs to be done, when, and by whom will suffice.

Key considerations at the action planning stage will include:

- Review of CCP management requirements from the HACCP plan against current control systems, identification of gaps, and development of necessary procedures (e.g. availability and calibration requirements of monitoring equipment).
- Identification of additional support initiatives for HACCP, comparison with existing support systems, and development of procedures to fill gaps in current systems.
- Listing of any modification requirements identified during the HACCP study, communication with appropriate personnel, and planning the necessary work.
- Consideration of personnel resources available and necessary to manage the HACCP plan on a day-to-day basis. Identification of knowledge and skills gaps and planning of appropriate training.
- Consideration of existing documentation, identification of gaps, and planning the redesign.
- Consideration of the general HACCP awareness levels of management and operations personnel, identification of implementation champions, and planning of management support strategy.

The action plans produced should be seen as a 'work-in-progress' and should be regularly updated as actions progress or new action requirements are identified.

12.4.4 Training

As discussed in Chapter 9, all staff in the operation will need some awareness training about the HACCP system and food safety requirements. Personnel who will carry out monitoring and corrective action will need more detailed training about their roles. Specifically, they will need to understand the monitoring procedure (i.e. exactly what they have to do), the frequency, where they should record results, and what to do if

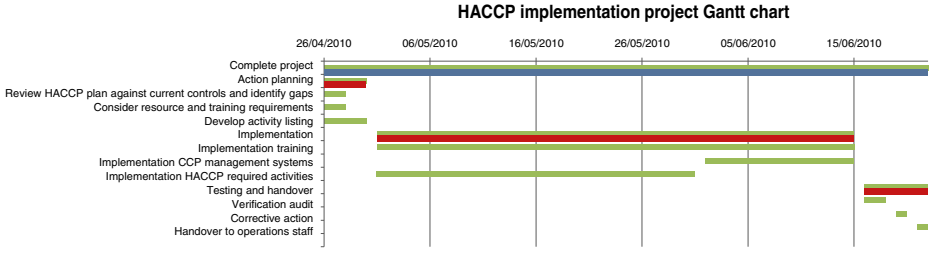

Figure 12.10 HACCP implementation project Gantt chart.

the results show that the CCP is out of control (i.e. the corrective action that must be taken). Management personnel, particularly those overseeing operations areas where the HACCP plan is being implemented, will also need both HACCP awareness training and an understanding of their key role to support the implementation. Promotional management (Wallace 2009) is seen as a key factor in the success of HACCP; in other words managers who are committed to the HACCP project and show this commitment both through ongoing promotion of HACCP requirements to their staff and by being instrumental in providing necessary resources and support for its implementation. Foremost in gaining this level of commitment is appropriate training about HACCP, the current status, and necessary steps to get the HACCP plan working.

HACCP training at the implementation stage is often done by HACCP team members or managers who have been involved in the HACCP process and who now have experience of applying HACCP to supplement their own knowledge. It is important that the personnel involved in this key step have appropriate training skills and that transfer of the key messages via training can be verified. In addition to the HACCP training, training in, and/or communication of, the application of the HACCP implementation action plan will be necessary, in particular how the implementation affects and amends current working practices. External trainers could be used to support this training but will need to be fully briefed on how HACCP fits the specific applications on site.

CCP monitor training will be a key aspect of the implementation training requirements. This may be done by HACCP team members but could equally be achieved by personnel from the production or engineering teams, or the wider food safety team, including human resources personnel. Training of supervisory personnel who will verify and countersign the monitoring records on a day-to-day basis is also crucial to ensure that they also understand the importance of monitoring and corrective action and that they know what to expect to see on the specific monitoring records. This will help to overcome the problem of defective monitoring and corrective action records (e.g. where monitoring has been missed or where CCP deviation is recorded but no corrective action is apparent) being signed off by supervisors without challenging the specific defects.

12.4.5 CCP Management Systems

CCP management systems include the monitoring and corrective action requirements for CCPs, plus the appropriate process control verification, including calibration. The required monitoring and corrective action procedures should have been defined in the HACCP plan. For successful implementation, the content of the HACCP plan needs to be converted into work instructions or standard operating procedures (SOPs) that will be followed by the trained personnel with monitoring and corrective action roles. At implementation it is important to make sure all the required facilities, equipment, and documentation are available and that the systems will work, i.e. will the monitoring detect deviation from the CCPs when it occurs? Will the corrective action procedure correctly identify and deal with (e.g. quarantine/destroy) the potentially unsafe product and bring the process back under control? This is also an opportunity to reconfirm the process capability to control hazards at the identified CCPs; this should have been established during validation of the HACCP plan elements but at implementation it is important to ensure that these systems will work in practice.

There is also a clear link between the CCP management systems aspect of HACCP plan implementation and training to make sure that the personnel involved in day-to-day management of CCPs understand their roles and responsibilities and the consequences of CCP failure.

Documentation for ongoing CCP management will include written/pictorial work instructions for CCP monitoring, corrective action and, where appropriate, calibration. Record-keeping systems will also be needed, and these should be carefully designed so that it is clear exactly what the records mean after the event. Experience shows that this is an area where weaknesses can be found when CCP records are examined during audits. For example, if a dash (-) is recorded on the monitoring sheet where a 'yes' or 'no' answer is expected, does this mean that there is a 'no' answer or that the CCP wasn't checked or that production wasn't running? Careful consideration of what information is needed from monitoring to demonstrate that the CCP is operating within its critical limits will help to ensure good design of monitoring record sheets. This will need to be supported by effective training to ensure that all CCP monitors are completing the records accurately and that this is being verified by supervisors on an ongoing basis.

Although it is not necessary to always develop completely new record-keeping formats if suitable record sheets are already in place, it is important to make sure that the existing formats are capable of capturing the required information in a structured way. Consideration should also be given as to how records will be archived, so that they can be readily identified at a later stage. Where electronic monitoring systems are to be used, it is important that the system can be proven as effective, including challenging to show that only trained CCP monitors can input data, that this can only be done in real time, and that the data can be archived securely and cannot be changed/overridden after the event.

Where HACCP is regulated, some companies keep HACCP records completely separate from other production records for ease of regulatory inspection. It is up to each individual company to decide the best approach for record keeping and retention for its business; however, the important point is to be able to demonstrate that food safety has been maintained during production so the chosen approach must achieve this at a minimum.

12.4.6 HACCP Required Activities

HACCP required activities are the actions that need to be taken to support implementation of a new or reviewed HACCP plan. This will include PRP elements that need to be developed and implemented to strengthen or fill gaps in existing PRPs (Chapter 10), plus any process, equipment, or process area modifications that have been identified as essential to support the HACCP plan.

As discussed in Chapters 9 and 10, it is important to perform a PRP gap analysis and to implement appropriate, formally managed prerequisites as a cornerstone for food safety. Any gaps identified at that stage must now be put in place plus further necessary amendments identified during the HACCP team's deliberations must be rectified. Since the HACCP plan can only be effective if these PRPs are also working in practice, it is normal to perform a completion check on prerequisites at the time of HACCP plan implementation.

Any other modifications identified as necessary for food safety by the HACCP team must also be implemented at this stage. This could include steps to tighten protection of product from the processing environment, such as additional/modified covers for production equipment or removal of redundant plant and equipment (e.g. pipe work).

12.4.7 Verification of Implementation

Verification of HACCP plan implementation is a vital step in achieving effective control of food safety. This forms the initial verification of the HACCP plan as a baseline for continued HACCP system verification, which will progress as part of the food safety system maintenance procedures (Chapter 14). Verification of implementation is normally done by auditing the system immediately after implementation, i.e. in the first few days. The audit should be performed by trained auditors who are independent from the system, both in terms of its development and its day-to-day management. This is best managed by trained systems auditors, who can challenge all aspects of the documented HACCP plan, the related work instructions and SOPs, and the items on the detailed implementation activity list. All findings from the audit must be documented and necessary corrective action must be taken immediately such that the HACCP plan implementation status is confirmed.

12.4.8 Handover to Operations Staff

Although operations staff will clearly be involved in the steps of implementation (Figure 12.9), formal handover for the day-to-day running of the HACCP plan is necessary so that the requisite staff take ownership of the system. Like all other aspects of HACCP implementation this needs to be carefully planned, such that sufficient personnel resources are available to take on HACCP management and that all personnel involved receive appropriate training for their roles.

When planning the handover, it will be necessary to review job descriptions for staff involved and to add their new CCP management responsibilities where appropriate. This should tie in with the work instructions/SOPs and training given to staff. It is important that operations staff understand the importance of the HACCP system and the crucial role that they play in its ongoing effectiveness. It is equally crucial that they are confident in their abilities to manage the CCPs and take necessary corrective action, and this should be verified following training. It is useful for members of the HACCP team or food safety team to work closely with operations staff for a short period after implementation to help build up confidence levels. This will help both to support personnel in taking the necessary actions at CCPs and to reinforce the food safety requirements.

12.4.9 Considerations for Implementing Updates and Changes to an Existing HACCP System

A common failure in HACCP systems is the failure to keep the HACCP plan up to date through controlled amendment. This is often clear from HACCP audit, where process and ingredient changes may become immediately obvious when following through the process flow diagram, and changes in control procedures are detected when assessing the records of the working HACCP system. The need to review and update existing

HACCP plans as key elements of the effective food safety management system will be discussed further in Chapter 14; however, it is important to consider the implementation of these amended HACCP plans at this stage in the HACCP application process.

The approach for implementing updates and changes to existing HACCP systems may be less formal than the step-wise approach discussed; however, it is essential to make sure that these changes are working effectively before passing the responsibility for their day-to-day management over to operations personnel. Any HACCP plan amendments that affect monitoring, record keeping, or corrective action will require retraining of the appropriate CCP management personnel and may necessitate further changes to job descriptions, work instructions/SOPs, HACCP record-keeping sheets, etc. It is easy for items to be overlooked, so a checklist of specific points, similar to the detailed activity list used for implementation of new HACCP plans, will be beneficial.

12.5 Conclusions

Application of HACCP principles is achieved by following a straightforward step-wise procedure outlined by the Codex (2009b) logic sequence. This will only result in an effective HACCP system if performed by HACCP teams made up of personnel with the correct blend of training, skills, and experience. The outcome of this HACCP study process should be a HACCP plan that clearly defines how all significant hazards relevant to the operation will be controlled.

The implementation of new HACCP plans or HACCP plan amendments is an essential aspect of food safety management, which requires careful planning and attention to detail. 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. 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. This requires appropriate support from the HACCP team and company management in addition to constant reinforcing of the importance of food safety requirements.

13

Food Fraud and Food Defence

13.1 Introduction

This chapter has been developed in recognition of the growing number of criminal incidents involving food fraud, the threats from potential food terrorism, and the need for food defence measures to protect the global food supply chain. Building on the previous edition of this book, there is recognition of similarity in the management and control procedures for these threats and those that have been used for decades to control the hazards necessary to assure food safety.

Throughout the 20th century a great deal of research was conducted to enhance the stability and safety of food products. As a matter of course, those efforts focussed almost exclusively on the prevention or retardation of food spoilage, the control of an ever-increasing array of microbial pathogens, and preventing the accidental introduction of toxic chemicals and hazardous foreign materials. Whilst continued research is necessary to better control microbial and chemical agents in the food supply chain, new threats have arisen in the past several decades because of human actions. The new threats – categorised as food fraud, food crime, economically motivated adulteration, and food terrorism – also demand our attention to protect the global food supply chain, to protect the public health, and to provide food security, that is, an adequate supply of food for an ever-expanding human population. Important to all consumers, the topic of food security was addressed in Chapter 3 (Section 3.2.2); however, the important topic of food defence, to prevent and control these new threats, will be considered in this chapter.

It is not easy to draw sharp boundaries between the new food fraud and food-defence efforts that are now being used in addition to the food safety and quality control programmes that have been developed and improved for more than half a century. Many of the same facility personnel will be involved in all of these efforts. It is essential that they can detect and prevent disruption of their supply chain, including ingredient procurement, transportation, and storage, and maintain the inspection and control of their processing facilities.

13.2 Essential Definitions

Food fraud, food terrorism, and food defence are complex areas with several interrelated concepts that need to be understood. There is little standardisation of language internationally but key issues in understanding the differences between these concepts are

Food Safety for the 21st Century: Managing HACCP and Food Safety Throughout the Global Supply Chain, Second Edition. Carol A. Wallace, William H. Sperber, and Sara E. Mortimore.

whether food is accidentally contaminated or deliberately contaminated (adulterated) with a substance or organism and whether that contamination is potentially harmful to the consumer. Unfortunately, some of the terms (e.g. *adulteration*) are used for both accidental and deliberate contamination in some parts of the world, and this adds to the complexity of this fast-evolving area of literature (Manning and Soon 2016) and practice. Definitions proposed by key groups working in these areas will be provided to give an understanding of current thinking on how this relates to protection of the food supply chain and consumer health.

13.2.1 Food Fraud

Food fraud is also known by the terms *food crime* and *economically motivated adulteration* (EMA). Key definitions are as follows:

Food fraud *deliberately placing food on the market, for financial gain, with the intention of deceiving the consumer (Elliott Review (HM Government 2014)).*

Food fraud *A dishonest act or omission, relating to the production or supply of food, which is intended for personal gain or to cause loss to another party (National Food Crime Unit [NFCU] no date).*

Food fraud *is a collective term used to encompass the deliberate and intentional substitution, addition, tampering, or misrepresentation of food, food ingredients, or food packaging; or false or misleading statements made about a product for economic gain (Spink and Moyer, 2011).*

Economically motivated adulteration *Fraudulent, intentional substitution or addition of a substance in a product for the purpose of increasing the apparent value of the product or reducing the cost of its production, i.e., for economic gain (Food and Drug Administration [FDA] 2009b; Spink and Moyer 2011).*

These definitions of food fraud and EMA illustrate the intentional element of food fraud and, most importantly, the fact that it is for financial gain. Similarly, although there is no harmonised European Union (EU) definition of food fraud, the EU Commission states that 'it is broadly accepted that food fraud covers cases where there is a violation of EU food law, which is committed intentionally to pursue an economic or financial gain through consumer deception' (European Commission 2017). All these statements and definitions indicate that food fraud is clearly criminal activity because fraudsters are deliberately misleading their customers and/or the consumer about food products which are not as they seem; however, food crime has also been defined separately and may be thought of as a more complex or organised activity. 'Food fraud becomes food crime when it no longer involves random acts by "rogues" within the food industry but becomes an organised activity by groups which knowingly set out to deceive, and/or injure, those purchasing food' (HM Government 2014).

Food crime *Dishonesty relating to the production or supply of food, that is either complex or likely to be seriously detrimental to consumers, businesses or the overall public interest (NFCU no date)*

13.2.2 Food Terrorism

Food terrorism is defined *as an act or threat of deliberate contamination of food for human consumption with chemical, biological, or radio-nuclear agents for the purpose of*

causing injury or death to civilian populations or disrupting social, economic or political stability (World Health Organisation [WHO] 2003)

The key differences between food terrorism and food fraud/crime relate to the intent of the contamination. Both are deliberate acts; but food terrorism is intended to harm consumers or disrupt political stability, whereas food fraud/crime is intended for financial gain.

13.2.3 Food Defence

Food defence (North America: food defense) is generally thought of as a set of countermeasures directed towards intentional contamination of the food supply chain. A widely accepted definition of food defence is:

> *The effort to protect food from intentional acts of adulteration where there is an intent to cause wide scale public health harm* (FDA 2016b).

Several other definitions of food defence have been proposed by different groups and are included here:

> *Procedures adopted to assure the security of food and drink and their supply chains from malicious and ideologically motivated attack leading to contamination or supply disruption* (British Standards Institute [BSI] 2014).
> *The collective term used to describe activities associated with protecting the nation's food supply from deliberate or intentional acts of contamination or tampering* (FDA 2014).
> *The process to ensure the security of food and drink and their supply chains from all forms of intentional malicious attack including ideologically motivated attack leading to contamination or supply failure* (Global Food Safety Initiative [GFSI] 2017).
> *Having a system in place to prevent, protect, respond and recover from the intentional introduction of contaminants into our nation's food supply designed specifically to cause negative public health, psychological and/or economic consequences* (Yoe et al. 2008).

Common in all these definitions of food defence is the concept of deliberate or intentional acts, and this helps us to see the difference between food safety management systems, which are directed towards natural or accidental contamination with food safety hazards, and food defence systems, which are geared towards protecting from intentional acts of harmful contamination. Whilst GFSI (2013) and BSI (2014) focus on damage to the supply chain, the current FDA (2016b) definition illustrates that we need to defend against attempts to cause public health harm, underlining the consumer safety aspect of food defence. The Yoe et al. (2008) definition expands on this concept, although also straying into the 'economic consequences' area related to food fraud. This further illustrates the complexity and evolution of thinking in this area.

13.2.4 Food Protection

Food protection is often described as *an umbrella term encompassing food defence and food safety* (Food Protection and Defense Institute, n.d.). A recent definition focusses on

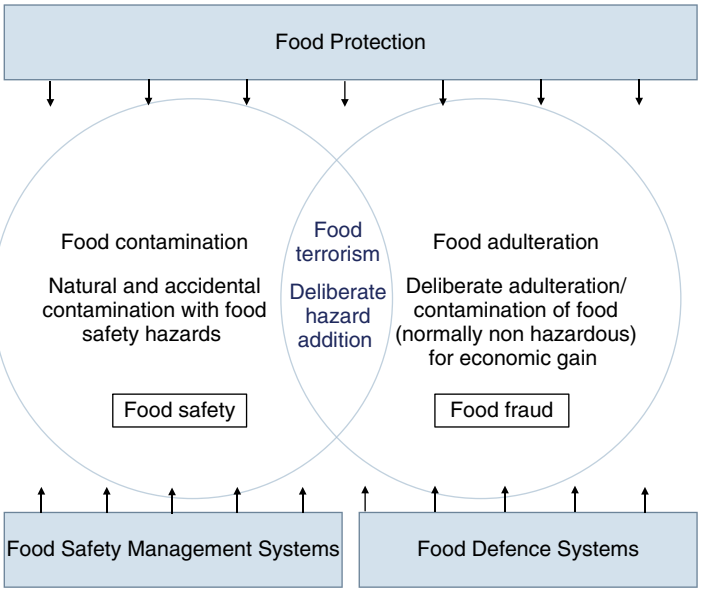

Figure 13.1 Food Protection Concepts.

protection from fraudulent incidents:

> ***Food protection*** *procedures adopted to deter and detect fraudulent attacks on food* (BSI 2014). However, many practitioners would still consider food protection as combining measures for defending from accidental and deliberate contamination.

Figure 13.1 shows the relationships between the concepts discussed in the preceding definitions and how they interact with food safety hazards and food safety management systems. In this chapter we will use the terms *food fraud, food terrorism,* and *food defence* when discussing these emerging elements of the world-class food safety programme.

13.3 Food Fraud

13.3.1 The Food Fraud Problem

As outlined, food fraud is the deliberate adulteration or misrepresentation of foods or food ingredients for economic gain. Fraudulent tactics can include dilution, substitution, origin masking, concealment, mislabelling, counterfeiting, or the addition of an unapproved additive or enhancement (Figure 13.2). The goal of food fraud is to make money; the perpetrators do not (normally) intend to cause illnesses or deaths in consumers. However, they can make mistakes and are unlikely to be thinking about food safety measures when planning and participating in this criminal activity. Over the years, food fraud incidents have resulted in numerous illnesses and deaths in consumers – human and animal.

The Grocery Manufacturers of America (GMA) estimated that food fraud might be costing the global food industry between $10 and $15 billion a year, affecting approximately 10% of all commercially sold food products (GMA 2010). According to food

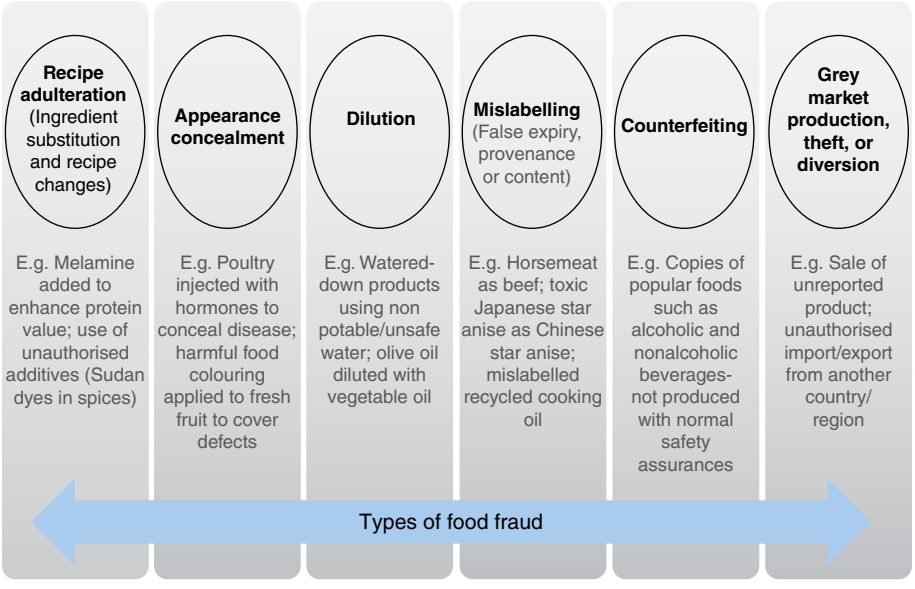

Figure 13.2 Types of Food Fraud.

fraud investigator, Mitchell Weinberg, 'Around the world, food fraud is an epidemic. In every single country where food is produced or grown, food fraud is occurring' (Andrews 2015). This is a global problem and food fraud is being taken seriously on many fronts. For example, beginning on 1 June 2016, food fraudsters in the Netherlands were fined 10% of their annual turnover instead of the previous maximum of €20 000. Because food fraud can jeopardise human health and erode the public's trust in the safety of their food, it is important that it be detected and remedied quickly.

The Global Food Safety Initiative (GFSI), a leading organisation in food-control standards and audit schemes, recognised that products adulterated by food fraudsters could create a food safety incident (GFSI 2014). Following its motto, 'Provide safe food for consumers everywhere', GFSI created a Food Fraud Think Tank comprised of experts in analytical testing, certification, supply chain security, criminology, manufacturing, and retailing. The think tank recommended two initial steps to mitigate the threat of food fraud.

- Each facility should conduct a 'food fraud vulnerability assessment,' collecting information throughout the supply chain and
- Implementing control measures that would reduce the risks from identified vulnerabilities.

Both of these recommendations will be discussed later. In addition, some countries are establishing national bodies to fight food fraud and food crime (e.g. the UK National Food Crime Unit). Collaboration across national borders is essential for effective food fraud investigation.

13.3.2 Learning from Examples of Food Fraud

Food fraud is not new but has occurred in various forms for hundreds of years. Throughout history beer and milk have been watered down, staples like flour have been

adulterated with chalk, and spices with dust and nutshells. Food fraud was a significant and widespread problem through the 19th and early 20th centuries and was a key reason for much early food legislation (Wilson 2008). In more recent years from the late 20th through to the early 21st centuries, several high-profile and significant incidents have brought focus once again on the food fraud problem (Table 13.1). The examples shown in the table highlight that, although not the initial intent of the fraudsters, food fraud can pose a significant public health risk, and this is a key consideration on top of the financial and reputational risks to the food supply chain.

These well-known examples (Table 13.1) show the major impact of food fraud; however, it is important to also consider in more detail the different types of food fraud (Figure 13.2) to understand some of the countermeasures that are necessary in the modern food system. Exploring examples of these issues helps us to understand the potential food fraud modes so that those responsible for the detection and prevention of food fraud can consider some of the areas where they might be vulnerable to economic adulteration of their company's products.

Recipe Adulteration (ingredient substitution and recipe changes)

All of the serious incidents in Table 13.1 would fit within this category of food fraud – although the Sudan Red incident could also be described as concealment – but it is important to think about other opportunities that may be lower profile. Often this type of fraud relates to replacing expensive ingredients with inexpensive fakes. There have been multiple incidents in which apple pieces were dyed blue or red to mimic the more expensive blueberries or cherries. Similarly, it has been reported that pomegranate juice has often been diluted or faked. More seriously, substitution of less expensive peanuts for other nuts such as pine nuts and hazelnuts has occurred on a number of occasions and this produces a double jeopardy – food fraud, with the additional hazard of allergenic reactions to the peanuts. There are many other examples in this category, including not only the fairly well known substitution of ground cumin spice with ground peanut hulls, which had significant food safety implications, but also other spices as these are often expensive and frequently targeted for EMA activities; black pepper, turmeric, chilli powder, and saffron have all been reported as being prone (Agres 2015). Other well-known examples include the addition of ethylene glycol (anti-freeze) to wine with potential toxic effects and addition of methanol to various alcohol products, which has been responsible for consumer deaths.

Appearance Concealment

This category often relates to practices to continue using products that are past their best (e.g. putting mouldy pumpkins into a blending machine for blending pumpkin pie mix where the mould will not be noticed). Poultry injected with hormones to conceal disease and benign or harmful food colouring applied to fresh fruit to cover defects are further examples. The addition of Sudan Red to spices (Table 13.1) was also aiming to suggest freshness of the spices concerned and conceal the age or poorer quality.

Dilution

Adulteration of raw whole milk by the removal of butterfat or the addition of water was commonplace at the beginning of the 20th century and remains a commonplace problem in some less-developed parts of the world. A University of Wisconsin professor, Stephen Babcock, invented a testing device that measured the amount of butterfat,

Table 13.1 Examples of major food fraud incidents.

Year	Country/ Region	Food	Fraud/ Contamination Issue	Notes on Incident and Causes	Impact	Safety Concern?	Reference
2015	United States	Ground cumin	Substitution with ground peanut hulls	Ground cumin was diluted with ground peanut and almond hulls. Speculation as to the geographic source centred on Turkey and India. The motivation was almost certainly economic fraud.	A major food-industry concern sparked a wave of activity for manufacturers who were using ground cumin in their products. Ground cumin and cumin containing products were recalled with more than 700 recalls and 40 manufacturers impacted	This was a definite safety concern for peanut allergen.	Agres 2015
2013	Europe	Beef products	Substitution with horsemeat	Horse DNA detected in beef burger samples in laboratory in Ireland. Subsequently found in a range of beef products from retail and foodservice channels. Investigation identified complex supply chains and implicated traders in eight countries (Ireland, United Kingdom, France, Luxembourg, Cyprus, Netherlands, Romania, and Poland)	Major loss of consumer confidence in supply chain. UK government review and setting up of National Food Crime Unit.	Unlikely. Some suggestion of potential contamination with veterinary drugs but levels meant this was likely low risk. Although poor hygiene standards could be an issue in meat fraud cases, the supply chain in this case seems to have been through regulated abattoirs.	HM Government 2014
2008	China/ Worldwide	Dried milk powder	Melamine addition	Economic adulteration with melamine to boost nitrogen and simulate appearance of increased protein content	Major public health impact. Estimated 294 000 children suffered urinary tract stones; 51 900 hospitalised, and 11 babies died in China. Melamine found in milk powder from 22 Chinese manufacturers and identified in Chinese dairy products exported to 20 countries.	Yes. Although melamine was generally considered to have low system toxicity, it can complex with other substances to form kidney stones and urinary tract precipitates, leading to kidney damage. Infants at higher risk due to proportionally much higher consumption of dairy products for their size	Schoder 2016

(Continued)

Table 13.1 (Continued)

Year	Country/ Region	Food	Fraud/ Contamination Issue	Notes on Incident and Causes	Impact	Safety Concern?	Reference
2003 onwards	Worldwide	Chilli powder	Sudan Red dye added.	Economic adulteration with Sudan red dye to improve colour and conceal natural age degradation	Major investigations and recalls/withdrawals. No deaths reported. Resulted in new legislation – emergency decisions and follow-up regulation in Europe	Yes. Sudan dyes are Class 3 carcinogens and banned worldwide as food additives.	Silvis et al. 2017; Haughey et al. 2015;European Commission 2003, 2005, 2009
1981	Spain	Olive oil	Substitution with toxic industrial use rapeseed oil mixed with other oils	Rapeseed oil which had been denatured with 2% aniline (a legal requirement for industrial use sale) was fraudulently mixed with other oils and sold as olive oil for human consumption. The oil was sold in unlabelled 5L containers by itinerant street vendors. The fraudsters had heated the oil up to 200°C to remove the aniline; however, the result was that the oil became poisonous through a complex reaction between the fatty acids in the oil and the aniline to form oleonilides. The government issued a warning and instigated an exchange system to replace all olive oil in people's homes with known good oil	Major public health impact: more than 20 000 people became ill and several hundred deaths occurred in the first phase (416 deaths within 2 years) following initial sets of symptoms (acute illness); longer-term chronic effects impacting initial survivors and leading to further deaths – 1799 deaths by end 1995 and 2577 deaths by end of 2001	Yes. Toxic oil syndrome. Previously unknown illness shown to be linked to the aniline dye-contaminated batch of oil. Uncontaminated rapeseed oil from the same original batch was sold in France with no cases of illness	Posada de la Paz et al. 1996; Gelpí et al. 2002; Sanchez-Porro Velades et al. 2003

which is about 3.25% in unadulterated whole milk. Use of the Babcock Butterfat Tester quickly and effectively eliminated the adulteration of milk, at least in the developed nations.

The dilution of fruit juices with water and/or beet sugar had been a relatively common practice, often happening in commodity supply chains for orange pulp or solids. An example was seen in US school lunch programmes. It was a profitable fraud because schools in the United States serve more than 60 million gallons of fruit juice per year. The General Accounting Office (GAO 1995), concerned with the possibility of juice adulteration, investigated and successfully prosecuted six juice suppliers. These were forced to pay fines ranging from $2 million to $37 million.

Dilution or addition of water to increase product weight is not just seen in liquid product areas. Examples are also often seen in seafood and meat and poultry chains, for example, injection of tiger prawns with water and gels to increase weights and profits or addition of water and use of water-retention additives such as starch, phosphates, and carrageenan in unlabelled raw meat and poultry products. Whilst this practice can be done legally in many countries, it becomes a fraud when the added water and additives are not labelled. Adding to the complexity here is the fact that some of the salts being used by fraudsters for water retention in raw meats are actually necessary in some cured, ready-to-eat meat products to combat the growth of *Listeria monocytogenes*. This shows the importance of understanding recipes and the role of ingredients in controlling food safety hazards.

Further examples of dilution effects include the addition of diesel fuel to tankers of edible oils to make up for theft of the more valuable edible oils and the addition of palm oil to milk.

Mislabelling

Country of origin labelling is another area where food fraud is apparent. Origin labelling for honey has been undermined by ultrafiltration to remove the pollen that is a natural constituent. The variable types of pollen in honey can be used to identify the country of origin. This filtration practice has also been used by fraudsters in countries that want to disguise the presence of antibiotics in their honey, so that their honey can be shipped in bulk to a country that does not use antibiotics or other adulterants and be packaged and labelled as a product of that intermediary country before shipment to its final destination. However, the labelling problem with honey is not purely related to country of origin and problems are seen with general honey products being labelled as specific flower type honeys. A well-known labelling issue relates to the premium Manuka honey from New Zealand, where the amount of 'Manuka honey' traded globally is far in excess of the amount actually being produced.

Country- and region-of-origin labelling fraud also relates to many other product types (e.g. Greenhouse peppers grown in Mexico have been shipped to Canada and labelled as 'Product of Canada' after the 'Product of Mexico' labels had been removed).

Counterfeiting

Many of the examples already discussed could also be classed as counterfeit. There are no fixed rules here with regards to how to think about these activities. Generally, counterfeit foods are cheaper products which are made or labelled to look like more expensive brands. Decanting of cheap wine into labels associated with higher-priced wines, lower-grade olive oils sold as extra virgin, and nonorganic products repacked as

organic. In some instances, a counterfeit operation will copy labels from the expensive brands and repackage goods themselves.

Grey Market Production, Theft, and Diversion

Individuals and corporations have enhanced profits by short-weighting packaged food products, particularly dried foods. Weight-control legislation varies around the world but often means that packages are typically overfilled to avoid underweight packages and the possibility of regulatory fines. However, fraudulent businesses and managers sometimes underfill packaged products by a relatively small amount, meaning that they can increase profits substantially over a large batch and are prepared to risk the chance of being caught for selling underweight product.

Further examples of fraudulent practices in this category often relate to sale of excess unreported product that has been diverted at manufacturing or resale of products intended for one market in another (often but not always with some form of relabelling). Condemned foods that were intended to be buried in landfills have also been diverted by truck drivers and other criminals and sold on street corners or to merchants or restaurants who think they are getting a bargain.

In addition to these types of food fraud directly affecting the product, it is also necessary to consider other types of criminal activity within food companies that could have an impact on products, food safety, and the consumer. These include deliberate actions by staff and management that affect issues around the production process (e.g. fraudulent hygiene records) and are often an indicator of poor food safety culture. These types of activities don't precisely fit the definitions of food fraud listed previously but instead are part of the wider food crime problem. Examples include shopping for testing laboratories that will report negative pathogen results, no matter what the actual tests might have shown – in this case both personnel from the food manufacturer and, potentially, the laboratory, could be complicit in the crime. Alternatively, repeating microbiological tests (e.g. for *Salmonella* spp.) until a negative presumptive test is obtained is a further related example, as is deliberately generating negative environmental swab results (e.g. by swabbing an area covered in sanitiser solution). Sometimes these types of issues are related to internal incentive programmes that are based on negative test results, showing the importance of understanding culture and human behaviour when developing key performance indicators. All of these are real examples of practices that are known to have occurred.

These examples are most certainly a miniscule portion of similar incidents that must occur each year, without detection, in food-production facilities around the world. Given the many thousands of ingredient suppliers, food processing and distribution facilities, and the massive network of global food trade, it is difficult to reliably detect economically motivated food fraud. The detection and prevention of such fraud is even more unlikely when company managers are directly involved in fraudulent practices.

The UK's Food Standards Agency has created a National Food Crime Unit. Any person with a suspicion about a particular food can contact this unit, Food Crime Confidential, by phone or e-mail, which acts to protect citizens from criminal activity that may affect the safety and quality of their food and beverages. Special attention is given to foods and beverages that may have been adulterated or substituted, to production and labelling

procedures that appear to be substandard or illegal, and to companies that make specific health claims that are suspected to be fake (Food Standards Agency 2016b). Effective whistle-blowing practices like these will be necessary in the fight against food fraud.

13.4 Food Terrorism

Thankfully less well-known than food fraud, food terrorism, in which food items have been deliberately contaminated to cause harm to consumers and/or for political gain, has happened in recent years. It is also conceivable that those who commit economic adulteration without physically harming consumers could easily modify their tactics to cause deliberate harm and public fear. Therefore, we must be prepared to think the unthinkable to understand the potential contamination modes.

13.4.1 Food Terrorism Examples

Such a terrorist plot may have been planned in Chicago in 1982, when someone contaminated bottles of Tylenol, a very popular pain reliever, with cyanide. Seven persons died. Although not a food product, there are obvious similarities in the production and packaging of consumer medicines. To this date the perpetrator(s) have not been identified. In contrast, in the early days of modern food safety, some food scientists and packaging engineers were concerned about the potential for product spoilage or human illnesses that could be caused by product tampering. In 1971 scientists at the Best Foods Research Center in Union, New Jersey, developed and applied tamper-evident closures for its bottled products (W. H. Sperber personal communication). Slowly, too slowly in the case of Tylenol, the food and drug manufacturers adopted modern tamper-proof and tamper-evident packages. Of course, even these barriers to tampering are not foolproof. Everyone involved in the production and distribution of food and drugs must be vigilant in understanding their packaged products and adopting or developing new tampering control procedures as such technologies become available.

A further well-known example of food terrorism is the contamination of salad bar foods with *Salmonella* Typhimurium in 1984 by the cult followers of Bhagwan Shree Rajneesh (Török et al. 1997). The outbreak strain was found to be indistinguishable from a strain recovered from a laboratory at the cult's commune in Oregon, USA. It was found that the outbreak, which was known to have affected 751 people who dined or worked at local restaurants, had been a trial run for use of this method to impact voting in an upcoming election (Török et al. 1997).

An earlier example from 1978 involved mercury being injected into Israeli oranges by a group sympathetic to the cause of oppressed Palestinian people. The contaminated batches of oranges were exported to several countries and were found in West Germany and the Netherlands, where five children had to have their stomachs pumped following consumption of some of the fruit. The 'Arab Revolutionary Army Palestinian Command' group claimed responsibility, and Dutch and German governments received letters stating: 'It is not our aim to kill the population, but to sabotage the Israel economy which is based on suppression, racial discrimination and colonial occupation.' It was believed that the oranges were contaminated in Europe rather than in Israel, most likely at the trading port of Rotterdam in the Netherlands (Doder 1978).

13.5 Food Defence

Food defence as we indicated previously is the term used to describe the countermeasures directed towards intentional contamination of food. In addition to the food fraud and terrorism issues already described, food defence mechanisms are also needed in cases where disgruntled employees are able and willing to disrupt a firm's operation by theft or sabotage of ingredients, products, or production equipment. Typically, tampering, theft, and other malfeasances in food facilities occur 'in-house' (Leathers 2014). Expensive ingredients such as bulk chocolate chips, raisins, and nuts are prime targets for theft, and in most cases, that is what it remains. In a few cases substitutions may be made to avoid getting caught. Employees of the facilities commit 88% of all such disruptive actions, of which males commit 82% and females 18%. Outsiders who may be motivated by competition or religious or national factors commit the remaining 12% of the disruptive actions. (Leathers 2014)

Possibilities of food tampering paled in comparison to the terroristic attacks on the United States in 2001 and more recently in other countries. The killing of more than 3000 people and the destruction of civilian and government buildings in the USA forced people to recognise that similar threats could also be directed against the many segments of the global food supply chain.

US federal agencies acted quickly to study the potential threats and to provide training programmes and uniform guidelines that would enable the food industry to reduce the likelihood of direct attacks on the food supply chain, both by terrorists and by disgruntled employees. One of this book's authors participated in the development and presentation of two training programmes that focused on the production of dairy products and bakery products. Each programme hosted about 30 quality assurance and plant managers, took about 8 hours, and was presented multiple times at locations throughout the USA. Many participants struggled to identify potential targets inside their facilities until it was suggested that everyone 'think like a terrorist' to identify vulnerabilities in their operations. For example, the participants were asked to imagine that their facility had been taken over by terrorists. What would a faithful employee be able to do to disrupt operations and prevent the production and distribution of food to the terrorist group? This approach worked well with most participants. Together with other governmental programmes, these independent training programmes worked well to heighten awareness of the manufacturing and distribution operations and how they could be better protected. Fifteen years later, there have been no documented attacks on US food-production facilities but we must never be complacent. The 'thinking like a criminal' mindset is now the accepted approach when undertaking a vulnerability assessment in any part of the world.

This section aims to discuss practical strategies and countermeasures to predict and prevent food fraud and food terrorism, including assessment of vulnerability and development of control measures at all stages of the food supply chain. Effective food defence programmes will have predictive forecasting and information review elements to identify likely threats (ATKearney/GMA 2010) so that the correct selection of countermeasures can be identified (Figure 13.3).

13.5.1 Food Fraud Prediction

Netherlands' researchers developed a programme to predict the expected type of food fraud for product categories and countries of origin to better deploy enforcement

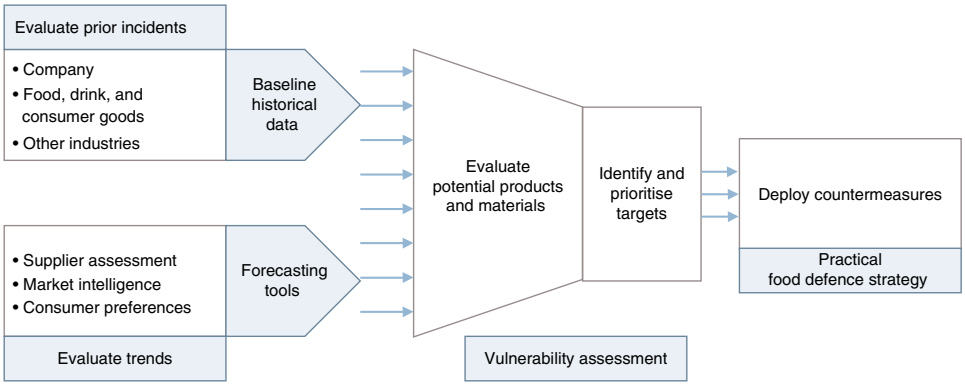

Figure 13.3 Food Defence: Framework for identifying, prioritising and defending against risks Adapted from ATKearney (2010).

activities (Bouzembrak and Marvin 2016). They used a Bayesian Network (BN) model that was based on adulteration and fraud notifications as reported in the years 2000–2013. In this period, 749 food fraud notifications were reported; these were grouped into six categories:

- Improper, fraudulent, missing, or absent health certificates,
- Illegal importation,
- Tampering,
- Improper, expired, fraudulent, or missing common entry documents or import declarations
- Expiration date, and
- Mislabelling.

The data from this study were used to develop a BN model. This model was validated using 88 additional food fraud notifications that were reported in 2014. The database covered nine types of food fraud – substitution, artificial enhancement, dilution, transhipment, counterfeit, misbranding, addition, replacement, and removal. Based on available data, this initial BN model predicted 52 of the 88 fraud incidents correctly. Should this model be refined and used widely, it could be useful in detecting and eliminating food fraud more quickly. The model also tabulated the incidence of food fraud based on country of origin: China, 23.8%; Turkey, 9.6%; United States, 4.4%; Brazil, 4.3%; Philippines, 4.1%; Japan, 3.6%; and Poland, 3.2%. The amount of fraud was directly related to the volume of food imported from these countries. Similar predictive modelling tools have been developed in the United States and are now available for commercial use.

Usually the ability to predict issues requires good knowledge of historical issues and circumstances surrounding contamination/fraud incidents as well as knowledge of conditions likely to promote economically motivated criminal activity in the global food supply chain. To help with this, there are several food information databases that can be consulted for background information. As mentioned in Chapter 3, the European Commission Rapid Alert System for Food and Feed (RASFF) Portal reports notifications of a wide range of food safety, contamination, and adulteration issues. This is a searchable database that can be accessed for free on the Internet at https://ec.europa.eu/food/safety/rasff_en. The Food Adulteration Incidents Registry from the US Food Protection and Defence Institute is another source of useful information available via a fee-paying Internet subscription service and is found at https://foodprotection.umn.edu/fair.

Increasingly attention is being paid to the potential for use of big data in prediction of food safety and food fraud incidents. An example of how this can work is the WHO 'FOSCOLLAB' food safety project. This integrates data from different sources and various disciplines, using, structured and unstructured data from, for example, animal, agriculture, food, public health, and economic indicator fields. (WHO 2015b; Marvin et al. 2016). FOSCOLLAB is freely available on the Internet and users can access several dedicated dashboards at http://www.who.int/foodsafety/foscollab/en/. Other similar initiatives have used weather-pattern information integrated with agriculture and economic indicators to predict patterns of food fraud. In the USA, the Grocery Manufacturers Association (GMA), Safe Supply of Affordable Food for Everyone (SSAFE), the University of Minnesota, and US Pharmacopeia have all developed modelling tools. Initiatives such as these can only help to strengthen food business vulnerability assessments and control measures.

13.5.2 Practical Food Defence Strategies

If September 11, 2001, awakened the United States and the world to the devastating possibilities of terrorist attacks, melamine was the trigger point which proved that economic adulteration could have global consequences – for both humans and animals. In the United States, the FDA food defence focus has broadened to include all types of intentional adulteration – terrorist or economically motivated. As a producer or distributor of foods (ingredients or finished products), it is a daunting task to consider broad supply chain defence mechanisms; yet over the course of the last several years in learning from failures, we have gained a better understanding of how to be better prepared in the years to come. Technological advancement will result in additional tools but for now, here is an overview of some of the practical strategies that are being used.

Vulnerability Assessments: Raw Materials

- *Supply Chain Visibility*: It takes some time to do but having a more detailed understanding of your supply chain through mapping can help identify the potential weak links. Supply chains today are rarely confined to a single country, and to do this thoroughly requires an understanding of where ingredients are coming from (back to the source) and where the products are distributed to. This level of detail may not be necessary (or even practical),for every component which is why many organisations do a risk evaluation as part of their vulnerability assessment.
- *Hazard analysis and risk evaluation (for vulnerability assessment)*: This has always been thought to be a difficult area. How do you predict something that has never occurred? With advancing technology and in particular, the use of big data, as described previously (Section 13.5.1) is starting to become more mainstream, with tools are becoming available in a number of countries. The way that these tools work in general terms is that they use existing sources of information and combine these inputs to draw intelligent conclusions. Examples of inputs are weather and likely crop failure, political situations such as strikes and unrest, natural disasters, major accidents such as at a nuclear facility, – any of which could lead to shortages and higher prices. Other data such as amount of a commodity produced, amount being traded, and country import data can provide an indicator of likely risk of being an EMA target.
- *Historical intelligence*: Here an organisation should be looking at past history in any of the categories in which it is involved. Use of readily available search engines will provide an often-surprising amount of insight and some of the portal tools mentioned in Section 13.5.1 will be useful here.
- *Ease of detection*: If analytical results for a contaminated food would be the same as when it is non-fraudulent, this is another indicator of vulnerability.

Vulnerability Assessments: Manufacturing or Process Environment

- This is where a terrorist, disgruntled employee or even an activist may be focused. Organisations need to assess the site security in terms of the ability to gain unauthorised access to the premises. A secure perimeter, controlled access into the facility itself, employee and contractor controls, including screening, all ned to be evaluated.
- Outside organisations may target disgruntled employees so relatively minor issues should not be disregarded.

- Access to the process itself should be assessed, particularly where employees work alone and unsupervised. The HACCP process flow chart can be helpfully utilised to ensure that no single step is missed out and that the entire process is assessed.

Vulnerability Control Plans

- For raw materials, where possible, an analytical detection programme should be developed for materials of concern. This can act as a deterrent when a supplier knows that their materials will be scrutinised, and for the purchaser. it offers increased confidence. Country-of-origin verification, agreed specifications, supplier audits (to the actual location), as well as ongoing incoming goods monitoring and testing are amongst the primary means of authentication. Knowing what to test for can be a challenge, but the use of historical data can be helpful as well as using the specification to identify a few key target criteria.
- For premises, people, and processes, a control plan should include:
  - screening of employees, contractors, and visitors.
  - site security, fences, walls, and boundaries. Not all personnel on site need access to process areas. This should be controlled, too.
  - control of delivery and shipping vehicles and their drivers.
  - surveillance of vulnerable process areas (including use of cameras), that is, where only one employee may be working and have access to the product stream.
  - control of electronic devices. Whilst many portable devices will be company supplied, given the ownership of smartphones, many will be owned by the employees or other authorised personnel on the site. Most phones have a camera which can be used to document access areas and the information later shared externally.
  - distribution controls. Knowledge of how the products are moved to storage and on through transportation networks should be used to put controls in place where needed. The same type of screening should be in place for personnel and facilities along the way.
- Ongoing horizon scanning – a plan should be in place to ensure appropriate access to emerging issues and events so that the organisation can continue to build history.

There are some useful tools, resources, and publications available for organisations to use. Several of these publications were utilised in putting this chapter together, including Campden BRI Threat Assessment guide (Leathers 2014), the Publicly Available Specification on Defending Food and Drink – PAS96 (BSI 2014) the ATKearny/GMA publication on Consumer Product Fraud: Deterrence and Detection (ATKearny 2010), the SSAFE Food Fraud Vulnerability Assessment Tool (SSAFE, 2015) and the WHO guideline, Terrorist threats to food: guidance for establishing and strengthening prevention and response systems (WHO, 2002). Fairly recently a software programme designed to assist operators with developing personalised food defence plans was made available by the FDA and is worth evaluating: Food Defence Plan Builder (FDA 2014).

Another approach that had been fairly successful in the United States, and a major reason for the record of success against food terrorism to date, was the development and use by the FDA of its Food Defense Program of a Food Sector Vulnerability Assessment tool called 'CARVER + Shock' (FDA 2009a). In brief, this tool was based upon sets of attributes, parameters, and criteria. The six attributes led to the CARVER acronym. In addition, the modified CARVER tool evaluates a seventh attribute, the combined health,

economic, and psychological impacts of an attack, or the SHOCK attributes of a specific target.

ATTRIBUTES

- *C*riticality – the measure of public health and economic impacts of an attack
- *A*ccessibility – ability to physically access and egress from the target
- *R*ecuperability – ability of system to recover from an attack
- *V*ulnerability – ease of accomplishing an attack
- *E*ffect – direct loss from an attack as measured by loss in production
- *R*ecognisability – ease of identifying target

PARAMETERS

- Type of food produced, type of attack and impact – injuries or monetary
- Assembling experts to conduct evaluation and establish parameters
- Detailed oversight of facility's supply chain from ingredients through to finished products
- Assign scores to determine most vulnerable targets
- Apply learnings through development of countermeasures

CRITERIA

- Criticality – threat agents' impact on injuries, loss of life, or economic loss
- Accessibility – ease of access to target
- Recuperability – time for specific system to recover productivity
- Effect – measure of system productivity lost at a single facility
- Recognisability – the ease with which a specific target can be recognised

Development and application of CARVER + Shock over the past 15 years has led to the adoption of many requirements and facility changes that have greatly improved site security. All personnel – employees, drivers, visitors, inspectors, contractors, pesticide applicators, and so on – should be provided with secure credentials to gain access to their designated areas. These requirements are enforced for all areas of the facilities – ingredient and packaging storage, production and packaging areas, chemical storage, loading docks, restrooms, cafeterias, offices, roofs and parking lots. The perimeter is enclosed with secure fences that also control access to the facility. Furthermore, increased mock product recalls and scheduled or unannounced audits and inspections have strengthened age-old quality control procedures.

The FDA expanded its efforts to improve food safety and food defence by advancing the Food Safety Modernization Act (FSMA), which was signed into law on January 4, 2011 (www.FDA.gov/FSMA). The final proposed rule, issued in December 2013, is aimed at mitigation strategies to protect the food supply from a large range of threats, including that of intentional adulteration. It applies to foreign and domestic companies that must register as food facilities with FDA as required by the Federal Food, Drug, and Cosmetic (FD&C) Act. Whilst much of FSMA is based upon the HACCP system, its supporting system of prerequisite programmes (especially good manufacturing practices), relates to the long-established CARVER + Shock programme.

This FSMA rule was the first to require that food processing facilities develop and implement food-defence plans. The Intentional Adulteration rule, 21CFR Part 121

(FDA 2017) requires FDA-registered food facilities to implement a written Food Defence Plan that would satisfy three elements: a vulnerability assessment, mitigation strategies, and mitigation management components. A qualified individual, defined by FDA as one who has received the standardised training or is otherwise qualified through job experience, must write or oversee the preparation of a facility's plan. The rule also requires training for employees who work at vulnerable steps in a food's production.

In the United States, the vulnerability assessment of a food defence plan is focussed on three aspects of food defence:

- The degree of physical access to the product,
- The ability of an attacker, including the possibility of an inside attacker, to successfully contaminate the product, and
- The potential health impact if a contaminant were added.

13.6 Conclusion

In modern food systems, we recognise the need for a broader food protection strategy. No longer is the focus just on natural and accidental contamination that is managed by food safety management systems; instead focus has widened to include the need to defend the global food supply chain from threats of food fraud and the potential for food terrorism. Examples such as those described in this chapter illustrate the vulnerability of the food chain to food fraud and food terrorism and highlight the need for effective preventative strategies. Whilst it may not be possible to fully eradicated the risks, use of prediction systems, increasingly based on big data, alongside food chain vulnerability assessment and development of strong countermeasures will minimise the risk to food products and public health. Many of the assessment and control procedures have similarities to those used in other food safety programme elements; however, the shear breadth of focus needed to cover all issues means that vulnerability to food fraud and food terrorism will normally be done separately to development of HACCP food safety management systems. Nevertheless, these approaches will continue to gain importance in the years to come and are already established as essential elements of the world-class food safety programme.

14

Maintaining and Improving a Food Safety Programme

14.1 Introduction

In any food business it is essential that the facility, ingredients, processes, and products are managed effectively on an ongoing basis to ensure that only safe food is produced and served for consumption. The food safety programme elements – safe design, prerequisite programmes (PRPs), and HACCP, along with food fraud and defence programmes – supported by effective management practices, will allow the requirement for safe food to be achieved. These essential requirements for ongoing food safety need to continue in the operations as implemented and be the subject of continuous improvement efforts; they are 'living' systems and must not be allowed to become out of date. Many of us will be able to think back to the early HACCP programmes that we were involved in implementing, and we'll know how very much stronger the systems are that we have today. Codex principles have been reviewed regularly over the last 20 years for opportunities to improve based on current knowledge and so too must we seek to strengthen the systems that we implement in our own businesses. This is important because any weak links in food safety programmes can have catastrophic results. Referring back to Chapter 2, we can see that the lack of, or weaknesses in, maintenance of food safety programmes continues to be a major reason for failure. Several high-profile food safety incidents have involved large companies who had long-established food safety programmes, and this demonstrates the importance of challenging the controls and keeping systems up to date. Going forward, it is important to assess regularly whether the systems are working and therefore demonstrate that there is continuous control of food safety.

In this chapter the essential requirements for food safety programme maintenance will be discussed. This will include consideration of PRPs, HACCP. and management requirements along with the tools and approaches that can be used to maintain an effective food safety programme.

14.2 What Is Food Safety Programme Maintenance?

Throughout this chapter we will use the term *maintenance* to refer to activities which both maintain and seek to improve the system.

Food Safety for the 21st Century: Managing HACCP and Food Safety Throughout the Global Supply Chain, Second Edition. Carol A. Wallace, William H. Sperber, and Sara E. Mortimore.

Maintenance of a food safety programme requires several key fundamentals:

- Challenging the effectiveness of the programme elements and constantly looking for opportunities to improve them.
- Ensuring that the programme remains accurate and up to date, both in terms of the ingredients, processes and operations on site, and with changing knowledge on food hygiene and food safety hazards.
- Making certain that the programme remains suitable, both for the provision of adequate hygiene foundations and for the effective control of all relevant food safety hazards.
- Keeping high visibility of food safety as a core value for the organisation – to proactively nurture and develop a strong food safety culture.

Effective food safety programme maintenance, therefore, requires the application of a range of different techniques and approaches and the involvement of personnel from different roles and areas of the operation. Tools and activities will include audit and management review alongside a variety of specific test procedures, and it will be important for personnel to have appropriate skills (e.g. in auditing and information searching/update) and access to current industry best practices. It is also essential to engage in activities that provide high level visibility of food safety, such as posters, campaigns, and provision of awareness training and education. The key elements of food safety programme maintenance are illustrated in Figure 14.1. These elements provide a similar ongoing cycle to the Plan-Do-Check-Act process discussed in Chapter 9 (see Figure 9.5)

Figure 14.1 Elements of food safety programme maintenance.

14.3 Responsibility for Food Safety Programme Maintenance

The responsibility for food safety programme maintenance lies at the senior leadership level of the food business. Senior leaders need to be involved, both as part of management review and to provide commitment and confirmation of resources for all required maintenance elements. It is important to promote an open environment and have regular discussions about the organisations own food safety programme effectiveness, as well as new developments in science, technology. and other industry failures. Maintenance will be less effective if personnel feel that they are working in a 'blame culture' where results of maintenance elements such as audit are used to criticise staff and work practices rather than as an opportunity for continuous improvement and strengthening of the systems.

Effective maintenance requires a multidisciplinary approach, involving personnel from all different levels of the organisation. Members of the food safety and HACCP teams will lead and be involved in a number of aspects of maintenance, through a proactive approach to ensuring continued suitability of food safety programme elements. Managers, supervisors, and line workers also have important parts to play in challenging the systems and keeping them up to date with the operations. Personnel with audit skills and responsibilities will play a key role in programme verification and the knowledge and skills of engineering and research and development (R & D) personnel will be vital, both in highlighting potential changes to products and processes and in ensuring the ongoing capability of processes to control food safety hazards.

14.4 Maintenance of Prerequisite Programme Elements

Part of the requirement to formalise PRPs is the need to ensure that these are maintained and are therefore working effectively over time. This is essential if PRPs are to provide the safe environmental foundations that are needed for safe food manufacture. In order to challenge the effectiveness of PRPs, audit and inspection are widely used tools that can determine if the prerequisites are working as intended and identify weaknesses in their operation. Regular hygiene inspections, environmental monitoring programmes, and audits are used by many food companies to assess their PRPs. These should include in depth visual inspections of the condition of facilities, plant, and equipment as well as examination of PRP records and documentation, and interviewing members of staff with prerequisite responsibilities. It is a given that ongoing financial investment will be needed to keep the facility in suitable condition. A risk-based assessment of the likely sources and vectors of contamination can assist with prioritisation of the ongoing investment needs.

Like all other parts of the food safety programme, it is important that the PRP elements are kept up to date with best practice and so food companies need to keep abreast of new information and potential improvements that could be made. Where PRP elements are amended, there will be a need to retrain staff in the new procedures and practices. It will also be important to include prerequisites in refresher training sessions for all staff, reminding them of the role they play in food safety management and failure prevention. Updates to prerequisite documentation and records will also be needed.

14.5 Maintenance of HACCP System Elements

After implementation (Chapter 12), the HACCP verification procedures identified in step 11 of the HACCP logic sequence (Codex 2009b) need to commence. A HACCP system will only achieve its purpose in managing food safety if its effectiveness is regularly **challenged,** and it is **kept up to date** through continuous maintenance. This will be achieved by a variety of different activities, including audit, records review, testing, and information searching. Participation in industry, academic, and regulatory network opportunities is also an important element of the maintenance programme.

14.5.1 HACCP Verification Activities

Key HACCP verification activities will include:

- **Audit of the system to check that it is working correctly**
  This should be planned so that the whole system is audited at least annually; however, more frequent assessment is recommended for ongoing control, and this can be achieved by looking at smaller sections of the system on a regular basis. Several published tools are available to assist in HACCP Audit (see Section 14.6).
- **Review of records**
  – HACCP records
  It is a requirement of HACCP that monitoring records are reviewed by a responsible reviewing 'official'. This is normally a trained supervisor or manager who can check that monitoring has been done, that corrective action has been taken where necessary, and can look for trends over time.
  – Customer complaint records
  As for PRPs, review of external data, such as any customer complaint records, is also useful in HACCP verification. Trending of customer complaint data can give information on the success of control measures and also give indications of where the system may be drifting towards loss of control.
  – Product and materials test records
  Although not useful in monitoring because of the time required to obtain results and the variability of microbial contamination within foodstuffs, routine microbiological and chemical tests on products and ingredients can provide useful information for HACCP verification. This can be particularly informative if data is reviewed and trended over time as it can give confidence in the effectiveness of critical control points (CCPs) for microbiological hazards.
  – Calibration activities and records
  Equipment used for CCP and PRP monitoring must be regularly calibrated for accuracy; therefore, reviewing calibration records will also be important.

These verification activities are often managed within the framework of a structured quality management system, such that they are performed regularly according to a defined schedule.

14.5.2 HACCP Maintenance Activities

The maintenance activities for HACCP are largely based around keeping the HACCP plans current and suitable for control of all relevant significant food safety hazards. This will include:

- **Keeping up to date with product and process developments**
  Where there are new products, new ingredients, or new processes, it is important to keep the working HACCP plan up to date. This involves checking to make sure the existing HACCP plan is still valid and making amendments where necessary for continued control. If the development is a new variant of an existing item with an identical process, then it is likely that no changes are required unless there are new raw material hazards to address or the product intrinsic factors have changed as a result of a reformulation. However, if it is a completely new process or involves amendments to existing process activities then a review of current controls will be required, and it is likely that a new HACCP study will be needed. With such changes, it can be expected that the process flow diagrams will need to be updated at the very least, with accompanying hazard analysis for any new/amended activities. Depending on whether any new significant hazards are present, and assuming that they can be controlled, then new CCPs or CCP amendments may also be needed, and this will obviously have resulting requirements for monitoring and corrective action procedures. Changes to HACCP plans will themselves need to be validated before implementation (Chapter 12) and will then pass into the ongoing maintenance cycle. It will be easier to capture changes to products and processes if there is regular communication with personnel involved in innovation and new initiatives such as product developers and engineers. Appropriately frequent meetings between HACCP team leaders or senior technical personnel and development personnel are therefore vital. This can sometimes be accomplished within the framework of regular management meetings, perhaps via a food safety team or via a formal design review process. A formal mechanism for approval is also recommended such that the proposed changes cannot be made until food safety has been reviewed and necessary amendments to HACCP plans have been built into the operation. This will likely require a documented sign-off procedure involving senior staff as signatories and could tie in with the product safety assessment process (Chapter 11).
- **Periodic review of HACCP system elements**
  In addition to reviewing suitability in response to changes to the products and processes, it is also important to perform periodic reviews of the HACCP system. This allows the system to be challenged for suitability to control all relevant significant food safety hazards and new information gained from the information-searching activities should be built in to this review. Even where the HACCP plans are being updated more regularly because of product and process changes, it is recommended that a periodic formal review should be timetabled as an independent check that the defined systems are valid. This should be done at least annually in all food operations.
- **Information Searching**
  It is vital to keep up to date with information that might suggest the need to strengthen or amend the HACCP plans. Information will come from a variety of

sources, and personnel need to be given responsibility for horizon scanning to ensure that all appropriate information is identified and actioned. Specific searching requirements will be needed for:

- Identifying and assessing new hazard information
  As discussed in Chapter 5, a number of microbiological hazards (e.g. *Escherichia coli* O157:H7) have emerged in recent years that were previously unknown within the food industry. Similarly, information changes on what is known about potential chemical hazards and their toxicity to human populations. This necessitates keeping up to date on all potential hazards, particularly with relevance to the segments of the food chain that are affected.
- Learning from other's failures for impact on own system
  Unfortunately foodborne illness incidents and outbreaks do happen and are generally well reported, at least in the media. Economic adulteration and food fraud are also increasingly reported and should be used for prioritisation of raw materials vulnerability assessments. It can be more difficult to find trustworthy information on the underlying causes of these outbreaks and incidents; however, many investigating authorities do publish findings either in peer-reviewed journals or on public authority websites (e.g. US Centers for Disease Control and Prevention at http://www.cdc.gov/).
- Regulatory changes
  The food business also needs to keep up to date with any new legislation or guidance from regulatory authorities on best practices for dealing with new food safety concerns. This should include review of information available from authorities in the countries of materials sourcing, manufacturing and sale, as requirements may differ.

- **Training and education**
  Ongoing training and education is needed for the successful operation of any HACCP system. This will include training of any new staff in HACCP at a level appropriate to their position in the business. For example, new line operators may need training in CCP monitoring and corrective action, whilst new HACCP team members will need detailed training in the application of HACCP principles. Regular refresher training sessions are also important to keep focus on HACCP and food safety hazards generally, as an essential element of the food safety management programme. In addition to the specific HACCP training, broad education (including using examples of internal and external failure) will be needed on an ongoing basis to continue to foster a dynamic culture of food safety and the continued sense of responsibility that comes with making food.

14.6 Maintenance of Food Fraud and Food Defence Systems

In the same way as for PRPs and HACCP, it is essential that defence programmes for food fraud and food terrorism are maintained such that they remain effective and are continually improved over time. Because focus in this area is more recent within the global food supply chain, many companies are still getting to grips with what they need to do to protect their ingredient, product, and distribution streams. Therefore, many food defence systems are currently at the development stage or in their infancy. This is a good time to plan for ongoing review and update of the systems.

Many of the maintenance elements for PRPs and HACCP will also be relevant, such as audit of the system and review of records to check that it is working correctly, although in this case it may be necessary to use simulations to test system elements. Keeping up to date with known information on food fraud and trends regarding malicious tampering and potential for terrorist activity will be essential activities for continual review of vulnerabilities and ongoing improvements in controls. In addition, an ongoing programme of training and education will be important to instil and maintain the necessary levels of vigilance throughout the workforce.

14.7 Use of Audit for Successful Food Safety System Maintenance

The verification and maintenance requirements discussed for PRPs, HACCP, and food defence necessitate the application of a range of management tools and approaches. Auditing is an important technique that can be used both in validation and verification of HACCP and in the assessment of PRP and food defence effectiveness. The audit process is generally a powerful tool for continuous improvement and should be seen as a positive opportunity.

In HACCP validation, auditing can be used to check for deficiencies in the HACCP plan. In verification, auditing is used to check that the working system is in compliance with the requirements of the HACCP plan. Similarly, auditing can be used to check suitability of newly developed PRP elements and also to establish ongoing compliance with specified programmes in practice.

The *Codex HACCP Principles and Guidelines for Their Application* (Codex 2009b) are often used as criteria to audit against. Because the HACCP principles are succinct, it is difficult to audit solely against their requirements and expert judgement and experience is needed so that the auditor can identify what is acceptable or deficient practice. The Codex HACCP guidelines give more detail; however, as guidelines, these are not mandatory statements so it would be difficult for an auditor to insist that compliance was required – this is why the development of HACCP-based ISO22000 was an important development for the food industry (see later). In addition, the scope of the Codex HACCP documents is limited to HACCP rather than the broader requirements of a food safety management programme. The *Codex General Principles of Food Hygiene* (Codex 2009a) also need to be used to assess PRPs, and these documents together are the minimum criteria used to determine if a food safety programme had been developed in line with international principles and guidelines. In addition to the evaluation of an entire food safety programme, auditing will often be performed at a much more specific level (e.g. to measure the effectiveness of a particular HACCP plan or PRP element, such as environmental hygiene, traceability, or supplier quality management).

14.7.1 Audit Definitions

It is useful to consider some key auditing definitions. The following come from BS EN ISO 19011:2011 *Guidelines for auditing management systems* (International Organisation for Standardisation [ISO] 2011).

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

Key points here are the independence of audit, such that it is a view from 'outside' the system, and that it is performed systematically so that no important aspects are missed.

Audit criteria: *set of policies, procedures, or requirements. Audit criteria are used as a reference against which the actual situation is compared.*

For example, an audit could be done using the HACCP principles, a specific HACCP plan or set of prerequisite requirements as the audit criteria. The term *Audit Standard* (or just *Standard*) is also widely used in quality and food safety management. A standard is a document that pulls together the audit criteria that are necessary for a particular purpose. Standards are widely used by industry and governments throughout the world and range from documents specifying technical criteria for products to requirements for management systems.

Audit evidence: *records, statements of fact, or other information, which are relevant to the audit criteria and verifiable.*

Audit evidence is the information that needs to be collected to back up the auditor's conclusions about the suitability and effectiveness of the system being audited.

Audit findings: *results of the evaluation of the collected audit evidence against audit criteria.*

This normally requires a judgement from the auditor, using the audit evidence found to evaluate whether the audit criteria have been met.

Auditee: *organisation being audited.*

Depending of the nature of the audit, this could be a company, manufacturing site, department, process area, or team responsible for application of a specific HACCP plan or PRP element.

Auditor: *person with the competence to conduct an audit.*

Competence is a crucial point here; all auditors of food safety programmes must have the required training, skills, and experience to determine effectiveness of the programme elements that they are required to audit.

14.7.2 The Auditor and Audit Skills

Food safety audits are carried out by people and, as such, rely on the skills, experience, and judgement of the individual concerned. Whilst audit skills can be taught, some people have more of a natural flair for this type of activity than others. The competence of food safety auditors is related to a range of aspects, including education, training, and experience; personal attributes; general knowledge and skills; and skills specific to food safety (including HACCP). Figure 14.2 outlines the essential elements of auditor competence.

Audit-skills training will be required to provide personnel (who should already have relevant education, knowledge, and experience) with the ability to challenge the food

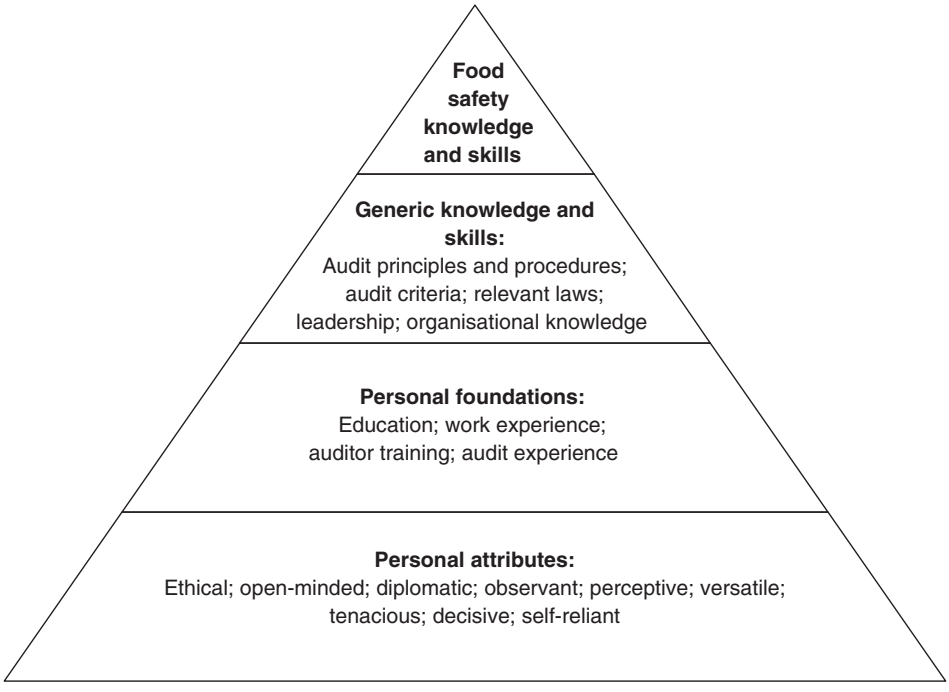

Figure 14.2 Essential elements of auditor competence. Adapted from ISO (2011).

safety programme (see Chapter 9). Skills required for successful audits in any field include:

- organisational skills,
- information-handling and sampling skills, and
- interview techniques.

Audit skills are required to collect information and evidence to:

- understand the operation of the systems,
- establish whether the requirements of the standard are met, and
- determine how effectively the system operates.

This is achieved through interviewing, observation, sampling, and testing of information. Interviews are used as a two-way information exchange process and questioning needs to be efficient to establish what is happening in practice. Types of questions used in audit will include:

- *Open questions*: these are most useful to allow the auditee to describe the situation in his/her own words.
- *Closed questions*: useful for confirming understanding.
- *Hypothetical questions*: useful for collecting information about how personnel would handle unusual events, such as CCP deviation.
- *Leading questions*: these are to be avoided in the audit situation because they give the auditee information about the expected response and may, therefore, influence the credibility of the audit findings.

Also important to the auditor are 'observational and listening' skills, including:

- Observational skills (e.g. paying close attention to the operating environment and spending time on the factory floor). Interpreting the nonverbal response (i.e. understanding body language and facial expressions).
- Keeping eye contact with the interviewee and making them feel comfortable to honestly answer questions.
- Being aware of special positioning and cultural issues (e.g. respecting personal space).
- Timing of questions, ensuring that the auditee's response is heard and understood before moving on.

These types of skills are often gained through auditor skills training. Food safety auditors who want to attend formal audit skills training normally attend courses on quality or food safety systems auditing to ISO standards (e.g. ISO 9001 (ISO 2015) or ISO 22000 (ISO 2005) or equivalent).

14.7.3 Audit Checklists

Auditors normally use a checklist or aide memoir to assist in structuring the audit. Checklists are valuable audit tools that can be used both to ensure that the important points are covered and to record the findings. In their simplest form, checklists may be a table as in Table 14.1.

In preparation for the audit, the auditor lists the main points to be covered in the left-hand column, identifies the approach they will take to address these points in the central column (e.g. observations I need to make, who will I talk to, what data will I look at, what questions will I ask, etc.) and uses the final column to record the findings on the day. When recording findings, auditors often develop their own coding systems to make it easier to identify deficiencies or non-conformances from their notes.

It is important that the checklist should not limit flexibility for the auditor to follow audit trails using their judgement. For this reason, very structured checklists are not favoured by some auditors. However, in professional auditing, it is important to ensure consistency of approach and application of the standard by individual auditors. In these cases, highly structured checklists detailing each clause of the standard may be used to ensure that every auditor covers every point.

A range of audit checklist examples can be found in the literature, particularly checklist tools for the assessment of HACCP (e.g. Sperber 1998; Wilkinson and Wheelock 2004; Wallace et al. 2005).

Table 14.1 Example of an audit checklist.

Point to be assessed (e.g. Process area)	Considerations, questions, and points to raise	Auditor's findings

Adapted from Mortimore & Wallace (1998)

14.7.4 Use of External Audit and Certification Schemes as Part of Food Safety Programme Maintenance

In HACCP and food safety, standards from a variety of sources are used. These may be legislative standards, national/international standards such as BS/EN/ISO, customer-driven standards, or expert group or food-industry sector standards. When combined with professional third-party audit and certification, these standards can provide a useful independent measure of food safety programme effectiveness. Examples of external audit and certification schemes for food safety management programmes include:

- **GFSI**
  The **Global Food Safety Initiative** (GFSI) aims to ensure equivalence between the various standards and auditing schemes (see Chapter 3). This is, therefore, a framework scheme, which evaluates the effectiveness and equivalence of individual schemes against the GFSI requirements. The latest copy of the GFSI guidance document is the seventh edition from 2017 and can be downloaded at http://www.ciesnet.com/2-wwedo/2.2-programmes/2.2.foodsafety.gfsi.asp
- **ISO 22000:2005**
  ISO 22000:2005 *Food Safety Management Systems – Requirements for any organisation in the food chain* (ISO 2005) is a purpose-designed audit standard based on Codex HACCP Principles and also the management requirements for an effective system. This standard includes the requirement to develop PRP elements (Clause 7.2); however, it does not include detail on what is required in each PRP element.
- **ISO/TS 22002-1:2009 (PAS 220:2008)**
  Because of the omission of sufficient detail on PRPs in ISO 22000, additional standards have been developed by industry (e.g. the document that was initially published as 'Publicly Available Specification' PAS220:2008 *Prerequisite programmes on food safety for manufacturing* [BSI 2008] and later became ISO/TS 22002). This document combined with ISO 22000:2005 were taken together by an organisation known as the 'Foundation for Food Safety Certification' (FSSC) to provide an auditable framework covering HACCP, PRPs, and management requirements. This has been developed into a new third-party audit scheme. called FSSC 22000, which has also been accepted through benchmarking to the GFSI standard. This also paved the way for additional specifications such as PAS222 (2011) for animal feed.
- **BRC**
  *The **BRC Global Standard** – Food* is a retail-driven standard that was developed in the United Kingdom and is used throughout the world. The standard was developed by a group of retailers to help them meet their responsibilities under UK legislation (at the time, the Food Safety Act of 1990) to ensure safety of the supply chain. This is a detailed standard containing requirements for HACCP, prerequisites, legal control, and quality management systems. The latest copy of the standard was published in 2015 and is titled BRC Global Standard for Food Safety – Issue 7. This has been benchmarked and approved against GFSI.
- **Dutch HACCP Code**
  The **Dutch HACCP Code** was put together by a group of HACCP experts working in the Netherlands who recognised the difficulties of auditing against Codex. This

standard, therefore, includes Codex HACCP Principles and PRPs but also management requirements and, as such, shows parallels to BS EN ISO 22000:2005. The Dutch HACCP Code can be downloaded free of charge at www.foodsafetymanagement .info It has also been benchmarked and approved against GFSI; however, it has been announced recently that the programme will be phased out over a period of 3 years from 2018 to 2021.

14.8 Incident Management

Whilst food safety management programmes are designed to prevent food safety issues and incidents, it is generally accepted that elements of systems and procedures do fail from time to time and thus it is necessary to develop management programmes to effectively deal with food safety failures. This is usually achieved by the establishment of formal incident management programmes, which should have the capability of tracking and trending internal incidents as well as those that go into the public arena. Similar to consumer complaints data, incident data can provide good insight into opportunities to strengthen the food safety programme.

In food safety failures, the primary concern must be public health protection, so incident management programmes must include methods to trace, recall, and quarantine a suspected product, as well as appropriate communication methods and channels to provide essential information and instructions to customers and consumers. The incident management programme's ability to manage incidents should be tested on a regular basis to ensure that consumers will be protected in the event of food safety system failure.

When food safety management failures occur, it is important to understand the cause of the failure and management tools such as root cause analysis can be used to assist with this activity. This should result in corrective action to strengthen the food safety systems and to prevent recurrence of the issue in the future. Preventative action to predict the likely failure modes within the food safety management programme should also be considered, for example, using tools such as 'failure mode and effect analysis' [FMEA] to predict potential weaknesses or 'why, why' analysis to get at root cause and identify means to strengthen the programme elements.

14.9 Conclusions

To ensure ongoing control of food safety, PRPs, HACCP and food defence systems need to work together as a cohesive system. The keys points to achieve this are:

- Verification of food safety system elements effectiveness, using tools such as audit and results review.
- Review of system elements and their suitability for food safety, with particular reference to changes in knowledge about food safety hazards (including those arising via food fraud), and their possible preventive controls and changes to ingredients, products, processes and operating practices at the processing location.
- Change control procedures that require formal safety assessment and approval for all proposed changes to ingredients, process activities, and products.

- Ongoing management and update of system elements.
- Hazard awareness and control training and retraining of staff, including new recruits and temporary personnel.
- Ongoing awareness and educational campaigns highlighting the importance of having a preventative food safety culture.
- Incident management programmes, including testing of their ability to protect the consumer.
- Regular networking and industry surveillance for new scientific knowledge and best practices.

Together with ongoing assessments of safe recipe/process design for all new products (see Chapter 11), and perhaps within the framework of an external, professionally audited certification scheme, these maintenance procedures will ensure effective functioning of the food safety programmes on an ongoing basis. Thus, the world-class food safety management programme can be achieved and continually improved, providing ongoing assurance of consumer health protection.

15

Food Safety Culture: Evaluate, Map, and Mature

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Principal, Cultivate Food Safety

15.1 Introduction

As discussed in Part 1 of the book (Chapter 2), foodborne disease continues to be a significant problem in the global food supply chain. Recent World Health Organisation (WHO 2015a) estimates suggest that 33 million healthy life years are lost annually as a result of food- and drink-related contamination. To mitigate such contamination regulators and operators have institutionalised recall practices and processes. Often these are regulated practices designed to minimise the loss of health and life by removing contaminated products from consumers' reach. In the United States and Canada alone 626 recalls were conducted in 2015 to remove products suspected of being harmful to consumers (Maberry 2016). Many of the food safety management programme elements discussed in the book are focused on processes and systems, including prerequisite programs (PRP) such as recall and cleaning, HACCP, and safe product/recipe design. Although these may be thought of as the system elements, the importance of people in making the systems work effectively is also understood (Chapters 4 and 9). However, some contamination of food and drink products results from the organisational culture of food and drink businesses (Griffith 2010; Powell et al. 2011) where assumptions are made about the appropriateness of actions taken or decided simply because it is the way we do things around here (Denison et al. 2012; 2004). Thus, to understand food safety culture, it is important to consider theories and findings from empirical studies regarding organisational culture (e.g. Cameron & Quinn 2006; Denison 1997; Schein 2004) and specifically within the context of the food industry (e.g. De Boeck et al. 2015; Griffith et al. 2017; Jespersen & Huffman 2014; Seward 2012) because these can provide insight into some of the reasons for these actions by people within businesses leading to the loss of healthy life years.

15.1.1 Food Safety Culture: Accepted Assumptions, Not Malicious Intent

Culture is number-one on CEOs' priority list for success in 2017 (Smith 2017). As such, our ongoing focus on building food safety in the organisational culture is as relevant as ever. The food safety culture conversation sometimes assumes that culture, any kind of culture (e.g. organisational, people safety, food safety, sustainability) is homogeneous

Food Safety for the 21st Century: Managing HACCP and Food Safety Throughout the Global Supply Chain, Second Edition. Carol A. Wallace, William H. Sperber, and Sara E. Mortimore.

and therefore more or less effective independent of the composition and structure of an organisation. Edgar Schein (2004) helps us understand that this can be a false assumption and that organisations are made of subgroups and macro-cultures (Schein, 2004). This is important for the food safety culture conversation as we, the individuals who make up these macro-cultures (e.g. people safety, food safety, and innovation) can make very different assumptions related to the perceived value of food safety, magnitude of food safety risks, importance of the food safety learning programs, and so on. Culture is generally made up of assumptions deemed valid, taught to new members of a group or team, and used to guide our behaviours (Schein 2004). These assumptions can vary across nations, companies, and functions, in macro-culture, and across the sectors in the food supply chain. Our assumptions affect our behaviours, and we need to remember that we also take direction from others who make decisions on food safety and who might have different assumptions from ourselves.

Most people are not maliciously trying to make consumers sick from the food produced, but we need to have an appreciation of people's assumptions to trust the culture within which we work. For example, owners of Jensen Farms did not intentionally purchase and put an unfit piece of washing equipment in place and Maple Leaf Foods did not intentionally distribute *Listeria*-contaminated sliced meat. Some will argue that Cadbury knew of their *Salmonella*-contaminated chocolate and that XL Foods knew of their high *Escherichia coli* days. These arguments would not be incorrect; but when examining the details of each of these cases after the fact, we see how incorrect actions were taken based on assumptions thought to be valid. Assumptions such as, good enough cleaning practices, good enough communication practices, and business decisions either trumping food safety facts or being based on inappropriate interpretation of microbiological data. When the industry and academicians focus on the importance of culture, it is precisely to better understand such assumptions and change them and the *way we do things around here* before an accident happens.

15.1.2 Essential Definitions

Like many other elements of the world-class food safety management programme, food safety culture is an area in which many words are used that have specific meanings pertaining to culture and where there is limited international standardisation of terminology. Table 15.1 outlines definitions of some of the key terms currently being used in the organisational culture and food safety culture fields.

15.2 Supply Chain and Critical Food Safety Behaviours

To illustrate this and the impact of food safety assumptions we can look at a simplified model of the food supply chain. The model shows the interconnectedness of each of the five sectors and a few of the many macro-cultures (Figure 15.1).

Within each sector, there are specific inputs and outputs required to run an organisation targeted at value creation. Within these organisations there are lots of employees who daily make assumptions around the actions taken to put out safe food in balance with ensuring the profitability of the organisation and the employment of its staff. These assumptions are at the root of an organisations food safety culture

Table 15.1 Essential definitions: Food safety and organisational culture.

Term	Definition
Adaptability	Organisational culture dimension that describes organisation's approach to innovation and sustaining change.
Consistency	Organisational culture dimension that describes an organisation's adoption of formal systems, technology, and data to drive food safety activities and decisions.
Ethics	Moral principles that govern a person's behaviour or the conducting of an activity.
Food safety climate	Employee' (shared) perception of leadership, communication, commitment, resources, and risk awareness concerning food safety and hygiene within their current work organisation.
Food safety culture	The global food safety initiative defines food safety culture as 'shared beliefs, and norms that affect mind-set and behaviours towards food safety across, in, and throughout an organisation's values.
Integrity	The quality of being honest and having strong moral principles.
Mission	Communicates an organisation's reason for existence.
Norms	Norms are social expectations through which values are turned into behaviours. Norms explain why people do what they do in given situations. Social psychology recognises smaller group units, such as a team or an office, may also endorse norms separately or in addition to cultural or societal expectations.
People system	Cultural dimension describing an organisation's decision around behavioural recognition, building employee competencies, and how these are used in food safety communication.
Responsibility	The state or fact of having a duty to deal with something or of having control over someone.
Trust	Firm belief in the reliability, truth, or ability of someone or something.
Values	Organisational culture dimension related to an organisation's ethics and integrity related to food safety responsibilities and expectations.

Jespersen et al. (2018, under review).

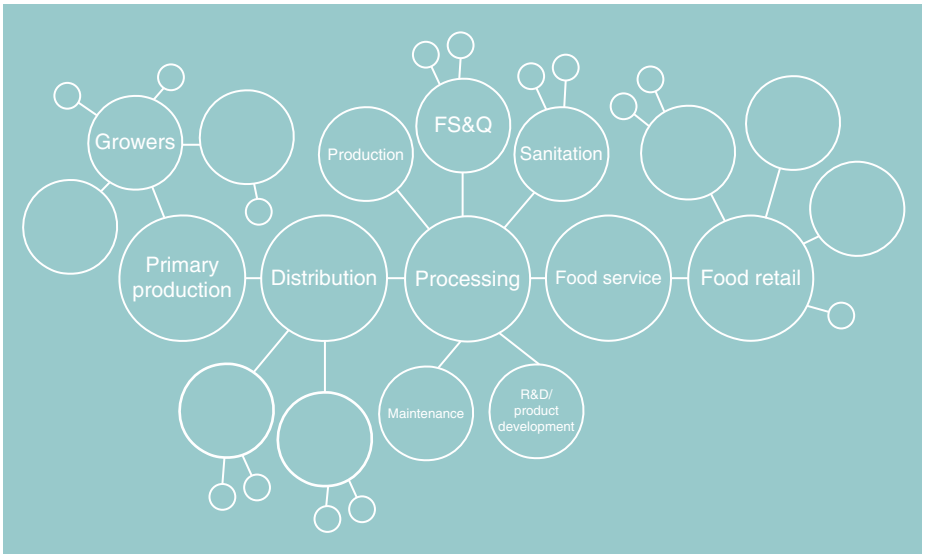

Figure 15.1 A simplified food supply chain that shows five main sectors and some of the macro-cultures in each of them.

(Schein & Schein 2017), and as we look at any organisation's food safety maturity, this will be directly impacted by the prevailing assumptions of groups and teams in that organisation. Assumptions are impacted by the organisation's values and mission, its people support systems, how consistent and adaptable the groups and teams act, and how it acts specific to risks and hazards in the sector and product categories. Such cultural dimensions are foundational to understanding how to evaluate, map, and improve/mature an organisations food safety culture. When studying each dimension, you will discover the assumptions that drive behaviours generally believed to be valid within the groups and teams of your organisation and, as such, both formally and informally taught to new colleagues (Denison et al. 2012; Denison & Mishra 1995). This information is hugely important in understanding the prevailing food safety culture in each business.

15.2.1 Dimensions of Food Safety Culture

To impact assumptions, we have five dimensions to play with (Figure 15.2; Jespersen, Griffiths, and Wallace, 2017). Each dimension was defined to help dissect food safety culture into dimensions that an organisation can both evaluate and impact to mature its food safety culture. The dimensions also form the basis for the food safety maturity model (See Section 15.4 and Table 15.3).

15.2.2 Follow the Leafy Greens …

To illustrate the importance of assumptions across the supply chain, we look at the process from farming leafy greens to serving to customers or selling to consumers through a food-retail outlet (Table 15.2). There are clearly defined inputs, outputs, processes, and food safety actions in each sector of the supply chain. Where it sometimes becomes harder to define and understand is in the food safety behaviours of supervisors and how these behaviours drive the assumptions of associates/operators (e.g., does the supervisor have a regular formal/informal communication touch point with associates?). Is there evidence of recognition of associates going over and beyond

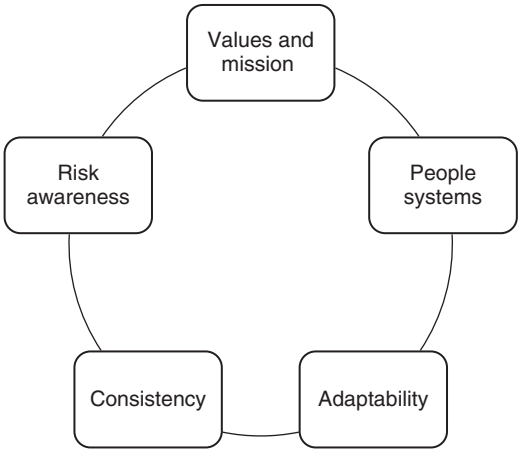

Figure 15.2 Food safety culture dimensions. Jespersen, Griffiths, and Wallace, 2017

Table 15.2 Follow the leafy greens: Example of actions, behaviours, and assumptions across the supply chain.

	Primary production/farming	Distribution	Processing	Foodservice/ catering	Food retail
Input	Water/seeds	Leafy greens	Leafy greens	Ready-to-use leafy greens	Ready-to-eat leafy greens
Output	Leafy greens	Leafy greens	Washed and packed leafy greens	Meals served to guests	Leafy greens in fresh produce bunker under load line
Process	Sow/Harvest	Load/transport/			
unload	Wash/pack	Unpack and serve mixed salad	Unpack and store leafy greens in bunkers at conditions and temperatures required		
Food safety task	I test every batch of compost for soil health and condition batch testing.	I check and document the temperature of the trailer for compliance to standard.	I test wash water for bacterial residue daily.	I check refrigerator temperature log and cook temperature log twice per shift.	I sample bags of ready-to-eat leafy greens bags/I check and document temperature of meat bunkers.
Supervisor assumption	We irrigate with the quality of water needed to grow and harvest quality leafy greens.	We receive leafy greens packed using the specified material and method.	We receive pathogen-free leafy greens shipped under specified conditions.	We receive pathogen-free leafy greens packed and shipped under specified conditions.	We receive pathogen-free leafy greens packed and shipped under specified conditions.
Supervisor FS Behaviour	I talk with my crew once a week over coffee about our business and food safety is first on the agenda.	I check in with drivers in one-on-one talks once every 2 weeks. We talk about their work and food safety is top of the list.	I share a summary of test results every Friday with wash crew, and we discuss findings and impact of family and friends who eat our leafy greens.	I review employee suggestions for food safety improvements in daily shift huddle, and we celebrate 'employee of the week' based on safety performance and customer feedback.	I share store performance once a week in our store huddle with all associates. Associates rotate monthly to provide safety performance update and lead discussion recognitions and improvements with colleagues.
Frontline associates FS Assumption	I believe that food safety is taken serious in the crew. Crew members help new members understand this by passing on knowledge, expectations, and practices by word of mouth.	I believe that food safety is critical to my employment and my manager listens to me, and it is expected that I voice any concerns I have. Not saying something if food safety is compromised or at risk would have negative consequences for my team.	I believe that I can harm family and friends if I do not understand if there are bacteria on our leafy greens. I share my belief when a new wash crew member shadows me.	I believe that I am part of a team that keeps every guest safe and feel proud every time a colleague is recognised by our supervisor for their daily actions.	I believe food safety is owned by myself and my colleagues and that we hold each other accountable by rewarding colleagues for great performance and for identifying areas of improvement.

FS, food safety.
(Examples are in a mid to higher mature food safety culture.)

their normal duties? Do associates have any responsibility in developing and delivering food safety communication? This is obviously only a small example of the system from process input to associate assumption and not a comprehensive supply chain example, but it is intended to give you some thoughts and inspiration to look both horizontally across the supply chain and vertically in the individual macro-cultures when designing your food safety management system.

15.3 Organisational Culture and Food Safety

When we look to understand food safety in the context of the organisational culture, we must acknowledge the importance of actions taken to adapt and integrate changes. The effectiveness of any organisation is directly linked to these actions and the assumptions that we all make to act is directly linked to, not only our own values and beliefs, but strongly influenced by the group we are part of and the overall organisational culture (Figure 15.3). A system for evaluating food safety culture is therefore not simply a system that checks the content of each building block (e.g. is there a learning program?) but the actions between building blocks (e.g. organisational culture, working group, and individual) that act as evidence for the organisation's ability to adapt and integrate change (Jepersen et al. 2018, under review).

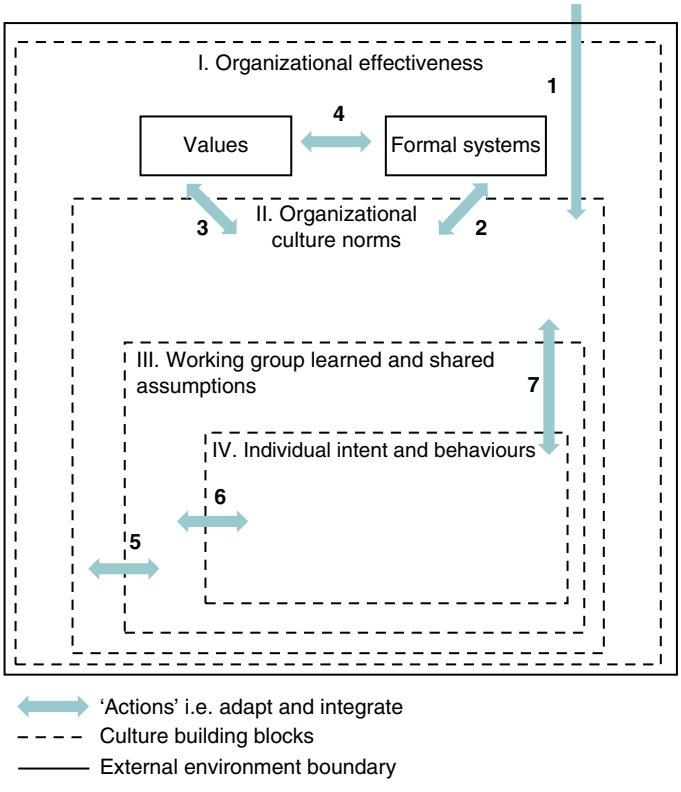

Figure 15.3 Organisational effectiveness with cultural building blocks and actions. Jespersen et al. 2018, under review.

A practical example from a day in the life of a food company can help illustrate this dynamic and complex system.

ACTION 1: 'Recall for *Salmonella*-contaminated products sold by category competitor' (marketplace) ⇨ External trigger.

ACTION 2: 'Automatically orders are given to review procedures to ensure risk is managed at company *x* (norm) ⇔ 'Management system includes written procedure for environmental monitoring' (formal system).

ACTION 3: 'Leaders automatically debate if the values at company *x* would help or hinder a similar event at company *x*' (norm) ⇔ 'At company *x* we care for customers, consumers, and the world we live in' (value).

ACTION 4: 'At company *x* we care for customers, consumers, and the world we live in' (value) ⇔ 'Management system includes written procedure for environmental monitoring' (formal system).

ACTION 5: 'A recall automatically increases food safety attention for a little while' (norm) ⇔ 'We know we will be talked to about food safety every time a competitor has a recall' (working group assumption)

ACTION 6: 'We know we will be talked to about food safety every time a competitor has a recall' (working group assumption) ⇔ 'I take it serious if my colleagues correct me if I make a food safety mistake but this mostly happens after a category recall' (individual behaviour).

ACTION 7: 'A recall automatically increases food safety attention for a little while' (norm) ⇔ 'I am confused about the importance of food safety but do what I think is expected of me' (individual behaviour).

15.4 Evaluate and Map Food Safety Maturity

15.4.1 Map to Food Safety Maturity

Maturity models are used in many different topics (e.g., IT, health care, and quality; Crosby 1972; Goonan et al. 2009). The great thing about any maturity model is that it typically breaks down a complex topic into dimensions and progressive improvement descriptors. This gives you a simple map to explain to others where we are and where we are going. You can also use the maturity model to evaluate your current stage and use this to discuss with your stakeholders where and how you want to prioritise future improvements. The food safety maturity model (Table 15.3) was developed and tested with five multinational food companies. Data were gathered from employee self-assessments, review of food safety documents, and 42 interviews with plant leaders, and by use of these multiple methods, the model was found valid and reliable as a map for maturing food safety culture. The model creates a strong connection to organisational values through the food safety culture dimensions and the norms statements in each value and stage intersect (e.g., 'employees have little trust that management will act on food safety without external pressure').

15.4.2 Walking the Food Safety Talk

Many methods to evaluate food safety culture use surveys which are sent to company employees, who are asked to assess themselves and their company culture. The challenge with surveys is that we all tend to respond in ways that makes ourselves and our organisation appear either overly positive or overly negative. This tendency is known as socially desirable responding or simply put *degree to which we walk the food safety talk*.

Table 15.3 Food safety culture - maturity model version 2.0.

		Stage				
Dimension	**Values**	**Stage 1 Doubt**	**Stage 2 React**	**Stage 3 Know**	**Stage 4 Predict**	**Stage 5 Internalize**
Values and Mission	Integrity and trust	Employees have little trust that management will act on food safety without external pressure	Employees trust that management will act and do the right thing for food safety after an issue have occurred	Everyone trusts that food safety issues are solved because we know it protects our business.	Everybody is trusted to invest in food safety information to make future performance stronger	Frontline employees are trusted to act to correct and celebrate food safety performance on their line/in their area
	Being responsible	Nobody knows who has the duty to deal with food safety	Everybody readily takes responsibility, but it is unclear what that means	Detailed food safety responsibility is written into job descriptions for everybody	Decision makers are certified food safety professionals and responsible for driving cost out of the food safety system	Frontline is responsible for bubbling improvement plans to leaders, leaders are responsible for incorporating these into long-term business planning
	Ethics	Moral principle …don't look	Moral principle…invest if we must	Moral principle…improve system	Moral principle…reduce cost by taking out variation	Moral principle…grow business
People System	Reward and recognize	Individuals complete food safety tasks out of fear for negative consequences.	Individuals are recognized sporadically after having solved a food safety problem	Leaders recognize teams and individuals according to a documented system of positive and negative consequences	Leaders reward teams for collectively improving food safety processes/procedures	Cross functional/level teams nominate other teams for being proactive and thinking strategic around food safety
	Competently communicating	Top-down 'tell' with little 'why' content and understanding of the importance of the task	Food safety information is communicated by FSQ as problems occur using, if available, facts discovered as the problem was solved	There is a deep understanding of the food safety system and performance is communicated by some functional leaders on a regular basis	Frontline leaders are having regular communications on food safety performance using data and tracking the teams' improvement actions.	Food safety communication cadence is an organizational habit that involves everybody in specific team discussions.
	Together we make the difference	silos…	problem communication…	fragmented delivery of information…	Food safety and quality critical conversations…	habit…

Adaptability	Innovate	Scrambling to meet changed requirements	Aware of coming change but do not update procedures before last minute	Change is analyzed and incorporated into written food safety system including changes to competencies/job descriptions	Innovation is driven by data internally to reduce food safety costs	Innovation is suggested by frontline teams and bubbling up to impact companywide system. Quick to adapt as they have technology interface in their hands.
	Embrace and drive change	Nothing is stable, so it does not matter if we must change…again	We know change is coming and will deal with it last minute…	We know the change and have analyzed the impact on individuals and teams according to a pre-defined change curve…	We look for cost reduction opportunities and plan these in our continuous improvement program…	Frontline teams have full autonomy to drive change in the food safety system, support teams are responsible for spreading new and best practices across the company…
Consistency	Data and reporting	Data are not used to solve problems and mostly sitting in a filing cabinet or in unused reports	It is left to the individual to identify needed data and ways to derive information from these	Leading indicators are used to find root causes of food safety problems and solutions are built into the food safety management system	Leading indicators are continuously updated through precisely and accurately collected data	Frontline teams and supervisors make use of leading indicators to improve food safety systems
	Technology enabled success	Little to no new value placed on buying or adopting technology	Technology is bought in reaction to a specific need e.g., faster pathogen testing results	Technology is seen in the context of the business system to integrate functions, procedures, and capabilities (e.g., ERP specification system)	Automation is used frequently and seen as an integral part of reducing food safety cost.	Enterprise Resource Planning (ERP) is used in an integrated way with automated workflows that make the enterprise quick to adapt.
	Quality of all we do	Unstructured problem solving to remove the immediate pain.	'plan, do, check, act' with emphasis on control and expectation of 100% perfect solutions from the start.	Structured, documented problem solving with high risk of analysis paralysis.	'plan, do, study, act' with emphasis on study and an iterative approach to improvement	Identifying risks through horizon scanning and continuous improvement followed by mitigation plans built into the food safety system.

(Continued)

Table 15.3 (Continued)

		Stage				
Dimension	**Values**	**Stage 1 Doubt**	**Stage 2 React**	**Stage 3 Know**	**Stage 4 Predict**	**Stage 5 Internalize**
Risks and Hazards	Risk perception	The organization relies mostly on external sources and inspections to understand and act on its risks and doesn't identify risks internally.	Actions to manage risks are mostly taken in response to external audits or inspections and internal identification is sometimes incorrect.	Risks are understood and continually challenged by a cross-functional team through planned risk management.	Understanding and reducing risks are an integral part of the organization's continuous improvement efforts.	The organization relies on frontline teams to manage existing risks and to identify new ones through peer observations.

This brings bias into our survey results but this can be compensated for by using a scale that captures the degree of social desirability, and we can act depending on the degree to which the participants *walk the food safety talk* by use of self-assessment statements. Variation in the social desirability score is explained through three components; assertion of positives, image management, and denial of negatives and is in line with general social desirability theory and studies. So how does this fit with measuring food safety culture? In a study, respondents were asked to indicate level of agreement with each statement on a five-point answer scale. The analysis showed that social desirability can be captured and evaluated in the food industry by the 14 statements of the FSDSR-scale (Jespersen, MacLaurin, and Vlerick, 2017; Table 15.4). Knowing how strong your organisations *food safety walk* is can give you invaluable information about what changes to suggest and what tactics to use as this information can potentially reduce the overall high but potentially false maturity results as a highly desirable response influences the combined evaluation result. For example, a self-assessed score of 4.5 could be reduced to 3.25 when factoring in social desirability. This result moves an organisations culture evaluation from Stage 4: Predict to Stage 3: Know.

15.4.3 Importance of Using Multiple Methods to Evaluate Food Safety Culture

Using multiple methods in the evaluation, in contrast to a single method, can provide your organisation with a comprehensive measure of food safety culture maturity and an

Table 15.4 Statements to rate degree to which we walk the food safety talk.

FSDRS-items	*Assertion of positives*	*Image management*	*Denial of negatives*
Always honest with myself about how I really feel about food safety	x		
Behaviour is consistent with my beliefs about food safety	x		
Know what actions to take regarding how best to protect food safety	x		
Do not regret my decisions about food safety issues	x		
Try to understand other people's opinions about food safety, when they differ from my own	x		
Appreciate other people's opinions regarding food safety	x		
Have very definite views about what government policy should be regarding food safety	x		
Never say bad things about people who disagree with my views on food safety		x	
Never say anything to hurt the feelings of someone who disagrees with me about a food safety issue		x	
Never get upset when people express opinions about food safety which differ from my own		x	
Feel resentful when I don't get my own way in a discussion about food safety issues			x
Try to cover up mistakes I make in conversations about food safety issues			x
Bothers me if people dislike me because of my views about food safety			x
Form opinions about food safety issues without always thinking about issues thoroughly			x

Jespersen, MacLaurin, and Vlerick, 2017.

insight into the variables that drive food safety behaviours across plants and functions. Methods can require more or less effort and also vary in the type of information that can be extracted. As such, surveys are often used but have limited capability to extract only information that the participant chooses to share. Interviews and observations require more effort to train the interviewer and more time from the interviewee but can provide important information about underlying assumptions and group beliefs. So, consider what you want to know before collecting your data and consider what you already do that includes food safety and people and how you can use these actions or data to evaluate your organisations food safety culture. For example, use food safety documents to look for roles and responsibilities. Is it always the same people taking on actions to close corrective actions? Also, ask your human resources to conduct structured and regular food safety focus groups. Human resources is group of professional *people* people; ask for their help, they will love it!

As an example of how these methods can work together, data from three methods, self-assessment survey, food safety documents, and interviews, were analysed in a research study of 21 plants from 5 multinational corporations; 816 self-assessment survey responses, codes from 379 performance documents, and codes from 42 interviews conducted on site at the 21 plants were used to evaluate the food safety culture maturity for each plant (Figure 15.4).

The use of these multiple methods gave each of the plants an accurate and trustworthy evaluation that they could act on to mature their food safety culture (Jespersen & Wallace 2017). Figure 15.5 shows and example of how this can be plotted, and in this case using, the data from five plants (Figure 15.5).

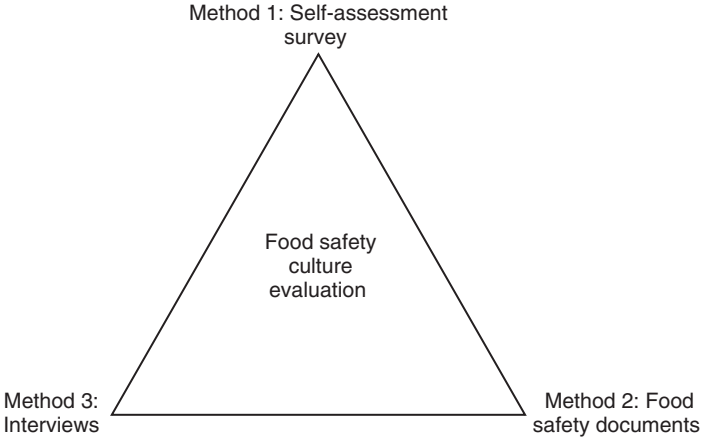

Figure 15.4 Evaluating food safety culture with multiple methods.

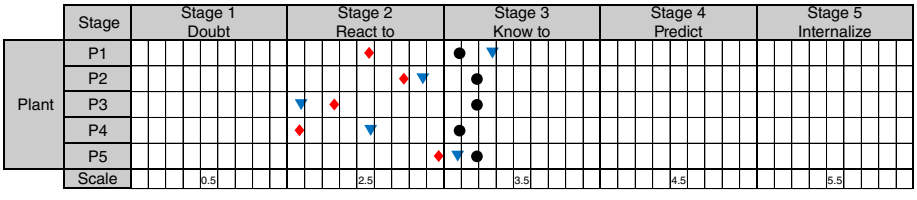

Figure 15.5 Plant maturity example: Plot of mean values as per method triangulation. Dot, self-assessment scale result; diamond, performance document coding result; triangle, interview coding result.

15.5 Tactics to Mature Food Safety Culture

Maturing and sustaining food safety culture requires a plan that is integrated into the overall business plan. In other words, do not expect food safety to mature if it is not part of the business priorities. This can be achieved through six areas tailored to the current state of your business' food safety maturity. This is critical as a given tactic for improvement can be either very effective or not at all depending on whether it is applied at the right stage of maturity. As such, a learning program must have different objectives if in Stage 1: Doubt rather than Stage 3: Know (Table 15.5). The doubt focus is on engaging the heart, minds, and hands of everybody and the know stage about creating problem-solving skills and root cause capability to build lasting processes and behaviours.

The five tactical areas for maturing food safety culture are shown in Figure 15.6. The order of steps is important because setting the wanted vision, strategy, and structure will enable the definition and operationalisation of roles and responsibilities and so forth. Examples of tactics from practitioners in stages doubt and know are captured by area in Table 15.5.

Table 15.5 Examples of tactics for improving maturity based on stage.

Area	Tactic for Stage 1: 'Doubt'	Tactic for Stage 3: 'Know'
Vision, strategy, and structure	Leadership session to agree on detailed wording, content, and structure for FSQ.	Workout sessions with senior leaders and operational groups to listen for needs and approve investments.
Roles and responsibilities; rewards and recognitions	Define individual responsibilities with functional leaders and write into job/work descriptions.	Develop rewards programme to celebrate team performance. Formally evaluate the individuals' knowledge of their specific responsibilities.
Learning and communication	Establish communications rhythm and use it to reward and correct performance (e.g. daily plant huddle, weekly leadership action meeting, quarterly executive review). Educate and train individuals on specific responsibility through food safety buddy.	Institutionalise 'rotating' chair. Enable everybody to take responsibility for their communication event (e.g. leadership action meeting). Schedule 'lunch and learns' or individuals to educate others on their food safety responsibility.
Change leadership	Select and train key individuals on change approach for food safety.	Change experts to meet and assist leaders in driving change around their new-found food safety responsibility.
Consistency	Incorporate responsibilities, communication rhythm, and change approach into the food safety management system. Cross-functional team develops measures for food safety culture performance.	Audit, inspect, observe the revised food safety management system, and engage leaders to improve where needed. Incorporate food safety culture performance measures in the communication rhythms and team rewards programme.
Risks and hazards	Company product- and process-specific risks and hazards are incorporated in responsibilities, learning and communications material.	A standing agenda item on any communication event is a scan for actions or changes that could impact the company specific risks and hazards (e.g. 'What changes in your area could have an impact on risk *x* and hazard *y*?')

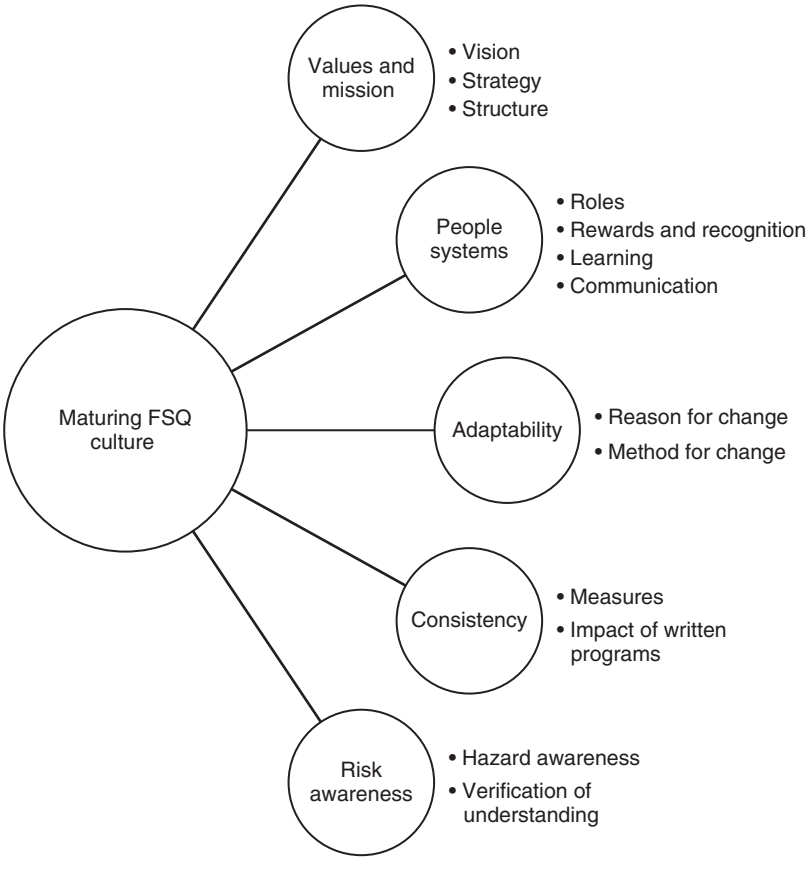

Figure 15.6 Culture dimensions and tactics for maturing food safety culture (cultivatefoodsafety.com).

15.6 Conclusions

Nobody comes to work wanting to harm consumers by sending out unsafe food. As such, food safety assumptions are made every day, and it is these assumptions that we seek to understand when evaluating, mapping, and maturing food safety in the context of the organisation's culture. Individual behaviours are driven by these assumptions and the norms in your organisation, and the norms are subsequently impacted by the company's values and formal systems. So, as you set out to better understand your organisations' food safety maturity ensure that you use multiple methods to evaluate it (i.e. use the *walking the food safety talk* statements to dig deep on the psychology of your colleagues). Use a method that makes it simple and straightforward, not just for you, but also for your stakeholders to understand food safety culture and provides an intuitive map forward. The food safety maturity model is an example of such a map; it is simple and ties directly into common terms applied in organisational culture. As you set out to

mature your food safety culture, do so by involving your functional peers; do not make the mistake of creating a specific food safety project to improve food safety culture. If you truly want to mature your company's food safety culture to get better and more effective performance you must insist that this effort is part of your business priorities and that you the commitment from other functions to work with you on this. Food safety is about people, by people, and by focusing on culture, performance will follow.

Part IV

Food Safety Management in Practice: Current Issues and Challenges in Areas of the Global Food Supply Chain

16

Food Safety in Agriculture: Determining Farm-Derived Food Safety Risk

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16.1 Introduction

This chapter reflects upon farm production-derived food safety risk and more specifically how different supply chain actors understand and approach food safety risk on farm and the options for risk identification and mitigation. The chapter begins with a consideration of food quality and food safety and reflects on value as an inherent attribute of food provision and as a risk to food safety. The influence of uncertainty and ambiguity and how it affects risk perceptions and decision making, the risks inherent to farmers' context characteristics and the lessons learned in terms of supply chain governance are then explored. A series of case studies are used in this chapter to explore themes, including the public health impact of driving value in the food supply chain, the factors that influence the development of private standards such as Red Tractor or GlobalGAP, and the context characteristics that can come together to influence inherent risk in a given farm situation. The chapter concludes with a reflection on risk-mitigation measures at farm level.

16.2 Notions of Food Quality and Food Safety

The reality of how our food is produced across the world is bounded in terms of the methods of food production on farm, the ways in which livestock live their lives, how crops are grown, and the influence of geography and climate. At the same time, the perception of what farming constitutes and how that is actually verified by consumers means that often only a limited number of attributes are used to make purchasing decisions and there may well be inferred characteristics applied to such cues and attributes (Schlag 1992). Attributes are, for example, organic farming, animal friendly, or regional provenance. Throughout the food supply chain, these characteristics influence notions of quality, food safety, and levels of risk.

Product quality is rooted in meeting customer requirements at each stage in the food chain and ultimately with the consumer. Product quality can be defined in terms of intrinsic or extrinsic product characteristics. Intrinsic quality characteristics define the

Food Safety for the 21st Century: Managing HACCP and Food Safety Throughout the Global Supply Chain, Second Edition. Carol A. Wallace, William H. Sperber, and Sara E. Mortimore.

size, shape, colour, taste, smell, length, freshness, nutrient content, and the inherent nature of a food (Manning and Baines 2004; Luning and Marcelis 2009). The more complex the food, the more detailed the technical specification for the food itself in terms of its intrinsic quality attributes. Extrinsic quality characteristics reflect how a food material is produced (e.g. organic production, environmental friendly) (Luning and Marcelis 2009). Consumer perception of farms and farming, and the associated food products, is influenced by personal consideration of extrinsic cues and the conversations people hear about food with friends, in the media, or online. Indeed, with the advent of the Internet, access to information by individuals, communities, and public interest groups is unprecedented (Krimsky 2007). When food is placed in the basket or on the checkout belt, considerations of how food is grown, processed, and transported to retail shelves in a nutritious state and with adequate shelf life and quality, how the workers are treated in the supply chain, and the true environmental impact of all those stages is of little consequence for some customer '**consumers**', whilst being very important for others, '**citizens** (Grunert 2006). This factor mediates how people perceive extrinsic quality. Product quality is thus often addressed in a preventative (assured) approach or as part of a control programme via inspection at prescribed stages in the supply chain, and it is useful to consider here the different definitions for food quality and food safety.

The Food and Agriculture Organisation (FAO 2003a, p. 3) stated that:

> Food safety refers to all those hazards, whether chronic or acute, that may make food injurious to the health of the consumer. It is not negotiable. Quality includes all other attributes that influence a product's value to the consumer.

Whilst these definitions may be well known, the vocabulary of food safety is fast evolving (Manning and Soon 2016), and the terms *food fraud* and *food defence* are developing (see Chapter 13), and regard the deliberate substitution, addition, tampering, or misrepresentation of food, food ingredients, or food packaging or false or misleading statements made about a product. Many of the food safety and quality management controls currently used on farms are derived from the need to comply with both national legislation, as appropriate to legislation in the country to which the food may be exported, and the standards contained in private schemes, such as Red Tractor in the United Kingdom or more widely GlobalGAP. These elements are integrated into a farm-assurance programme that is farm specific and addresses the particular situational risk of the farm environment and the crops or livestock grown.

During the structured iterative process of revising farm-assurance standards, such as GlobalGAP, over time, new notions of food safety and food quality may be integrated into these standards and adopted at farm level. An example of this is the inclusion within GlobalGAP standards (Version 5) of the requirement for food-defence protocols at farm level. This means that integrated farm-assurance systems need to specifically focus on food quality and food safety issues associated with the products and processes employed on the particular farm. These systems must also be agile enough to underpin resilience at farm level and also within the wider supply chain.

16.3 Value as a Food Attribute in Primary Agriculture

Value, as an inherent attribute of food provision, mediates supply chain dynamics, standards, and protocols and how businesses and individuals at the farm level behave.

Perceptions of value, rather than merely profitability and price, are subjective and vary within the supplier: customer interface at all stages of the food supply chain, and as such, value is a dynamic variable, experienced before purchase, at the moment of purchase, at the time of use, and after use too (Sańchez et al. 2006).

Multinational corporations (MNCs) have developed over the last half-century to mediate the transformation of food from raw commodity to final processed state, and as a result, to feed ever-higher proportions of the world's population. Globalisation has driven consolidation, vertical and horizontal integration, economies of scale, increased purchasing power, and greater intellectual, technological, and physical resources to draw upon (Manning and Baines 2004; Manning 2015; Manning and Smith 2015). To be able to logistically move foods great distances, and as cities grow and megacities develop around the world, complex processing is required. As a result, the inherent structure of what we eat changes to lengthen shelf life and maintain food viability whilst in transit and storage. This influences what farmers can and do produce and what management controls are developed at farm level.

Prices of food commodities on world markets, adjusted for inflation, declined substantially from the early 1960s to the early 2000s, when they reached a historic low level (FAO 2011). Knutson et al. (1998) cited by Miller and Coble (2006) argue that governments have overtly pursued cheap food policies to keep the price of food below the competitive equilibrium price (Manning 2015). Luning and Marcelis (2007) expand the phrase *product quality,* as previously described, to *food quality,* a term that encompasses multiple criteria including: product quality (in terms of intrinsic and extrinsic attributes), cost, availability, flexibility, reliability and service. Food price does influence access to calories and food security, and there is a disaggregation across global society as to how important price is as a factor when purchasing food. Price is, therefore, not the only product attribute that is used to determine food quality. Instead the ways that quality is determined at any supplier: customer interface is more nuanced.

Zeithamal (1988) differentiated value, as opposed to food quality, in four ways around the 'give-and-get' dynamic:

1) Value as a factor of **money** (i.e. low price equals value).
2) Value as a factor of **attributes (**i.e. value is what I want in a product; its utility in terms of ease of preparation, convenience).
3) Value as a factor of **quantity** (i.e. value as a ratio of price to portion size, pack size, or other measure of amount). Burns et al. (2013) describe this as acquirability (i.e. having enough food to fill you up often energy dense rather than nutrient dense food).
4) Value as a factor of **quality** (i.e. value is the quality criteria I get in terms of the price I pay). These criteria can be intrinsic as previously described or extrinsic in terms of the method of production or ethical factors such as animal welfare or environmental attributes.

Moreover, Burns et al. (2013) define *affordability* as this perception of food quality in terms of intrinsic and extrinsic factors and also describe value in terms of *hedonistic* features. Hedonistic features align with the emotional worth of food to individuals, families, or communities (i.e. the psychological response to food). This can be linked to stress and anxiety as equally as happiness and contentment, so called 'comfort foods'.

From a quality and a food safety viewpoint, food is in its raw, basic, commodity state at farm level. Fresh produce may be sold directly to the consumer from the field or protected environment; although in many fresh produce supply chains, there is a terminal

food safety control step such as a chlorine-washing or irradiation. Alternatively, farm outputs are then processed into the foods most people eat or are fed to livestock and converted into the meat and animal-derived products that are then consumed.

Case study 1 considers the bovine spongiform encephalopathy (BSE) and new variant Creutzfeldt-Jakob disease (vCJD) incident experienced in the United Kingdom nearly 30 years ago and focusses on the challenges when a farm-derived *unknown* food safety hazard then subsequently needs to be controlled in the wider food supply chain. The drive for cost reduction at farm level lies at the heart of the incident described in the next case study. This case study is also significant because it was at the time a driver for improvements in technical standards, scientific understanding, legislation, and the need for appropriate communication throughout the supply chain.

16.3.1 Case Study 1: BSE and the United Kingdom

Based on epidemiological evidence, United Kingdom food-regulatory bodies had been aware of the potential risk of BSE to consumers from 1988; however, until 1996, any suggestion of potential risk to the public from eating beef was discounted by government, the scientific community, and policy makers through media sources (Knox 2000). For United Kingdom consumers, BSE as a food scare came after a decade that saw Spanish toxic oil syndrome 1981; antifreeze in Austrian wine in 1985 and Italian wines in 1986 that killed 16 people; and alar in apples in 1988. Manning and Baines (2004) reflect that in the BSE inquiry report (Policy Commission 2002), key conclusions were reached on how potential food safety hazards were, or were not, addressed:

> At the heart of the BSE story lie questions of how to handle a hazard – a known hazard to cattle and an unknown hazard to humans. The Government took measures to address both the hazards. They were sensible measures, but they were not always timely nor adequately implemented and enforced.

Governments in this situation could be lobbied by supply chain actors who reflect not only a scientific viewpoint, but also the view of those liable to the economic consequences of certain actions the government could prescribe. This could lead a government to take a 'political' policy decision rather than take an objective scientifically based view (Manning and Baines 2004), especially in the instance of an emerging food-related hazard in which much is simply unknown. The challenge of when to communicate risk and when to remain silent in the face of known and unknown hazards ultimately influenced in this case the impact of both the animal disease BSE and the human disease vCJD of which 177 people had died in the United Kingdom as of December 2015 (CJD 2016). The crisis led to the slaughter of 3.3 million cattle and estimated economic losses of £3.7 billion (Beck et al. 2005). Jensen (2004) outlines that government failure to communicate risk, unaddressed uncertainty, a lack of transparency, and weak risk characterisation as well as recommendations that were ambiguous and hard to interpret was as a result of policymakers' concern of overreaction by the general public because of their perceived inability to reach a balanced judgement. At the time, very few consumers realised that a drive for reduced costs in the supply chain, and *cheap food,* that meant the adoption of more intensive agricultural practice involved using animal derivatives in feed provided for herbivores (Anderson

2000). The challenge with BSE was the emergence of a new kind of hazard, a *prion* – an agent where the scientists required a greater level of proof before they felt confident to publish their conclusions but when risk communication to the general public may have actually been required at lower levels of certainty.

16.4 Uncertainty and Ambiguity Affecting Risk Perceptions and Decisions

Uncertainty is simply a state or condition that involves a deficiency of information (BS ISO 31000 2009). Uncertainty influences perceptions of risk. Fear of the consequences of playing with nature, in terms of feeding vegetarian animals with sources of animal origin, also influenced the general public in their attitudes towards BSE and created a loss of trust in those who were expected to protect the general public (Wales et al. 2006). It was essentially the decision of when to communicate risk and on what level of evidence that underpinned the problems that arose here. Different actors had to make decisions when they had varied tolerance of the degree of uncertainty the point at which they felt they could confidently take action. The role of uncertainty, and the point at when to take action, the acceptance of personal and group culpability for decision making and its resultant economic and social impact lies at the root of this case study. Therefore, food safety risk at farm level is not just a technical construct, instead it is bounded too by political factors. In saying this, the term *political* is being used in its core sense meaning 'of, for, or relating to the citizens'.

Higher-order systems such as the interaction of regulation and enforcement surveillance and the interaction between policy and market governance are complex. Luning and Marcelis (2006) propose a techno-managerial approach to concurrently analyse behaviour of food and human systems aimed at realising food quality, safety, and integrity. To make more accurate predictions of food quality, safety, and integrity, more information is needed to reduce uncertainty and greater knowledge to reduce ambiguity on food behaviour in food production as well as human behaviour in management (social) systems. However, to a certain extent because of the complexity and dynamics of food systems as well variable and complex human behaviour, food quality management systems (QMS) will still remain unpredictable (Luning and Marcelis 2007).

Vulnerability, uncertainty, and ambiguity are inherent attributes of context factors, such as product- and production-related characteristics of the environment in which a food safety management system (FSMS) operates. They influence the degree of risk associated with decision making (Kirezieva et al. 2013; Luning et al. 2011). Methods of production shape the degree of riskiness of these context factors and are farm specific (e.g. use of soil-based production versus sterile substrate; rain-fed production versus irrigation; use of crop protection products versus non-use; protected crops versus unprotected crops, and so on). Each environment will have different product and process context factors. This makes it difficult to produce a common FSMS system and associated good agricultural practice (GAP) standard that spans all farm enterprises and environments. As a result, with farm standards such as Red Tractor or GlobalGAP, a modular, or sector approach, has been used to develop the private standards and this forms the next case study.

16.4.1 Case Study 2: Red Tractor Standards

Farm-assurance standards relate to food safety requirements and the aspects of extrinsic quality associated with food products (i.e. how they are produced and grown in terms of management practices, animal welfare, traceability protocols, environmental controls, etc.). Many of the elements of GAP also contained within these standards have been adopted because they address the control and management of food safety in terms of the biological, chemical, and physical hazards that could present themselves on farm. One of the main drivers of the development of farm and supply chain assurance schemes in the United Kingdom was the Food Safety Act (1990) and the inclusion of the legal defence of 'due diligence' within this legislation (Kirk-Wilson 2002; Manning and Baines 2004). The Red Tractor Scheme was launched in the United Kingdom in 2000 by the National Farmers Union (NFU) and other stakeholders under the control of the scheme owner Assured Farm Standards. The term *baseline* indicates a scheme that is operating at the base, or foundation level of a series of standards. The baseline concept aims at the majority participation of a sector, as opposed to 'higher-level' schemes, which are said to have premium or higher standards compared with what is included in the baseline (Kirk-Wilson 2002). Food safety and legal compliance is a given across all standards and the need to demonstrate compliance with associated regulatory requirements. The term *higher* refers to consideration of extrinsic standards associated with how the product is produced and relies on consumers' willingness to pay for the additional quality attributes (e.g. organic standards or marine stewardship standards). The Red Tractor crop and livestock standards (Red Tractor 2017) have been compared to demonstrate the pre-requisites that are developed, which are context specific (Table 16.1).

There are five standard elements that are common across all six commodity standards namely: documents and procedures, staff and labour providers, traceability and assurance, vermin control, and environmental protection and contamination. However, others are context specific (e.g. fresh produce and temporary crop protection structures, and harvest and field packing). The risks inherent to farmers' context characteristics are now explored.

16.5 Risks Inherent to Farmers' Context Characteristics

Context factors influence the degree of risk associated with a food product and thus the associated GAP standard that is developed to mitigate such risk. These context factors can be external to the business environment or internal business factors. Further, the context factors can be active (i.e. influencing the organisation on an ongoing basis) or can be dormant awaiting a trigger factor that will then enact them. Internal trigger factors include changes such as new farming systems, technology, new individuals in key management positions, or a change in customer requirements whereas external trigger factors can be influences such as evolving consumer demands (e.g. animal welfare) or environmental standard changes that influence food safety and quality performance on the farm.

Luning et al. (2011) determine the context factor characteristics that impact food safety management activities, and these can be applied at the farm level, being:

Table 16.1 Comparison of elements of farm-assurance requirements for Red Tractor standards, 2017.

	Red Tractor Livestock Standards to Oct 2017					
	Fresh produce	**Combinable crops and sugar beet standard**	**Dairy**	**Beef and lamb**	**Pigs**	**Broiler**
RA	RISK ASSESSMENT					
IA	INTERNALAUDITS					
DP	DOCUMENTS AND PROCEDURES	DOCUMENTS AND PROCEDURES	DOCUMENTS AND PROCEDURES	DOCUMENTS AND PROCEDURES	DOCUMENTS AND PROCEDURES	DOCUMENTS AND PROCEDURES
SC	STAFF AND LABOUR PROVIDERS	STAFF AND LABOUR PROVIDERS	STAFF AND LABOUR PROVIDERS	STAFF AND LABOUR PROVIDERS	STAFF AND LABOUR PROVIDERS	STAFF AND LABOUR PROVIDERS
TI	TRACEABILITY AND ASSURANCE STATUS	TRACEABILITY AND ASSURANCE STATUS	TRACEABILITY AND ASSURANCE STATUS	TRACEABILITY AND ASSURANCE STATUS	TRACEABILITY AND ASSURANCE STATUS	TRACEABILITY AND ASSURANCE STATUS
VC	VERMIN CONTROL	VERMIN CONTROL	VERMIN CONTROL	VERMIN CONTROL	VERMIN CONTROL	VERMIN CONTROL
EE	ENERGY EFFICIENCY					
RC	RESIDUES AND CONTAMINANTS	RESIDUES AND CONTAMINANTS				
EC	ENVIRONMENTAL PROTECTION & CONTAMINATION CONTROL	ENVIRONMENTAL PROTECTION & CONTAMINATION CONTROL	ENVIRONMENTAL PROTECTION & CONTAMINATION CONTROL	ENVIRONMENTAL PROTECTION & CONTAMINATION CONTROL	ENVIRONMENTAL PROTECTION & CONTAMINATION CONTROL	ENVIRONMENTAL PROTECTION & CONTAMINATION CONTROL
EI	ENVIRONMENT IMPACT/ CONSERVATION AND SUSTAINABILITY	ENVIRONMENT IMPACT/ CONSERVATION AND SUSTAINABILITY				

(Continued)

Table 16.1 (Continued)

	Red Tractor Livestock Standards to Oct 2017					
	Fresh produce	**Combinable crops and sugar beet standard**	**Dairy**	**Beef and lamb**	**Pigs**	**Broiler**
IM	INTEGRATED CROP MANAGEMENT	INTEGRATED CROP MANAGEMENT				
SM	SITE AND SOIL MANAGEMENT	SITE AND SOIL MANAGEMENT				
IG	IRRIGATION					
SN	SEED, ROOTSTOCK AND YOUNG PLANTS	SEED				
CV	CHOICE OF VARIETY OR ROOTSTOCK & PLANT HEALTH CERTIFICATION					
TC	TEMPORARY CROP PROTECTION STRUCTURES					
HS	HARVEST AND FIELD PACKING					
PH	PRODUCE HANDLING & PACKHOUSE PACKING					

ST	STORAGE	POST-HARVEST TREATMENT & STORAGE				
HT	POSTHARVEST TREATMENT					
TP	THIRD PARTY STORAGE					
GM	GENETICALLY MODIFIED ORGANISMS					
HW	HEALTH AND SAFETY AND WORKER WELFARE					
EH		EQUIPMENT HYGIENE				
OT		OWN TRANSPORT FOR OFF FARM DELIVERY				
MP			MILK PRODUCTION			
HF			HOUSING, SHELTER AND HANDLING FACILITIES	HOUSING, SHELTER AND HANDLING FACILITIES	HOUSING, SHELTER AND HANDLING FACILITIES	HOUSING, SHELTER AND HANDLING FACILITIES
FW			FEED AND WATER	FEED AND WATER	FEED AND WATER	FEED AND WATER
AH			ANIMAL HEALTH AND WELFARE	ANIMAL HEALTH AND WELFARE	ANIMAL HEALTH AND WELFARE	ANIMAL HEALTH AND WELFARE

(Continued)

Table 16.1 (Continued)

	Red Tractor Livestock Standards to Oct 2017					
	Fresh produce	**Combinable crops and sugar beet standard**	**Dairy**	**Beef and lamb**	**Pigs**	**Broiler**
CR			ARTIFICIALLY REARED YOUNGSTOCK (CALVES AND LAMBS)	ARTIFICIALLY REARED YOUNGSTOCK (CALVES AND LAMBS)		
BI			BIOSECURITY AND DISEASE CONTROL	BIOSECURITY AND DISEASE CONTROL	BIOSECURITY AND DISEASE CONTROL	BIOSECURITY AND DISEASE CONTROL
AM			ANIMAL MEDICINES AND HUSBANDRY PROCEDURES	ANIMAL MEDICINES AND HUSBANDRY PROCEDURES	ANIMAL MEDICINES AND HUSBANDRY PROCEDURES	ANIMAL MEDICINES AND HUSBANDRY PROCEDURES
FS			FALLEN STOCK	FALLEN STOCK	FALLEN STOCK	FALLEN STOCK
LT			LIVESTOCK TRANSPORT	LIVESTOCK TRANSPORT	LIVESTOCK TRANSPORT	
OP					OUTDOOR PIGS	
DE						DEPOPULATION
PT						POULTRY TRANSPORT

Adapted from Red Tractor (2017)

- **Product characteristics** (i.e. the *intrinsic* properties of initial materials and final products).
- **Production characteristics** (i.e. the *extrinsic* conditions utilised during primary production, processing, or handling).
- **Organisational characteristics** specific to the organisation itself. These can be further subdivided into **individual** (people) characteristics, **group** characteristics (transformational characteristics associated with food safety culture and quality culture), **organisational** structures (transactional division of tasks, responsibilities, rules, procedures), and information systems, which affect peoples' decision-making behaviour.
- **Chain characteristics** (i.e. the conditions during supply) and relationships with other companies and organisations in the chain (Luning and Marcelis 2007; Luning et al. 2011; Kirezieva et al. 2013).

The interplay of these factors for a given farming business will underpin the level of food safety risk on farm. Case study 3 reflects on the 2010 recall in the United States of half a billion eggs from one organisation and demonstrates this point.

16.5.1 Case Study 3: Quality Egg

On 13 August 2010, in the United States, Quality Egg of Iowa initiated a voluntary recall of eggs for *Salmonella Enteritidis* contamination, which it widened on 18 August and then on 20 August expanded again to include Hillandale Farms of Iowa encompassing more than 550 million eggs (Li et al. 2017). This proved to be the largest recall ever in the United States. The Food and Drug Administration (FDA) Egg Safety Rule that required farmers to establish new measures to prevent pathogenic contamination, such as *Salmonella* only came into effect the month before (Laestadius et al. 2012). Nearly 2000 cases of illness were linked to the incidents, and on 30 August, the FDA made its inspectional observations and detailed multiple violations of the Egg Safety Rule at both companies (FDA 2010a). Examples of instances of non-compliance included basic requirements of GAP including:

- Failure to prevent stray poultry, wild birds, cats and other animals from entering poultry houses.
- Animals, including rodents, able to enter the poultry houses due to structural damage that included things like missing siding and air vents or gaps at the bottom of doors.
- Failure to eliminate birds from laying houses and to control rodents or flies.
- Live flies were observed on and around egg belts and walkways to different sections of the egg laying areas.
- Live flies were crushed underfoot when employees walked in the aisles at work and there were live and dead maggots observed in the manure pit at one plant.
- Investigators observed the failure to implement practices to protect against the introduction or transfer of *Salmonella* Enteritidis between and among poultry houses.
- Specifically, investigators observed a lack of separate entrances to each poultry house, thus requiring the use of shared corridors between certain houses.
- Employees were observed failing to change protective clothing when moving from one house to another, and failed to clean and sanitise equipment prior to moving between poultry houses at one plant (FDA 2010b).

In April 2015, the US Department of Justice issued a press release that stated:

> Austin 'Jack' DeCoster, 81, of Turner, Maine, who owned Quality Egg, was sentenced to serve three months in prison to be followed by one year of supervised release, and fined $100 000. His son, Peter DeCoster, 51, of Clarion, Iowa, who was Quality Egg's chief operating officer, was also sentenced to serve three months in prison to be followed by one year of supervised release, and fined $100 000. Quality Egg was sentenced to pay a fine of $6.79 million and placed on probation for three years. (US Department of Justice 2015)

This case study example clearly shows a breakdown with regard to business system characteristics as a result of the inherent known risk associated with *Salmonella* and eggs, the vulnerable extrinsic production characteristics identified driven by the physical structure of the poultry houses and practices during production and handling, and organisational failures associated with people, protocols, tasks and decision making. Whilst context factors have been mapped to farm-assurance standards and their requirements and within regulations, too, this does not prevent deterioration of processes in a given situational context.

16.6 Supply Chain Governance and Food Safety

Supply chain governance, whether legislative or market derived involves a moral stance and requires policy makers, nongovernmental organisations (NGOs), civic society, retailers, and MNCs to drive decision making on behalf of individuals or communities. This requires that consumers are willing to give up autonomy over their food supply in return for safe food, full shelves, and assurance of both consumers' collective and personal self-interest being place above the interests of others in the supply chain. Thus, implicit, tacit rules or norms are formulated and enforced, often by the retailer, to whom the said consumers have ceded their natural rights (see Driver 2007) and explicit characteristics within the wider construct of corporate social responsibility (CSR).

Hartmann et al. (2015) differentiate between levels of trust including: **macro-level trust** (i.e. institutional based trust based on formal governance controls such as legislation, private GAP standards, or informal governance controls such as corporate reputation or community norms) and **meso-level trust** through to **micro-level trust** (i.e. the interaction-based or relational-based trust based on personal experience between two actors at the supplier: customer interface). Trust links with the relative tolerance of uncertainty and ambiguity by individual supply chain actors, and as a result, the degree of trust then influences what is then prescribed within contractual conditions of supply (Kleboth et al. 2016).

Cheap food can be determined in terms of both its price and its moral value. Organisations up and down the supply chain face a strategic and moral dilemma, between seeking new ways of reducing costs to remain competitive while also meeting, if not exceeding, legislative and regulatory requirements over food safety (Manning 2016). Case study 1 and issues such as the 2013 horsemeat scandal demonstrate what happens when supply chains get it wrong. Cheng (2012) regards this as 'cheap capitalism' characterised by low price, poor quality products, and degraded business morality. The Department of Justice press release (2015) regarding the activities at Quality Egg highlights this reduced

business morality as follows:

> Quality Egg also pleaded guilty to introducing misbranded eggs into interstate commerce with the intent to defraud. As part of its plea agreement, Quality Egg admitted that, beginning no later than January 2006 and continuing through Aug. 12, 2010, its employees affixed labels to egg shipments that indicated false expiration dates with the intent to mislead state regulators and retail egg customers regarding the true age of the eggs. Quality Egg acknowledged that there were a number of ways that the company mislabelled older eggs with newer processing and expiration dates prior to shipping the eggs to customers in California, Arizona and other states. Sometimes Quality Egg personnel did not put any processing or corresponding expiration dates on the eggs when they were processed. The eggs would be kept in storage for several days or up to several weeks. Then, just prior to shipping the eggs, Quality Egg personnel labelled the eggs with processing dates that were false in that the dates were more recent than the dates that the eggs had actually been processed and with corresponding false expiration dates.

Safe food is not a luxury but an essential component of food regardless of perceived value. Indeed, food-related illness encompasses both acute and chronic hazards associated with food. Manning (2017) and Trench et al. (2011) identify multiple factors driving increasing health risk in 'value food chains' including:

- Urbanisation leading to reliance on anonymous supply chains, where the primary producer and those working in MNCs do not personally know the consumer.
- Greater demand for convenience and fast food in city and urban areas with consumers giving up responsibility to others for growing, cooking, and preparing food and for controlling food safety through a shift in consumption patterns towards more high-risk foods and processed foods.
- Large-scale food production creating an emotional detachment and a geographic isolation between food producer and consumer.
- Globalisation of food supply increasing the potential for pathogens and zoonoses, diseases that can pass from animals to humans such as avian influenza, *Salmonella*, reaching a wider population.

Providing value to consumers in a food supply chain where there is an embedded social contract, decisions made by governments and MNCs on behalf of their customers can lead to processes or protocols at farm level which the general public are largely unaware of until controls fail and there is then a subsequent incident, such as in the case with BSE or Quality Egg. Moreover, in many developed countries, food safety is simply 'a given' for consumers. However, the scope and depth of the processes and protocols that are undertaken on farms across the world and activities later in the supply chain to keep them safe and free from harm are seemingly remote and often too complex; some might even say they are opaque and difficult to understand (see Kussaga et al. 2014; Nanyunja et al. 2015).

16.7 Risk Mitigation at Farm Level

HACCP is not a risk-management tool designed to deliver zero food safety risk. For many, on-farm food safety issues, such as hazards that can arise from personnel or

the premises, HACCP-derived operational prerequisite programmes such as GAP have been traditionally adopted to minimise, but not eliminate risk. By the sheer physical nature of the activities that occur on farm, there are very few process steps, from field to farm gate, that are developed specifically to eliminate a food safety hazard; most are designed to minimise the hazard or reduce the risk to what is deemed through the HACCP approach to be 'acceptable'. Often process designed critical control points (CCPs) lie in the manufacturing stages such as cooking, pasteurisation, sieving, metal detection, and so on or ultimately when the product is consumed. However, if the product is eaten raw or the agent that can cause harm that arises at farm level cannot be adequately controlled on farm and subsequently cannot be 'processed out', the HACCP approach will have limited value and the product will have an inherent food safety risk. Instead, product recall and disposal may be the only option available to safeguard the public from certain farm-associated hazards.

Risk is a combination of, the probability of an occurrence of a particular threat, and the possible subsequent impacts (Slovic 2002). The Food Law Code of Practice (England) (Food Standards Agency 2017, p. 147) defines risk as 'the chance or probability that a person will be harmed or experience an adverse health effect if exposed to a hazard'. Slovic (1999) differentiates between experts and scientists, who consider risk as 'real' in terms of objective, analytical, and rational criteria and alternatively others, especially the general public, who see risk as a 'perception' and often make judgments that are subjective, value based, or irrational leading as a result to a spectrum and sometimes polarity of viewpoints. The use of inference by 'lay people' is often because they have limited access to information or lack the understanding to interpret, complex statistics (Slovic et al. 1981). As a result, they use cues from past experience or observation in their decision making. Therefore, Slovic (1999) argues that risk itself cannot be considered as an objective, abstract characteristic, but instead should be viewed as being a concept that humans have developed to understand and cope with uncertainty and as a result cannot be independent of bias and cultural influences. So how individuals make decisions, and more particularly assess risk, can be a complex, and individualistic approach. A heuristic can be described as an approach, or technique, that is used by individuals to solve problems, make judgements, and form decisions. Thus, to consider, deliberate, and come to a decision on a given problem, a heuristic can be a reductionist way of navigating a given set of issues or challenges. This approach can be described instead as considering 'risk as a feeling'.

Due diligence is the process through which organisations, and indeed whole supply chains, identify, assess, mitigate, and prevent the actual and potential adverse impacts of their activities (OECD-FAO 2016). Due diligence in itself, whether it originates as a result of regulation or MNC risk-reduction activities, drives the complexity and scale of risk elimination and risk-management approaches throughout the supply chain and especially at farm level. Protocolisation, especially when linked to a diligence defence can be described as the formalisation of organisational operations as a response to minimising issues of blame and liability (Hood and Rothstein 2001). Thus, Rothstein et al. (2006, p. 97) assert:

> risk assessment can be seen as a way of formalising organisational operations in order to provide bureaucratically rational 'due diligence' defences in the face of increased accountability pressures.

Slovic et al. (1981) argue that **risk assessment**, in all its stages, first, problem determination, then predicting consequences, risk analysis, and finally risk communication, are underpinned by elements of subjective judgment. If those receiving the risk communication see it as less relevant, credible, or trustworthy, based on their own judgment systems, then this will lead to ineffective hazard management (Slovic et al. 1981). Thus, perceptions, understanding, and mitigation of risk at all stages of the supply chain, but specifically on farm, is crucial. Garvin (2001) describes scientists, policy makers, and the public's contrasting approaches to risk, with 'experts' tending to evaluate risk in the 'technosphere', while lay evaluations emerge in the 'demosphere' bounded by different rationality, and representing different cultural understanding. An individual or group's risk tolerance lies upon a spectrum from risk averse to risk neutral to risk seeking (Fischl et al. 2014) mediated by supply chain power and dependence relationships.

When MNCs consider **food safety risk and its mitigation** to reduce risk exposure, they may seek to implement risk management controls with their upstream suppliers, when the suppliers may have a different (e.g. greater) risk tolerance and acceptance of uncertainty than the MNC themselves, their shareholders, or other external stakeholders. One option for MNCs to reduce risk exposure is to develop private farm-assurance standards or demand compliance with third-party assurance standards as a prerequisite to supply, as highlighted in case study 2 with Red Tractor. The development of private standards is underpinned by the assertion that in a high-risk context, employing control and assurance activities based on scientific knowledge, known information, systematic methods, and independent positions, will lead to a predictable and controllable system output, in this case safe food (Luning and Marcelis 2006; Luning et al. 2011, 2015; Kirezieva et al. 2015). Whilst there is a management-led drive for due diligence, certainty and risk mitigation at farm level, and within the wider supply chain, this can lead to an increase in supply chain complexity and a rise in protocolisation. It is important that such developments are focused on scientific knowledge and trust rather than implementing procedures and standards simply as a process to offset potential culpability or liability.

16.8 Conclusion

This chapter has considered farm production-derived food safety risk and more specifically how different supply chain actors understand and approach food safety risk on farm and their options for risk identification and mitigation and how this influences wider risk communication. Definitions of food quality, food safety, and value as an inherent attribute of food provision and perceptions of value as a risk to food safety have been considered. The influence of uncertainty and ambiguity and how it affects risk perceptions and decision making, the risks inherent to farmers' context characteristics, and the lessons learned in terms of supply chain governance were then explored.

A series of case studies have been used to explore themes including the impact of driving value in the food chain, the factors that influence the development of standards such as Red Tractor or GlobalGAP, and the context characteristics that can come together to increase inherent risk in a given farm situation. Risk mitigation has also been explored. Increasingly, to gain market access, farmers are required to demonstrate continued compliance with private GAP standards whilst at the same being driven by their customers to

meet other value-based standards. too. This creates a juxtaposition at farm level between the need to deliver 'value' whilst also being required to increase production costs due to the additional process standards demanded. Urbanisation, the drive for convenience and 'cheap food', and the globalisation of food supply increases the complexity of FSMS and QMS at farm level. Whilst context factors can be mapped to farm-assurance standards and their requirements and within regulations, too, this does not prevent deterioration of compliance in a given situational context on a farm. Therefore, a range of strategies need to be adopted to ensure food safety and food quality is assured at farm level, and uncertainty and vulnerability with regard to food safety is minimised. Whilst technological approaches can be adopted, these will not succeed if there is not an associated consideration of the food safety and quality cultures that also exist at farm level.

17

Helping to Overcome Food Safety Challenges in Developing Markets

17.1 Introduction

Today, many of us feel as though we have too much to accomplish, in too little time, and with insufficient resources. It is difficult for those of us living and working in the Western world, to even imagine the challenges faced by food business operators in countries where knowledge and resources are much less readily available. This book would not be complete without consideration of the challenges faced by food producers in developing markets where provision of safe wholesome food for the local population is an important element of the global food system.

This chapter provides several case studies, drawing upon the experiences of a number of individuals who have had the opportunity to become involved in supporting operations through US-funded development programmes in Sri Lanka, Bangladesh, Rwanda, and Kenya. These individuals are all from the United States and were trained in food safety management as described in previous chapters. In living and working as part of the local operation, they could appreciate and comment on the difficulties in trying to implement programmes when access to knowledge, education and reliable resources is scarce.

The first set of Case Studies (Sections 17.2–17.4) come from Ashley McDonough, Daniel Coen, Andi Musselwhite, and Kai Knutson who are all employees of Land O'Lakes, Inc., and took on their assignments through Land O'Lakes International Development (ID). Founded in 1981, Land O'Lakes International Development is a US-based non-profit affiliated with Land O'Lakes, Inc., a US$13 billion farmer-owned cooperative with a farm-to-fork view of agriculture and food production. The ID organisation has implemented more than 300 projects in nearly 80 countries since its inception (http://landolakes.org/). The final case study (Section 17.6) is being run by a small US-based nongovernmental organisation (NGO), the International Water and Health Alliance. (http://www.waterinternational.org/) and comes from experiences in Kenya as described by Robert and Mary Beth Metcalf.

Food Safety for the 21st Century: Managing HACCP and Food Safety Throughout the Global Supply Chain, Second Edition. Carol A. Wallace, William H. Sperber, and Sara E. Mortimore.

17.2 Sri Lanka Hygiene and Management Systems Development Projects

Ashley McDonough and Daniel Coen

17.2.1 Context

Sri Lanka is an island off the southern coast of India with more than 20 million inhabitants in 25 332 square miles. The country is known for its many exports such as garments, tea, spices, coconuts, and gems. The country has many beautiful beaches, a historic Buddhist pilgrimage site called Adam's Peak, and some of the most welcoming people in the world.

Funded by the US Agency for International Development (USAID), and implemented by ID, Volunteers for Economic Growth (VEGA) heads the VEGA/BIZ+ programme, based in Colombo, Sri Lanka. Sri Lanka was chosen because of the tsunami that hit in 2004 and the aftermath of their civil war that ended in 2009. These two events had a major impact to the country and were the main drivers for establishing the VEGA/BIZ+ Programme in Sri Lanka in July 2011. VEGA/BIZ+ provides technical assistance and supports selected enterprises to help them prepare for business expansion and future success. The investments made can transform a business, and with growth, come challenges. An internal team for VEGA/BIZ+ rigorously reviews all grant applications based on key employment and performance targets, such as the number of women employed by the business expansion. Several of the projects are a useful example of the challenges posed when producing food in less-developed markets.

17.2.2 Support for the Development and Implementation of Environmental Management Plans

Daniel Coen

One of the projects assigned while at VEGA/BIZ+ was to develop concise and actionable environmental management plans for all the grantees in the Sri Lankan programme to enable them to verify that they are meeting all legal Sri Lanka standards for a food business.

Project Work

The scope of the project was not only to assist in the creation of environmental management plans for each grantee but also to discuss and review each plan while training local university environmental students who audit and assist each grantee with their plans as they move forward.

Environmental management plans are important because the enterprises must follow expected hygienic practices to produce a safe product for consumers, operate legally in Sri Lanka and protect the Sri Lanka environment. Any business in Sri Lanka can be shut down by the government if they are not following the proper food industry hygienic operating standards, such as verifying water safety and quality when using water in a food processing plant. It was essential to create a simple, yet all-encompassing tool for enterprises to use and manage effectively to meet Sri Lanka standards. The amount of recording and monitoring associated with these standards would have been difficult to

manage without a tracking tool. This project was a high-priority item because operations can and will be stopped by the Sri Lanka government if not abiding by these standards.

The review and organisation of requirements from the Sri Lanka standards and guidelines for construction (http://www.ictad.lk/sub_pgs/advisory.html), waste management (http://www.cea.lk/web/images/pdf/Guidlines-on-solid-waste-management.pdf), and environmental management (http://www.cea.lk/web/images/pdf/noise/reg924-12.pdf) was the first step in creating a tracking tool for the grantees. The tool consisted of a brief statement of each standard, the concern with regards to compliance, mitigation measure, monitoring indicators, responsible party, monitoring method, and confirmation that the business was compliant with each standard. The standards were organised into 13 categories:

- Construction;
- Waste Management: Solid Waste;
- Emission/Pollutants and Noise Management;
- Water Resource Management;
- Employee Sanitation and Welfare Facilities;
- Occupational Safety and Health;
- Operations Commissioning of Production;
- Training;
- Machinery Operation;
- Maintenance, and Cleaning;
- Chemicals and Hazardous Materials;
- Regulatory Requirements; and
- Miscellaneous.

Each category contained the standards that were required to be met by each Sri Lanka business and the tracking tool that was developed showed every step that needed to take place to be compliant with Sri Lanka regulations. An example section from the tracking tool is shown in Table 17.1.

The tool also had a percentage compliance tracking graph to drive a clear picture of how close the grantee was to being 100% compliant. An example of a standard in the Waste Management category is that a lack of a proper mechanism to regularly collect solid waste may cause pile-up on a site and pose hygiene and safety threats. A mitigation measure was provided which was to design and implement a suitable solid waste management plan, source separation of waste material, and designate areas for collection and storage. Monitoring indicators, person responsible, proper documentation, and frequency of monitoring were indicated in the tracking tool to be compliant with this standard.

The challenge was that each business was unique to the Sri Lanka standards because they were high level and not specific to each industry. A monitoring plan for each specific grantee was created to verify all standards were met without performing unnecessary tasks to meet nonapplicable standards. Each participating company was trained on their specific tool and aligned on the expectations.

Local university graduate students were brought in to collaborate on the implementation to monitor and partner with grantees to fully adhere to their specific plan. This one is clearly a project that involved many businesses, but the collaboration between the external aid providers on the project and the local academic institutions is important for ongoing sustainability of the programmes.

Table 17.1 Example section from environment management tracking tool.

Category of activity	Specific environmental threats (current or potential)	Mitigation measures	Monitoring indicator(s)	Parties responsible for monitoring	Monitoring method (documentation/ verification)	Frequency of monitoring	Compliance (yes or no)
(ii) Waste Management: Solid waste	Lack of a proper mechanism to collect solid waste regularly may cause waste pile up on site and pose hygiene and safety threats. Reference: http://www.cea.lk/web/images/pdf/Guidlines-on-solid-waste-management.pdf	• Design and implement a suitable solid waste management plant • Source separation of waste material • Designated areas for collection and storage	• Review of waste management plan • Review of CEA recommendations and EPL conditions	Business	• Observation of site maintenance. • Monthly reports • Review of waste management plan. • Review of EPL Conditions stipulated by CEA	Monthly	yes

Insights and Lessons Learned

Most companies did not meet many of these expected standards when the project started both due to lack of knowledge and through not having an actionable plan. The grantees were open to meeting standards but needed the guidance and tools to be compliant with Sri Lanka law. At the end of the exercise, the percentage compliant metric was shown and discussed to reiterate the work that needed to be done to reach 100%. The grantees reacted well and were eager to use this simple tool to ensure compliance because they knew that they did not have an effective way to manage this process before this project.

17.2.3 A Manufacturer of Dairy-Based Curd and Popsicles

Ashley McDonough

This company, based in the area near Anuradhapura, is both a buffalo farm and a producer of popsicles/ice lollies, yogurt drinks, and buffalo curd (which was growing in popularity in their region). They filled a unique niche; buffalo milk is rare in the northern region, so they had to rely heavily on their own supply. There is little knowledge of buffalo farming best practices in the country, so the ability to have a self-sufficient supply was critical. However, both a farm and a manufacturing site on the same land created some major challenges with cross-contamination. Their wastewater treatment plant backed up multiple times because of its location next to a sewage pit on the farm. There was a daily struggle with flies and other bugs in their milk receiving area that migrated over from the farm. These and other hygiene-related issues were identified by consultants and technical advisors in the first round of the project. Although some progress was made to segregate the farming operation from the food-production facility, it was difficult to make significant progress without daily, on-site staff to reinforce good quality practices.

Project Work

There was a substantial lack of practices and procedures related to quality and basic hygiene. Many consultants had visited the location and identified the need for better hygiene practices but did not stay on long enough to help with implementation. 'Hygiene Practices' is such a broad category; without explaining the need for a certain number of bathrooms or the requirement that all doors be fully closed to prevent animals and foreign material from coming into the facility, the manufacturer didn't know how to improve the situation.

Fortunately, the company had hired a qualified quality manager who not only understood the importance of good manufacturing practices (GMP) but could also help perform an audit on hygiene practices and equipment. He had some prior dairy manufacturing experience which was an advantage. Because he was relatively new, going through the audit helped him to better understand the expectations and necessary changes needed for the facility. The project team devised possible ways to comply with basic GMPs that were site-specific and acknowledged the resources available. With more knowledge on how a facility *should* operate, it gave the quality manager the capacity to drive the necessary change and implement the required practices in conjunction with the business owner.

Accomplishment

A GMP tracking tool was established to aid with prioritisation of required corrective actions. It comprised more than a hundred questions on hygiene and GMPs and was based on the GMP best practices from US Code of Federal Regulations 21 Part 110.1. This helped the company to develop a targeted action plan for improving the hygiene at the facility. This came at a critical time because the prior week the government announced that all food manufacturers would be required to become GMP-certified in 2017.

Insights and Lessons Learned

Although it is beneficial to share best practices for quality and GMPs, a business must internally value food safety and quality enough to implement them. If the business does not have dedicated quality resources that are aligned with the business, it will be challenging to have successful quality programmes.

Although regulations may be the same on paper around the world, *how* they are implemented can vary drastically. Without the appropriate government enforcement, there is often minimal incentive for a start-up business to dedicate time and resources to a full-scale quality programme. Whether that is right or wrong, good practices are often dependent on the integrity of the business owner.

Dairy entrepreneurs face many challenges regarding milk supply, so having a reliably good supply is critical. The quality challenges facing dairy entrepreneurs in Sri Lanka cannot be resolved in the short term, so an ongoing focus is required in day-to-day operations.

Whilst the Codex principles of food hygiene (and HACCP) are global in their application, they are top-line requirements and lack detail, offering minimal guidance to companies wanting to learn what 'good' looks like. Companies getting ready to supply multinational retailers or manufacturers often get given more detailed guidance documents, but unless they are part-way there already, it is unlikely that they would be considered as a supplier at that level. Organisations such as the Global Food Safety Initiative (GFSI) with the Global Markets Programme can offer a structured

improvement mechanism, but guidance and support is not only highly impactful but also essential as companies work their way through. In this instance, the company was able to utilise the expertise that came as part of being a grantee in the aid project.

17.2.4 A Small Packaging Manufacturer in Sri Lanka

Ashley McDonough

The company were hoping to expand their current polythene sack business into the flexible intermediate bulk container (FIBC) industry. They were currently producing small bags to support the local rice industry within Sri Lanka but had no export business. They were faced with a serious challenge in this business venture because in Sri Lanka, the market is small for this type of product, which meant that to expand they would need to look to the export market and play by export rules. Large potential global customers comply with globally recognised food safety and quality standards to keep consumers safe. If they were to purchase packaging from our project manufacturer in Sri Lanka, they would be expecting the operating standards to meet those same global expectations.

Under existing regulatory requirements in Sri Lanka, complying with HACCP, GMP, and an overall quality programme was not required for the packaging they were providing to the local rice industry. That means, for example, if a pebble is in one of their bags and ends up in the rice, there is no way to trace it back to the packaging or to hold the packaging supplier accountable within Sri Lanka. When selling to these larger global customers, however, they would likely have the systems in place to investigate and trace causes of extraneous material. This was a complete shift in mind-set for the team in the packaging company and emphasised the accountability and responsibility associated with selling food-grade product. The project included helping them understand the quality requirements associated with selling packaging to food companies in the international/export market. Lack of resources was the major challenge to the company involved in this project and to many other similar companies.

We are fortunate in the developed nations that we have easy access to so many resources. Sri Lanka only has about 20 000 university-level places throughout the whole country. That means, if students are not at the top of their class and able to obtain one of these, they have to further their education outside of the country (which many choose to do and then remain in the foreign country) or get only a high-school education. This creates a huge gap in the level of technical knowledge throughout the country. When the packaging company in the project was looking to gain further knowledge about food-grade quality programmes, FIBC manufacturing, and the packaging industry, they were forced to look outside of Sri Lanka because it was a new product to be made in the country where there was limited knowledge in these subject areas. We take for granted how easy it is to attend a conference, network with an individual with the background knowledge, or visit a similar non-competing manufacturing location. Any one of these activities would require a significant investment for this small company in Sri Lanka to gain the additional knowledge they needed to be successful at a basic level. Even finding someone who knew about HACCP certification and the steps needed to reach it was a challenge. As a growing business, this slowed progress because of the large financial contribution that would be required.

Accomplishment

Through the support of the team, the company was able to be linked up with the Flexible Intermediate Bulk Container Association (FIBCA) in the United States. FIBCA would help market the new product they would be producing and, if successful, it would help employ more than 700 people. Also they were introduced to Pack Expo, one of the world's largest packaging trade shows, that they could attend to further market their product. Initial marketing materials were created that helped define their competitive advantage in the industry. The team could then build on these for their full-scale marketing plan when they were ready to start selling FIBCs internationally.

Insights and Lessons Learned

In a competitive and price-sensitive industry, such as poly sack bags, additional resources can be extremely beneficial, even if small. For example, putting this small Sri Lankan based company in touch with online resources from FIBCA to provide further education on the FIBC industry was a very easy reference to provide from someone who knew about the resource and had access to it; yet this small action added immense value for expanding their business.

Dairy entrepreneurs face significant start-up costs, but many successful grantees in the Sri Lankan/VEGABIZ+ portfolio did not involve just dairy. Although Land O' Lakes is uniquely qualified to help dairy companies, the knowledge and resources can be applied across many different industries. It may not seem obvious at first, but as a large user of poly sack and FIBC bags, there was deep knowledge of these industries at the parent company back in the United States. Although not all in-house information could be shared for proprietary and conflict-of-interest reasons, it was pleasantly surprising how much a large-scale company could contribute to the success of this, and other, grantees.

In Chapter 3, we referred to the IFT Traceability initiative. Whilst this is based in the United States, it highlights the need for a global understanding of best practices which includes packaging. Some of the GFSI benchmarked schemes have a packaging standard. These are increasingly being used and not only in the Western world. A number of Asian packaging companies who supply internationally have been able to utilise these to good effect – increased assurance of food safety, a shift in culture, recognising that packaging is important for food safety, and hopefully, increased business through a recognised certification.

For our next case study example, we go from packaging to ice cream which has a different food safety-risk profile. Ice cream, if contaminated and if abused, can be highly problematic as we saw in the examples in Chapter 2. Hygiene standards, strong ingredient supplier programme, and use of tools such as HACCP are all essential if food safety is to be properly managed.

17.2.5 A Small Dairy (Ice-Cream) Processor

Ashley McDonough and Daniel Coen

A dairy business, in an eastern province of Sri Lanka, was just being started by a family who were interested in producing ice-cream products for the local market. Preparing a business to start producing any product from the beginning is challenging and also very exciting.

This ice-cream manufacturer built their first facility with some knowledge of food science but without any previous experience in the dairy industry. As a result, they were missing some critical elements in their operation. The infrastructure was in place, but with the help of VEGA/BIZ+, they could purchase the rest of the equipment they needed to start producing ice cream.

A key example of the knowledge gap was that they did not realise they would need a milk balance tank. When starting up a new facility, things are bound to go wrong during commissioning. As the family established new sources of milk, they had to receive it every day, ready or not. If the facility is down, the milk must have somewhere to go or it will spoil, and that's costly. A balance tank was a critical element to prevent spoiled milk, lost income, and in gaining the trust and confidence of potential suppliers in a competitive milk market.

Other challenges included: milk sourcing (understanding key players in the area, what they were doing to ensure good quality and how that affected pricing), factory commissioning, and general dairy consulting.

Project Work

An initial analysis of the local milk supply was conducted, but upon validation, there were significant gaps in the litres of milk available relative to how much the much larger and global competitors were consuming in their operations. After talking with various co-ops and farmers in the region, they were able to establish a milk network database to document where farmers were selling their milk, how large their herds were, how many litres they were generating, the quality practices they used, and if there was potential to buy milk from them in the future. This allowed the smaller family-owned dairy to continue building relationships with farmers in the region and use the database as a working document to track changes in the local milk market.

As part of the project, a quality programme was developed which included the various essential elements for producing a safe quality ice-cream product. The proper testing methods were developed for both the raw milk, the ingredients, and the finished good products. Working together to identify hygiene zones and proper equipment helped them understand how following these strategies would mitigate the risk of product contamination. One of the biggest challenges was convincing the team of the vital importance of certain food safety and quality factors such as temperature control in the raw milk, how critical it is to clean and sanitise equipment in a proper schedule as well as to verify cleanliness. They also developed operational in-process checks, worked on ice-cream formulations and batch tracking, and storage techniques.

Accomplishments

The result of the milk market investigation was a secured supply of 1500 litres of milk at the time of factory commissioning and future partners to supply milk to the company as the demand increases.

General quality programmes were identified that the small family team can build upon in the future as they expand their operations to new items and increased production.

Insights and Lessons Learned

A new operation that needs to be built from the ground up requires significant time, resources, and technical knowledge far in advance of commissioning a manufacturing

site. Starting quality programmes from scratch is an intensive process, and without adapting the programmes to context, you can drown in the details. These must be created over time, with individuals who are properly trained on quality processes. Milk supply can be a great challenge because a short shelf life, agriculture fluctuations, and intense heat can all inhibit good quality milk.

Although all entrepreneurs in the VEGA/BIZ+ programme undergo a vigorous application process, some businesses have deeper knowledge of their industries than others. For a small family dairy business such as this, Land O'Lakes, Inc., and Land O'Lakes International Development could provide the necessary level of support that was needed for them to be successful.

This example demonstrates the importance of education and culture change as the business developed. By being a part of the VEGA/BIZ + project, the company could access the former which in turn helped with the culture change.

17.2.6 A Coconut Processor in Sri Lanka

Daniel Coen

The company is situated in the northern province of Jaffna. They currently distribute coconuts to the northern area of the country but are expanding into producing white virgin coconut oil given an opportunity for that product not just in the local marketplace but potentially for export to the United States. Coconut oil is becoming a prized (and not inexpensive) ingredient in Western baking. Having the right food safety and quality standards was going to be important to the success of this enterprise.

Project Work

The project had a goal of improving the food safety and quality management system whilst also identifying management improvements.

The food safety and quality system was a primary focus because of the importance of managing time, temperature, and moisture as it relates to the drying process of coconuts before extracting the oil. The quality of the ingredient supply is obviously critical to the food safety and quality of the finished product so this also had to be in scope.

The challenge with this project was that it also included the development of an entire operational model of the coconut oil process. A business plan was created which included employee compensation models, implementation of a detailed process map with operational, personnel, and quality procedures, and development of key performance indicators to ensure business success.

Accomplishments

Ensuring the correct staff was in place for the process to flow along with assigning responsibilities for each position was the first step. The scope of the process included coconut receiving, coconut splitting, coconut dehusking, drying, pressing, bottling, and storing.

Once the staffing (and employee compensation) structure was in place, a more detailed and systematic drying process map was developed. Setting the quality and operational procedures was important to verify that oil spoiling was mitigated through proper procedures. These factors needed to be set, tracked, and kept in the acceptable range such as drying time and temperature, so standard operating procedures

(SOPs) were developed along with daily documentation. Flavour and shelf life are also important factors which were managed through implementing the more robust quality system. The staff reacted well to this training on these documents and were excited to implement this on the first day of production.

The project team worked collaboratively to develop a supplier performance tracking system based on percentage oil yield from coconuts, as well as an inventory (raw material and finished good) management system. This was vital in ensuring that the coconuts were high quality and yield was verified; if the coconuts were picked too early which would show a lower yield percentage.

Given the desire to export into the United States, quality and operational programmes had to be consistent with likely customer expectations and regulatory requirements.

At the time of writing, the company had not yet achieved the export goal, but being a grantee in the VEGA/BIZ+ programme was a great opportunity to understand how big a gap they had to close.

Insights and Lessons Learned

Earlier in this book we highlighted the importance of having good business management practices. This grantee was willing to learn and partner to develop a business plan and operational system that will ensure success if managed properly. The commonality between grantees is the willingness to accept and embrace change and the diligence to drive the business forward. Whilst this case study example does not go into a lot of detail, it does emphasise the importance of having commitment to getting the entire business model right – not just one element of it.

17.2.7 Quality and GMP Training in Sri Lanka

Ashley McDonough and Daniel Coen

The final project undertaken on this assignment was to develop and deliver a quality and GMP Workshop. The other projects had involved working with specific enterprises on this topic, but this gave the opportunity to impact multiple enterprises. It was vital for the grantees to understand *why* quality is important as well as *what* they had to do to achieve it. Overall, it was a success, and the enterprises were engaged and excited to further develop the quality culture at their business.

Project Work

Using appropriately modified training material from the United States, the topics of personnel practices, good housekeeping, and many other GMP topics were reviewed. The individuals in attendance had various levels of knowledge regarding quality and GMP so it was important to explore even the most basic concepts and allow the individuals with more advanced knowledge to help facilitate the discussion regarding how the concepts could be applied. The site visit was included to solidify the understanding of the attendees and allow them to network with other business owners in the country that were experiencing similar challenges.

Accomplishment

A full-day training was developed and included a factory visit with members from each enterprise focused around the 'Importance of Quality'. More than 60 people from 25 businesses were in attendance along with a panel of industry and government experts

Figure 17.1 Quality and GMP workshop.

in the Sri Lankan business field. Based on feedback from the individuals in attendance, it was beneficial to explore these topics with the larger pool of grantees. Overall, it was a success (Figure 17.1), and the enterprises were engaged and excited to further develop the quality culture at their business.

Insights and Lessons Learned

A review of basic food safety and quality principles is helpful, especially for individuals that are not aware of them. Seeing them in practice at a manufacturing site allowed for more engagement and understanding of how they could be applied to each entrepreneur's unique operation.

Although some principles transferred easily to the Sri Lankan culture, others did not and needed to be explored further. For example, risks associated with not having adequate quality practices which could result in product recalls. As the team reviewed some of the bigger recalls in recent years in the Western world, the effect was lost on many of the attendees because they indicated if a similar situation occurred in Sri Lanka, there are not as many regulators to hold the responsible company accountable.

Much of the 6 months' tenure that the assigned team had in Sri Lanka was spent collaborating with the enterprises mentioned. They faced many challenges but worked together to develop systems and procedures that are simple, cost-effective. and all-encompassing. The Sri Lankan enterprises care about quality, but the initial cost of using testing methods, labour, and energy required for quality systems is the largest deterrent. It was rewarding to find alternative solutions and systems to ensure that the product quality does not suffer while minimising cost. At the end of the day, these small- to medium-sized enterprises do not have the resources to compete, but they understand that a lack of quality can lead to a lack of success in their field. Many larger organisations have valuable brands and consumers to protect but also the knowledge and resources to do this day-in and day-out. The Sri Lankan enterprises in the project have this same desire, but some lacked the experience and knowledge to know what must be done to ensure a high-quality product.

17.3 Rwanda Dairy Development Projects

Andi Musselwhite

17.3.1 Context

Rwanda is the most densely populated country in Africa with almost 12 million residents in slightly more than 10 000 square miles. Its economy suffered greatly after the 1994 Rwandan genocide but has since strengthened. Following the 'One cow per poor family' programme rolled out by the government of Rwanda in the early 2000s, the overall milk supply increased along with the opportunity to improve on the overall dairy value chain in Rwanda.

The Rwanda Dairy Competitiveness Programme II (RDCP II) is a 5-year USAID-funded programme, implemented by Land O'Lakes International Development. RDCP II has the goal of increasing competitiveness of Rwandan dairy products in regional markets. One way this is being done is through improving milk and dairy product quality and increasing local demand. The opportunity was not only to increase local demand and consumption but also to help open the export market for value-added dairy products into neighbouring countries with quality as a unique point of differentiation. At the start of the programme, it was recognised that there were limited dairy industry regulations leading to inconsistent quality practices because of the gaps in knowledge and compliance. New Ministerial Instructions on milk handling, transportation, and retail were in the process of being prepared and implemented during the duration of the Rwanda programme.

The project involved working directly with dairy processors and milk-collection centres in Rwanda on overall quality preparedness through mentorship and coaching alongside the local support staff of the project. That meant different things for different participants. For some it meant making changes to their day-to-day work and processes to meet the new higher standards in the Ministerial Instructions before its roll out. For others, it meant going above those standards to meet the Rwanda Standards Board (RSB) 'S' mark for Quality. This 'S' mark could open the door for breaking into the export market. For a final processor, it meant following up on their recent HACCP certification (one of only two of its kind in Rwanda) to amend and follow up on their efforts to maintain the prestigious certification. The project assignment focused on a couple of producers: a growing dairy company in Northern Rwanda and a rural yogurt and fermented milk manufacturer and their upstream milk collection centre cooperatives.

17.3.2 A Growing Dairy Company in Northern Rwanda

The owner started as a dairy farmer in Northern Rwanda but eventually expanded into transporting and marketing milk from this northern district to a large processor in the capital city of Kigali. Eventually with a surplus of milk in his area, the owner decided to open a dairy to process the excess milk into yogurt, cream, mozzarella cheese, and eventually butter.

The dairy was the first dairy plant to secure HACCP certification in Rwanda and upon the start of the assignment, they had been certified for about 6 months.

Project Work and Accomplishments

Together with the quality manager and production manager, the team focused on ensuring that the HACCP programme they laid out continued to be developed and followed. Documentation related to their quality management system and prerequisite programmes was developed. Training for employees on general hygiene was conducted, and a plan was developed to include future training topics, the frequency of the training, and required training documentation. The quality manager was then able to see what needed to be managed in order to make this a sustainable programme.

The documentation updates consisted of batch records and sales traceability forms to capture ingredient-to-store shelf traceability. For the cooperative supplying the dairy with milk, they started using a milk reception form for the tracking of test results of organoleptic, alcohol test, lactometer, and temperature results of each can of milk received in. A mock audit was carried out to prepare for their HACCP recertification audit in the coming months. At the end of the assignment, the findings and follow ups were primarily related to consistently using the existing and new documentation. The dairy company witnessed the benefit of gaining HACCP certification as it created a competitive advantage for their yogurt over competitors and helped to secure them distribution to RwandAir, the national airline. This distribution provided them with increased and consistent weekly demand. It is this that helped to prove the benefit of HACCP that helped to influence the adoption of new documentation and practices.

17.3.3 Yogurt and Fermented Milk Processor

This company started with the owner selling just 5 litres of milk per day to neighbours, but has since grown to processing about 3000 litres of milk per day. The owner had the goal of meeting the new Ministerial Instructions put out by the government of Rwanda and working towards attaining the RSB 'S' mark for quality. This company was much less mature in their quality journey but with high aspirations to close the gaps on what they did not meet to gain the 'S' mark certification which would provide them with the perceived higher-quality indicator as well as the ability to export to neighbouring countries that have ease of trade with this East African accepted mark of quality.

Project Work

The project started by understanding the gaps in meeting these standards and making additions to documentation including batch forms, incident/corrective action log, cleaning records, and milk receiving form for their milk supplying cooperative.

These records helped the dairy to not only meet these new documentation standards but also to start to see consistencies with particular milk transporters' poor milk quality. For some milk transporters, they were consistently getting rejections with the alcohol test, which shows the relative stability of milk for processing. With the milk receiving forms, they tracked these rejections and that helped identify which milk transporters and their farmers may need some education/assistance on mastitis prevention or better milk-handling practices. It allowed the farmers to learn and improve and the cooperatives to better track their members and the milk they were bringing in. It was important to stress the benefit of hiring someone with food safety background to help keep up with these changes for long-term success because this S mark would be reevaluated annually.

The company was in an area of Rwanda with electricity that could be limited for a time. They could either run the cold room refrigerator or the pasteuriser, but not both at the same time. They adapted the time in the day that they would pasteurise so that when they did have to shut off the cold room refrigerator, it would be at night when the outside temperature was the lowest. Upon the end of the assignment, the cold room where finished products were held was not cooling down to the recommended <40° F (<5°C) . They had someone hired to come and look at it to see if it could be repaired before applying for their S mark certification because that would be a requirement.

Accomplishments

The company did indeed achieve their S mark following the documentation and process changes and having the equipment repaired.

With the time spent at various dairy processors in Rwanda, several things stood out, including the lack of written processes and procedures as well as the fact that the yogurt and cheese often had varied taste and consistency batch to batch. The programme brought in a master cheese maker from South Africa to hold training for programme participants to get exposure to new types of cheeses and to get formal training for some of the products they were making. This enabled a request to have the materials put together in a book. The intention was to distribute these instructional manuals to the cheesemakers for their later reference. Once the materials were obtained in English and it was possible to start distributing them, it was clear that for some, these technical documents were difficult to follow and likely wouldn't be used unless translated. A local translator was asked to translate and publish written copies of these trainings in both English and the local language, Kinyarwanda, and to distribute them to the 19 dairy manufactures that were a part of the programme.

Figure 17.2 Andi Musselwhite in Rwanda.

Figure 17.3 Milk can pasteurisation.

Insights and Lessons Learned

Understanding what motivates individuals and businesses is important for success. In the absence of government defined and consistently enforced quality standards, the risk of damaging the company reputation, getting a monetary fine or concern over the business being shut down isn't sufficient motivation for change.

- In every recommendation given, it is important to understand what would drive the entity to follow through. What may drive a quality culture in the United States may not be equally motivating in a developing country such as Rwanda.
- The Annual Cheese Championship and Expo provided a showcase to these companies and a concrete example of how customers, when given the choice between yogurt suppliers, consider the S mark as differentiating and gives a competitive advantage over manufacturers who don't have it.

Immerse yourself to change your mind-set:

- Walking in, it was hard to 'let go' or lighten up on what we would generally believe to be 'appropriate' quality standards. By being immersed in the businesses, it was possible to get a better picture of what would be feasible for these businesses.
- Recognise the importance of not just implementing stand-alone quality practices, but in developing a holistic quality culture. Going beyond surface-level quality practices is essential for them to be effectively implemented, for example,
  - Plastic boots for employees may be a good idea to help maintain hygiene in a manufacturing environment but not if they are worn outside through a cow pasture and back into the manufacturing plant.

Data is important to tell a story.

- By having the yogurt and fermented milk producer track the temperature using two different thermometers hourly for a 24-hour period, it was possible to prove the temperature gauge in their cold room was incorrect and that they were storing their products below the recommended 40° F.

Limited knowledge and resources are a major challenge.

- With the translated cheese instruction manuals, we wanted to try and close the gap in knowledge by giving them access to knowledge and making it as easy as possible by providing it in the local language as well.

The concept of a future-focused mind-set isn't prevalent like it is in the Western culture.

- Making changes that are future-focused is difficult if they don't also have near-term benefits.
- Consumer concern tracking on quality issues isn't commonplace, neither is the tracking of internal failure data for identification of trends and future improvement opportunities.

Keeping the changes made as part of daily operations without seeing a concrete benefit is difficult.

- For the multiproduct dairy who was the first dairy producer in Rwanda to become HACCP certified, gaining distribution to RwandAir was a major win that allowed them to see in months that becoming certified benefitted their business.

17.4 Bangladesh Milk Supply Chain Development Project

Kai Knutson

17.4.1 Context

Bangladesh is said to be the most densely populated country and has the largest delta in the world. The country has one of the highest densities of cattle but the lowest milk production per cow. Per capita availability of milk is 52 g/day, less than the FAO recommended 250 g/day and less than consumption in neighbouring India (245 g/day) and Pakistan (630 g/day). The most common herd size is one to two cows.

In 2014, the US Department of Agriculture (USDA) Food for Progress awarded funding to Land O'Lakes International Development to implement the Bangladesh Dairy Enhancement Project (BDEP). The goal of BDEP was to improve the livelihood of dairy farmers in rural Bangladesh, primarily by connecting them to the formal market, enabling them to sell their milk to larger milk processors rather than just to their neighbours and middlemen. BDEP partners with dairy processors to establish milk collection centres (MCCs) staffed with advisory services that can help farmers improve their cows' productivity and their farms' profitability.

In mature dairy industries, milk is chilled as soon as it is drawn from the cow and a 'cold-chain' of continuous refrigeration is maintained through transportation, manufacturing, and distribution to consumers. Where cold-chains are interrupted or fragmented, the quality of dairy products is negatively affected. In many developing countries, farmers do not have sufficient resources to install chilling equipment on their farms nor are the means of transporting their milk refrigerated. Thus, the first point in the supply chain with chilling capability is often a regional collection centre located far away from the villages where most milk is produced. In Bangladesh, milk procurement systems have multiple 'tiers' in which milk from many farmers is aggregated by an intermediary or agent of the processor and transported, unrefrigerated, from a milk

collection point to a regional milk chilling centre. At the time of this project, one processor had recently established a single-tier procurement system in which farmers transport their milk directly to small MCCs located in their villages. By decreasing the distance that raw milk travels to the first point in the supply chain with refrigeration capability, it is thought that the single-tier system reduces the growth of bacteria and better preserves milk quality.

17.4.2 Project

The quality of milk procured by milk processors in Bangladesh through the widely employed multi-tier system was compared to that of the recently developed single-tier system. Two partners' laboratory facilities were made available for testing to quantify the bacteria in raw milk at numerous points in the milk supply chain. These laboratories were selected both for proximity to the sampling sites and for the availability of equipment necessary for the analysis (autoclave, laminar flow hood, and incubator). Samples were collected and analysed by the standard plate count (SPC) method, in which milk is spread on growth media and incubated to quantify the bacteria in each sample.

Protocols for milk sampling and SPC testing were adapted for the local context, a research assistant was trained, and laboratory personnel were briefed on best practices. More than 400 samples were analysed, but with inconsistent results. Ultimately, the source of error was identified as a critical failure in supplier quality management.

17.4.3 Insights and Lessons Learned

Food safety is fundamental at all levels: Food safety and quality is not only the responsibility of the senior-most or highest-ranking persons within these systems, it is the responsibility of each and every person. The challenge in Bangladesh today is to widely develop this sense of responsibility as well as standard protocols, quality materials, and good laboratory practices. A trained person may conduct a quality test, but if the cleaner switches off the incubator during the night, or if the laboratory technician does not autoclave the water used to dilute samples, or if any number of day-to-day laboratory activities are not performed attentively, the results will ultimately be as inconsistent as those we observed in our analysis. Attention to detail and record keeping are fundamental to laboratory science and must be practised at all levels of an organisation.

Process control may be more challenging in some circumstances but is no less necessary: The conditions of the laboratories in which the analysis was conducted introduced uncertainty and inconsistency into the results. During every experiment, at least one, and often more, power failures interrupted the operation of laboratory equipment. Laboratory staff may also have contributed to the variability by opening laminar flow hoods with the fans off and switching the incubator off when they leave the laboratory with plates inside. When power to an autoclave is disrupted, the sterilisation process can be restarted with no ultimate effect on the experimental results. But when samples are contaminated inside the laminar flow hood or incubation is interrupted for an indeterminate period, the effects cannot be accounted for. Many of these issues could be resolved through the implementation of standard laboratory protocols, but systemic problems such as power failures may require larger-scale solutions.

Figure 17.4 Kai Knutson sampling milk in Bangladesh.

Trust, but verify. Ultimately, after all experimental data had been collected, the chemicals used to sanitise laboratory instruments were found to be counterfeit of unknown origin and composition. The supplier admitted to the fraud, acknowledging that labels had been forged and seals tampered with to appear genuine. We could have had the best staff, equipment, and facilities in the world but with no quality control of materials, we would never expect to attain accurate, precise results. The lack of valid chemical supplies was a major blow to the project, and yet it highlights the very real difficulties faced by organisations that want to do the right thing and follow global expectations in local contexts lacking some of the basic prerequisites for quality management programmes.

17.5 Key Points Learned as Assignees to a Less-Developed Country

- Adapt to the context in which you're working
  - Not all Western world food industry standards can be successfully implemented as-is; they must be modified to meet the needs of the situation. For example, a dairy manufacturer with a leaking roof cannot implement finished goods testing if they do not have the funding to fix the most basic quality issues.
- Value of building relationship
  - Understand the importance of building a team
  - Cross-cultural teams provide unique perspectives and solutions to challenging situations

- Fundamentals of entrepreneurship
  - Understand the basics of running a business and how much time, dedication, and strategic decision making is required to be successful.
- Diligence required for a farm-to-fork model
  - When working with the ice-cream manufacturer, we were looking at everything from what crops we could grow to increase dairy herd milk yield to how to distribute a frozen product in a very hot climate. This made us realise how much dedication and commitment it takes to support this model, and what an interesting company we work for in the United States, in that they are one of few companies that have the know-how to do this successfully.
- Transportation
  - Often there isn't the infrastructure in place to get around the assigned country quickly or transport goods efficiently.
- Pace of business
  - Everything moves much slower and there is a lower sense of urgency. Every afternoon there would be a break for tea.
- Lack of enforcement
  - This was both on the government and business level.

17.6 Kenya Development Project: International Water and Health Alliance (IWHA)

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17.6.1 Context

'Water is life' is often stated, but the corollary to this is that contaminated water can be a source of disease and death. Although waterborne diseases have been almost eliminated in developed countries through efficient water treatment and sewage disposal, more than a billion people in extreme poverty worldwide are still plagued with waterborne diseases, estimated to cause between 4 to 6 million cases of diarrhoea and more than 2000 deaths *daily*. Yet this misery is preventable: kill the germs with chlorine or heat, and people don't get sick.

Once it was understood that faecal contamination of water could be the source of disease-causing bacteria, the question arose about how to test water for faecal contamination. It was recognised that testing for all the known waterborne pathogens was impractical. Instead, a universal microbial indicator of faecal contamination was sought. By 1900, *Escherichia coli* was selected as the best microbial indicator of recent faecal contamination because of these properties: (1) *E. coli* was always present in the faeces of humans and other mammals in large numbers, whether one is healthy or sick (approximately 100 million to 1 billion *E. coli* cells per gram of human faeces); (2) it doesn't multiply when it leaves the body and enters water; (3) it slowly dies when shed in faeces, but it survives in water at least as long as bacteria that cause typhoid fever, cholera, and dysentery; and 4) it is relatively easy to detect.

Table 17.2 Correlation of *E. coli* levels with WHO disease-risk categories.

Level of *E. coli*	WHO disease-risk level[a]	WHO action priority	MSF action[b]
<1 in 100 mL	Very low	None	None
<1 in 10 mL	Low	Low	Consume as is
1–10 in 10 mL	Moderate	Higher	Treat if possible
1–10 in 1 mL	High	Urgent	Must be treated
>10 in 1 mL	Very High	Urgent	Reject or thoroughly treat

[a]WHO/UNICEF: A Toolkit for Monitoring and Evaluating Household Water Treatment and Safe Storage Programmes (2012), Figure A-1, p. 62.
[b]Médecins Sans Frontières (1994) Public Health Engineering in Emergency Situation. Médecins Sans Frontières: Paris.

The presence of *E. coli* in drinking water, therefore, indicates recent faecal contamination, raising the possibility that disease-causing microbes may also be in the water. The World Health Organisation (WHO) correlated levels of *E. coli* in drinking water with the risk of disease and the priority for action. Médecins Sans Frontiéres (MSF) correlated these levels for action in emergencies (Table 17.2).

For water testing, a new approach called the Defined Substrate Technology (DST), or chromogenic method, was introduced as Colilert® (IDEXX, Westbrook, ME) in 1988. In the Colilert test, a chromogen, abbreviated MUG, is an energy source that *E. coli*'s β-glucuronidase enzyme will cleave into the sugar (G) that *E. coli* can use for growth, and MU, which will fluoresce when a long wave UV light shines on the culture. Colilert also contains a second chromogen, ONPG, that the β-galactosidase enzyme of all coliform bacteria can use as an energy source, cleaving the sugar (G) and leaving ONP, which turns the culture yellow.

Colilert was first released as a 10 mL presence/absence (P/A) test in a glass tube with sterile, dry nutrients. After inoculation and incubation, a clear tube indicated no coliform bacteria in the sample, a yellow colour indicated the presence of coliform bacteria, and a blue fluorescence indicated the presence of *E. coli* in the sample. The most widely used form of Colilert today in high-income countries is the plastic snap pack to inoculate a 100 mL water sample for a P/A test, complying with current US Environmental Protection Agency drinking water standards of no coliforms in 100 mL treated water. The simplicity of using Colilert makes it possible for unskilled individuals to perform accurate tests after a brief training.

17.6.2 Challenges in Low-Income Countries

Water quality monitoring is often a missing factor in programmes to improve access to safe drinking water in low-income countries, despite its importance from a public health standpoint. This is because standard tests using multiple tube fermentation or membrane filtration require specialised equipment and training and are not easily adapted to field testing. In addition, the linkage between water quality and disease is commonly not appreciated at the community and household level.

Public health problems arise in urban areas as a result of water supplies being intermittent or if coagulant/disinfectant supplies are missing. Rural areas often lack public support for providing and maintaining improved water sources. People must use contaminated local sources such as streams, ponds, rivers, or shallow wells.

In September 2015, at the United Nations in New York, countries of the world adopted 17 Sustainable Development Goals (SDGs) with a time-frame of from 2016 to 2030. SDG 6.1 states: 'by 2030, achieve universal and equitable access to safe and affordable drinking water for all'. There is a lack of urgency in SDG 6.1. when more than 1 billion people are susceptible to waterborne diseases in 2016. There is also no specific plan to achieve this goal.

Water-quality testing must be a component where drinking water is involved. For low-income countries with limited resources, it is recommended they establish realistic, interim achievable standards instead of the 10 mL standard that has been successfully adopted in high-income countries (IWA Manual on Human Rights to Safe Drinking Water, Section 7.8).

17.6.3 Addressing the Water-Testing Challenge in Low-Income Countries

Recognising the importance of water testing in low-income countries but also recognising there are limited funds and equipped laboratories to perform the water-quality tests used in high-income countries, criteria for water tests in low-income counties should include:

1) Specific for the faecal indicator *E. coli*.
2) Ready to use, just add water.
3) Easy to perform with minimal instruction.
4) Easy to interpret and correlate with WHO disease-risk levels.
5) Vetted methods that are low cost and commercially available.

Information in Table 17.2 states that the absence of *E. coli* in a 10 mL test identifies the source water as a low-disease risk, a realistic and achievable standard for service providers in low-income countries to monitor drinking water throughout a distribution system in towns and cities. The 10 mL Colilert P/A test fits this requirement.

Information in Table 17.2 also states that high and very high disease risk sources have 1–10, and >10 *E. coli* per millilitre. To identify these highly contaminated sources, a test for 1 mL is ideal. For this purpose, since 1995, we have successfully used the *E. coli*/Coliform Count Petrifilm™ (Petrifilm, 3M, St. Paul, MN), a 1 mL quantitative test that is widely used in the food industry. The Petrifilm is a flat 7.5 × 10 cm rectangle composed of a bottom layer coated with sterile dried nutrients to support bacterial growth, a white foam layer with a 5 cm circular opening over the dried nutrients, and a transparent top film that encloses the sample within the Petrifilm. The β-glucuronidase substrate in the Petrifilm is a colourless chromophore abbreviated BCIG. If an *E. coli* cell is present in the 1 mL of water that is added to the Petrifilm, in 12–18 hours it will grow into millions of cells that can be seen as a small blue colony. The blue colour results from *E. coli*'s β-glucuronidase splitting the G (sugar) from BCI, leaving an insoluble blue compound that colours the colony. As growth continues, the blue colony will enlarge and be surrounded by small gas bubbles as *E. coli* metabolises lactose in the medium to produce gas bubbles (hydrogen and carbon dioxide). Environmental

coliform bacteria that turn the Colilert tube yellow but do not cause fluorescence will grow into red colonies with gas bubbles on the Petrifilm. Red colonies, with or without gas bubbles, have no public health significance.

E. coli grows most rapidly near body temperature, 35–37°C. In the absence of a suitable incubator, if ambient temperatures are <30°C that delays the appearance of positive tests, Colilert tubes can be placed in a small sack or sock, and Petrifilms can be placed between thin pieces of cardboard to incubate both tests close to the body for results in 12–24 hours. The option of body incubation is a major advantage of these tests. For service providers testing in the distribution system, it avoids the requirement to get tests to an incubator in a central laboratory where gridlock traffic can make this a time-consuming challenge. In rural areas, Colilert and Petrifilm tests can be taken to villages where these tests can be inoculated and incubated within the village. This educates the community directly about the disease risk of drinking water sources. The development of a blue *E. coli* colony from an invisible cell on the Petrifilm provides striking visual evidence to communities that the drinking water source has bacteria from faeces and that water from that source must be avoided or treated all the time.

17.6.4 Accomplishments

Since 2000, we have combined 25 each of the Colilert tubes, Petrifilm tests, sterile plastic pipettes, and stand-up Whirl-Paks along with a battery-operated, long-wave UV light as a Portable Microbiology Laboratory (PML) that fits inside a gallon-size zip lock

Figure 17.5 Bob Metcalf with Sagam teachers.

plastic bag to take to the field. We also have developed a comprehensive teaching component to accompany the PML that includes the UN-Habitat booklet co-authored by Robert Metcalf *A practical method for rapid assessment of the bacterial quality of water* (available at http://waterinternational.org/wpcontent/uploads/2011/07/UN_Habitat_Water_Booklet_V2.pdf).

The teaching component and test results demystify microbiology at the community level and lead to an understanding of the relationship between contaminated water and disease. This is critical because in many areas with contaminated drinking water sources, communities are unaware that microbes from faeces are responsible for waterborne diseases. An example is our experience with 70 000 people in Lower Nyakach, Kenya, near Lake Victoria. Since 2012, we have worked with The Friends of the Old (FOTO) community-based organisation to eliminate waterborne diseases in this area where there are only highly contaminated, unimproved drinking water sources. To do this, FOTO staff members were taught how to perform and interpret the Colilert and Petrifilm tests. They now take the testing and teaching to communities with monthly trainings. Before community testing and teaching, most people in Lower Nyakach thought that water was made 'in the beginning' and couldn't cause disease. However, as a result of testing and teaching by respected members of their communities and observing the striking visual test results, the people in Lower Nyakach now understand that drinking water sources are contaminated with faecal bacteria and must be treated all the time.

Through a small US-based NGO, International Water and Health Alliances (www.waterinternational.og), funds are provided to FOTO monthly for free distribution of Aquaguard, a 150 mL bottle of 1.2% sodium hypochlorite to households and schools through village chiefs and elders. A capful of Aquaguard, 3.5 mL, will disinfect 20 litres of water in a commonly used jerry can. As an example of the effectiveness of this FOTO project, between January, 2015 and January, 2016, more than 2500 cases of cholera occurred within Lower Nyakach's Kisumu County and in neighbouring Migori and Homabay Counties, but no cholera cases occurred in Lower Nyakach (www.imageevent.com/bobmetcalf/thegoaliszero).

For more than 1000 of the 14 000 households in Lower Nyakach that have the simple Cookit solar cooker, sunshine can also be used to pasteurise water by heating to 65° C, using a reusable wax-based water pasteurisation indicator (WAPI) to verify that 65° C has been reached making the water is safe to drink (Safapour and Metcalf 1999).

Given that more than 1 billion people are unaware that local drinking water sources are contaminated, the introduction of readily available water-quality testing and monitoring methods that are easy to use and interpret could significantly contribute to a decrease in the global burden of waterborne diseases. The successful use of the PML in Lower Nyakach could be replicated in low-income communities worldwide.

17.7 Conclusions

From the experiences shared, we can see a few common themes:

- Education and knowledge are not easy to obtain. Programmes such as those described and others such as the GFSI Global Markets programme do make a difference and many companies, as well as governments, are stepping up to help close the knowledge gap.

- The dairy examples highlight just how enormous the difference is between a large Western dairy operation where multiple farms (which can have in the region of 10 000 cows) send their milk to mega sized dairy processing operations and a small two cow farmer in the developing countries who as an improvement can now send the milk to a milk chilling and collection centre. China is fast moving from one end of the spectrum to the other which demonstrates that it can be done. The cause for change has been not only the improvement in food safety and human health but also the commercial opportunity for business growth that both the government and industry see as a coveted prize.
- The reliability of required resources cannot be taken for granted. Authentic chemicals, reliable test methods, documented reference materials, and good quality training are foundational for an effective food safety and quality management system.
- Many small producers do not have the money to pay for the above even if it is available.
- Whilst we cannot expect that the standards and practices we have come to expect in the West and other developed nations will be easily or quickly duplicated, supportive collaborative efforts can be effective and all parties can learn from each other. It was interesting and encouraging to observe how hazard analysis is being used – sometimes informally to make decisions and sometimes more formally in the shape of HACCP programmes.
- There are many small food companies (and some not so small), in the developed nations who have similar lack of programmes; some because they don't want to have to take on what they see as additional work and cost, some because they are complacent and think failure happens to others, and some because they genuinely don't know how to make the changes and certainly not how to think and act based on food safety hazard analysis.
- Access to reliable resources is a very real challenge in the developing countries, as is a lack of funds, but there are many who are hungry for knowledge and see it as a means to avoid hunger of a different kind in their countries.
- Supported projects like those that we have seen in the case studies provide a much needed boost to local enterprises. The proof of their success of course is whether those behaviours and facilities have remained changed and in place once the projects are finished.

18

Consumer Food Safety

18.1 Introduction

Whilst all links in the farm-to-table food supply chain are important, the last link – the point of consumption – seems to be the most important because it is the last opportunity to assure the safety of a food before it is eaten. There are many points of consumption in this last link, including restaurants, institutional settings such as schools and hospitals, and the home. Restaurants and institutions can usually provide significant assurance of food safety because the food is usually prepared and served by trained personnel. In contrast, the home environment is much more vulnerable to food safety mistakes and the occurrence of foodborne illnesses because those handling and serving the food are typically untrained and often unaware of the potential hazards. Often they are children or well-meaning but ignorant adults, working in a confined space that may include pets and infant children. Furthermore, the principal food safety controls in the home: use of safe water and raw materials, cooking, refrigeration/freezing, cleaning, and separation, are not always used properly. It is most important to recognise, particularly in the home, that the consumer has a significant role in food safety, a role that is shared with the many participants in the food supply chain.

Recognising that a lack of knowledge contributed to the spread of many infectious diseases and foodborne illnesses in the home, an online resource, the International Scientific Forum on Home Hygiene (IFH), was established in 1997 to promote health by means of improved hygiene in the home. A detailed report on progress during its first 10 years is a most helpful resource for consumers (Bloomfield et al. 2009). Additional efforts to increase consumer understanding have been initiated by the UK Food Standards Agency, whose stated goal, reported in 2009, was to promote kitchen hygiene in order to reduce foodborne illnesses in the home by 20% over the next 5 years (Food Standards Agency [FSA] 2009). Specific campaigns included stopping the practice of washing poultry to reduce campylobacter cross-contamination risks and a 'Kitchen Check' tool to help consumers implement best practices (https://www.food.gov.uk/news-updates/campaigns/kitchen-check); however, an evaluation of these campaigns has not been published. Similar approaches have been seen in other countries; for example, in the United States, the Partnership for Food Safety Education provides education and resources to support consumers and prevent foodborne illness through its Fightbac campaigns (http://www.fightbac.org/).

Food Safety for the 21st Century: Managing HACCP and Food Safety Throughout the Global Supply Chain, Second Edition. Carol A. Wallace, William H. Sperber, and Sara E. Mortimore.

This review and case study will provide information for educators and consumers to make them more aware of the potential foodborne hazards in the home, practical means of hazard control, and specific control measures that could be established. Ideally, potential hazards could be prevented or 'managed' in the home environment, similar to the management of hazards in food processing facilities by means of HACCP and prerequisite programmes (PRPs).

18.2 Potential Hazards

The wide range of microbiological, chemical, and physical hazards that can be found through the food supply chain can often be encountered in the home kitchen.

Potential microbiological hazards will vary depending on the ingredients and food groups consumed, as well as the country of origin and local contamination rates, but may include:

- *Salmonella* and *Campylobacter* in raw eggs[1], meat and poultry, also from pets who live in the home, and sometimes, their pet food.
- *Listeria monocytogenes* in cooked, ready-to-eat (RTE) meats and soft cheeses, or as an environmental contaminant.
- *Escherichia coli* O157:H7 in raw ground beef, raw milk and juices, and fresh produce.
- *Clostridium botulinum* in improperly processed ambient foods (e.g. certain home-canned products), improperly fermented and acidified foods (e.g. uncontrolled fermented meats), garlic in oil, or improperly stored vacuum-packed foods (e.g. vacuum-packed fish that should be refrigerated stored at room temperature).
- *Clostridium perfringens* in dressed, roasted poultry and in improperly cooled foods (e.g. soups, casseroles, and gravies).
- *Bacillus cereus* in improperly cooled cooked rice and potatoes.
- *Staphylococcus aureus* in custard or cream-filled cakes, and any hand cross-contamination combined with poor temperature control.
- Both *B. cereus* and *S. aureus* produce heat stable toxins that survive reheating of previously cooked foods.

Potential chemical hazards include:

- allergens,
- cleaning chemicals, and
- pesticides and rodenticides.

Potential physical hazards include:

- broken glass and brittle plastic,
- choking hazards where the condition (size and shape) of the food itself is the hazard (e.g. grapes and young children), and
- other foreign material that could cause choking or injury (e.g. metal or wood).

The potential introduction of hazards into a prepared food can be heightened by several environmental factors, including the presence of pets and infants in the household,

1 This risk may vary depending on the local policy and practices for vaccination of laying stock.

combined with inadequate hand-washing by the food preparer after handling the pet or changing diapers, etc. Accumulated dust on the floor is a common cause of infant botulism (Nevas et al. 2005). Whilst not directly a food safety issue, this important fact emphasises the need to maintain a clean kitchen. Cross-contamination from raw to cooked foods can result from inadequate hand washing or using, without adequate washing or disinfection, the same utensils to handle raw and cooked or RTE foods. For example, a cutting board used to prepare raw fish or poultry can contaminate fresh salad ingredients with *Salmonella* or *Campylobacter* if the board, utensils, and hands are not properly washed in between. Washing practices for raw foods can also be of concern where there is potential to transfer bacteria from a contaminated raw food to the kitchen environment and other RTE foods via water sprays and aerosols.

Of course, such potential sources of cross-contamination are not limited to the home kitchen. The public health issues related to the handling of raw meat and poultry and fresh produce in the same food preparation area are also a major concern in retail and foodservice establishments that prepare food for consumption.

18.3 Potential Control Measures

The principal control measures available to assure food safety in the home kitchen are use of safe water and raw materials, proper temperature control (i.e. refrigeration/freezing and heating by cooking thoroughly), together with prevention of cross-contamination through separation of raw and RTE foods, cleaning, sanitation, and personal hygiene (Marchiony 2004). These control measures are highlighted in the World Health Organisation's (WHO) five keys to safer food initiative that aims to promote safe food handling behaviours and educate all food handlers, including consumers (WHO 2006b).

18.3.1 Safe Water and Raw Materials

Safe 'potable' water is taken for granted in most developed countries but absence of safe water sources can be a major difficulty in many developing countries and regions (see also Chapter 17). It is important that water used for washing items that will be consumed without cooking (e.g. salad vegetables) does not contaminate the items due to poor water quality. In developing nations, this may mean there is a need to boil or otherwise sterilise water and cool it before use in certain areas. In developed countries, incidences of water supply contamination are rare, and it is normally safe to use water directly from the source in the kitchen. Nevertheless, outbreaks of foodborne illness (e.g. Cryptosporidium) have occurred in municipal water supplies, and it is important for consumers to follow any local instructions to boil water if an issue is reported.

Safe raw materials may also be taken for granted in developed nations due to the variety of ingredients available in grocery stores and supermarkets. Here, it is important to buy from reputable sources and to question offers of cheaper food from unusual sources; the Spanish toxic oil incident (Chapter 13) illustrates the potential for harm from unknown 'bargain' ingredients. It is also important to remember that some raw ingredients are, by their raw nature, likely to be contaminated with pathogenic microorganisms, and so their handling in the home kitchen is important to prevent the

spread of contamination to RTE items. In developing nations, there may be less choice of ingredients available but the principle of understanding the source of food is also important.

18.3.2 Refrigeration

Providing proper refrigeration of perishable foods begins when foods are purchased. Perishable foods should be refrigerated at 4°C or below as soon as possible, or within 2 hours of purchase. Attention should be given to the product's recommended shelf life date so that it would be consumed before spoilage could occur. Care must be taken to promptly refrigerate leftover foods in order to prevent the growth of spoilage or pathogenic microorganisms. A very good, and widely taught, US guideline for holding foods is that cold foods should be stored at or below 4°C, hot foods should be stored at or above 60°C; other countries have slightly different temperature recommendations, such as the UK hot-holding recommendation at 63°C and chill holding at a maximum 8°C (FSA 2016a). Whilst these standards vary slightly, they are designed in order to prevent the growth of pathogens by holding either above or below the danger zone of pathogen growth for most organisms of concern. This is an important consideration during holidays when family meals are served to large groups of people. Leftovers should be placed directly into refrigeration at 4°C within 2 hours of serving; it is not recommended to cool foods at room temperature before refrigeration. Large quantities of food that would require many hours to reach refrigeration temperature should be divided into smaller portions so that they will be properly chilled within several hours (i.e. maximising surface area to volume). Leftovers should be reheated to 75°C, if necessary, and consumed within 2 days of refrigerated storage (again, specific temperature recommendations may vary in different countries). Family members may disagree on whether a refrigerated food is on the verge of spoilage or not. A wise saying applies in this case. 'When in doubt, throw it out'. Some people, in the interest of saving money, have died of botulism after eating leftover food that was either questionable or obviously spoiled.

Refrigeration temperatures should be verified periodically with a reliable thermometer. It would be a public health service if refrigerator manufacturers built reliable thermometers into the refrigeration unit such that the interior and door temperatures could be monitored. It is known that the door temperatures are substantially higher than the interior temperatures of household refrigerators. Therefore, items that do not spoil rapidly, such as condiments, acidic beverages, or high-salt foods, should be stored in the door, rather than more perishable foods (Godwin et al. 2007).

Many frozen foods need to be thawed before cooking. These should not be thawed at ambient temperatures, as pathogens could grow on the warming food surface while the interior of the food remains frozen. Preferably, frozen foods should be thawed in the refrigerator or under cold running water if properly sealed. Raw meats and poultry should never be washed in the sink due to the difficulty with containing cross-contamination. They can also be thawed in a microwave oven, provided that they are cooked immediately after thawing.

18.3.3 Heating (Cooking)

In preparing processed foods for home serving, the manufacturers' label instructions should be followed for any form of cooking (e.g. baking, roasting, microwaving, boiling,

or frying the product). It is the responsibility of food processors to validate that the food preparation instructions will have a sufficient margin of error to assure the safety of the product. Usually, the heating process required to yield an organoleptically acceptable food, such as boiled potatoes, is substantially higher than that needed to kill vegetative forms of pathogenic microorganisms, thus providing a substantial margin of safety.

Raw meat and poultry products must be cooked to a minimum centre temperature in order to assure food safety. The recommended centre temperatures are (Marchiony 2004):

- 71°C raw ground beef, beef, and pork
- 74°C raw ground poultry, leftover foods
- 82°C whole poultry or pieces

It is highly recommended that an accurate meat thermometer be used to measure the centre temperature before serving. This is especially important with ground meats; if not adequately cooked, the centre of the ground products can potentially contain pathogenic microorganisms that had been on the meat surface before grinding.

18.3.4 Separation, Cleaning, Sanitation, and Personal Hygiene

Many opportunities for contamination and cross-contamination exist in the kitchen. Elimination of the causes of contamination, when applied in millions of kitchens worldwide, will reduce the burden of foodborne illness. Examples of causes of contamination include:

- Cross-contact of raw and cooked foods
- Unclean kitchen counters and utensils
- Inadequate hand-washing (e.g. after handling raw foods, changing diapers, taking out garbage, visiting the bathroom)
- Preparing food when ill, particularly if suffering from a foodborne illness
- Improper use of dish towels (e.g. using them to wipe counters after raw food preparation) and infrequent changing of washing up sponges and cloths
- Playing with pets while preparing foods and/or allowing pets to climb on kitchen counters
- Smoking, sneezing, or coughing while preparing food

Several common sense practices will minimise the possibilities of a foodborne illness originating in the home, and many of the potential contamination problems in the kitchen can be minimised or eliminated by using prerequisite programmes (PRPs), to extend the use of this term from the rest of the food supply chain. Moreover, some control measures could be established and monitored as critical control points (CCPs) in the home kitchen (see Section 18.4). Example control measures include:

Microbiological:

- 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 (see Chapter 17).
- Clean and disinfect bottles used for infant feeding before filling with properly heated milk or infant formulas.

- No pets are allowed on tables or countertops.
- Do not wash raw meats, fish and poultry in the sink.
- Minimise cross-contamination with frequent hand-washing and by using separate utensils for raw and cooked foods.

Chemical:

- Maintain allergen controls if a family member has a food allergy. Be aware of food allergies that visitors may have.
- Do not use empty food containers for chemical storage (e.g. rodenticides).
- Do not store toxic chemicals in the kitchen or in other areas where foods are stored.

Physical:

- Be aware of the age of the consumers in the home, including visitors. Take appropriate preventative action (e.g. cut grapes in half before serving to avoid a choking hazard).
- Be aware of breakages. Clean and inspect areas around glass breakage and if in doubt throw out any open containers in the vicinity. It is surprising how often consumers will send in a complaint to a manufacturer that turns out to be caused through a domestic glass breakage in the home kitchen.

18.4 Potential CCPs and Preventive Controls (PCs) in the Home

Simple but effective CCPs and PCs could be established in each home kitchen to create awareness of potential hazards and their means of control. Examples of home CCPs and PCs include:

- Controlled refrigeration temperatures
- Controlled cooking temperatures
- Removal of target allergens when susceptible individuals are known or expected to be present
- Preventing consumption of raw milk and raw purchased juices, raw cake batter, and unbaked cookie dough
- Restricted or prohibited consumption of certain types of food by immunocompromised individuals. For example, to avoid listeriosis, pregnant women should not consume soft or surface-ripened cheeses, precooked RTE meat and poultry products, unless the latter have been reheated to 75°C before consumption.

18.5 Consumer Education

Creation of a home 'HACCP Plan' or 'Food Safety Plan' (similar to having a tornado or fire evacuation plan) would be a good educational device for the entire family, with an added benefit for society as a whole – many of the children in families will spend part of their early life in part time jobs in the foodservice industry, preparing and serving a vast number of meals outside the home. If these children learned proper food safety procedures in the home, they would be better prepared to use safe food

handling practices when working outside the home. Education would include basic information about foodborne hazards, means of control, susceptible consumers, and so on, as described previously. Some schools are doing this and are to be commended. Education will be helpful outside the home too, for best practice shopping habits as well as barbecue picnics and on the go snacking.

Education for consumer food safety should begin in the early years so that good practices are learned at a young age (this happens in the United Kingdom; see Chapter 4). A number of techniques can be employed to continually reinforce the early learning: public service announcements by radio, television, or print media, public health agency websites, academic extension services, and so on. Family members who participate in food safety awareness training will be better prepared to use safe food handling practices in the home and on other occasions, to the point of actually using CCPs in the home, or creating the 'Home Food Safety Plan'.

TV cooking show hosts should be educated to eliminate the poor practices which many currently use, and should instead help to educate their viewers on the good practices needed in the kitchen – and why. Education of home appliance manufacturers could also be beneficial. For example, refrigeration units will have built-in, reliable thermometers that would facilitate observing and recording interior temperatures without opening the door, as standard. Optical scanners by which consumers can retrieve food safety information either from in-store displays or from label encryptions could be developed (Mortimore and Wallace 1998). This is now a reality with a number of countries adopting smart label technology, including the United States and others.

18.6 Good Consumer Practices (GCPs)

As shown in Chapter 1, modern food safety practices began in the United States in the 1960s with the joint development of HACCP by The Pillsbury Company, the US Army, and the National Aeronautics and Space Administration (NASA). In 1992–1993, HACCP was adopted by the Codex Alimentarius Commission (CAC) and the US National Advisory Committee on Microbiological Criteria for Food (NACMCF).

It soon became obvious that HACCP could not function in a vacuum; it needed the support of environmental and quality control efforts. Now known as PRPs, these emerged as good manufacturing practices (GMPs), good agricultural practices (GAPs), good hygienic practices (GHPs) (or good catering practices) in foodservice, and good distribution practices (GDPs). None of these provided guidance for consumer protection in the home. After several years of development, this void was filled by the introduction of good consumer practices (Leighton and Sperber 2015). It has been difficult to place good consumer practices on the same pedestal as GMPs, GAPs, GHPs, and GDPs. Globally, both the food industry and regulatory agencies have been nervous at suggesting that consumers should bear some responsibility for the safe handling of their food, making a reality of the 'farm-to-table' food safety responsibility. However, in some countries, consumer advocacy groups have promoted consumer education, working in partnership with schools and industry, and both retailers and manufacturers.

It is obvious that HACCP can assure the food safety only of those foods for which a CCP procedure can be established (e.g. cooking, pasteurisation, sterilisation,

refrigeration, freezing, dehydration, use of preservatives, and control of water activity or pH). Foods that are typically consumed raw, such as fresh produce, cannot be controlled by a CCP nor can raw foods that are deliberately consumed undercooked. The practice of offering rare/pink burgers in restaurants in some countries is of particular concern where it might mean this practice is transferred to the home. Since control measures like ionising radiation and high frequency e-beam irradiation that could help reduce the potential contamination of these types of raw foods are not universally available due to policy and consumer requirements around the world, it is important that risks are understood and effective cooking is applied wherever possible.

A number of consumer advocacy groups have been effective in promoting consumer practices that will reduce, though not always eliminate pathogens in raw products. One group that has included a kill step in its consumer advice is The US Center for Foodborne Illness Research, founded by Dr. Barbara Kowalcyk, which promotes digital thermometer usage and recommends that consumers ensure that foods are cooked to a safe internal temperature: whole meats above 145°F (above 63°C), ground meats above 160°F (above 71°C) and all poultry above 165°F (above 74°C).

Considering possible venues in which consumers could contract foodborne illness (home, grocer/retailer, foodservice, and institution), the possible CCPs and preventive controls can be summarised (Table 18.1).

Table 18.1 A Summary of CCPs and Preventive Controls by Category and Location.

		Category			
		CLEAN	**SEPARATE**	**COOK**	**CHILL**
Good Consumer Practices	**HOME**	Wash hands for 20 seconds with warm, clean water and soap. Use of a nail brush is recommended. Dry with paper towel. Clean and sanitise cutting boards, countertops and utensils before and after preparing food. Wash and scrub all raw produce except leafy greens, stem vegetables and floral vegetables. Do not wash prewashed leafy greens.	Store raw meat, fish and seafood below ready-to-eat foods and produce in the refrigerator. Store in containers that prevent dripping. Utilise 'egg shelves' or other container designed to store raw eggs.	Cook raw chicken and ground meats to required internal temperature (160°F/71°C for ground meats; 165°F/74°C for chicken). Verify temperature using independent thermometer; do not rely on the appearance of the meat to determine 'doneness'. Avoid the consumption of raw cookie dough, raw milk, raw commercial juices, sprouts and other raw products with a history of causing foodborne illness.	Thaw/defrost frozen foods in the refrigerator, in cold running water (placing food in airtight container) or in the microwave. Marinate raw meats in the refrigerator. Maintain refrigerator temperature at or below 40°F/5°C (ideally measured by an independent thermometer and checked once every 3 months). Avoid over packing refrigerators. Uneaten, prepared foods ('leftovers') should be refrigerated within 2 hours of preparation and consumed within 48 hours of preparation.

(Continued)

Table 18.1 (Continued)

		Category			
		CLEAN	**SEPARATE**	**COOK**	**CHILL**
Good Consumer Practices	**GROCER/RETAILER**	Wash hands for 20 seconds with warm, clean water and soap. Use of a nail brush is recommended. Dry with paper towel. Clean and sanitise cutting boards, countertops and utensils before and after preparing food. Clean and sanitise conveyor belts and laser scanners frequently.	Provide shopping carts with a separate section for raw meat, fish and seafood. Provide colour-coded plastic bags exclusively for raw meat, fish and seafood transportation.	Avoid serving raw cookie dough, raw milk, raw commercial juices, sprouts and other raw products with a history of causing foodborne illness.	Maintain refrigerator temperature at or below 40°F/5°C (ideally measured by an independent thermometer and checked once every 3 months).
	FOOD SERVICE	Wash hands for 20 seconds with warm, clean water and soap. Use of a nail brush is recommended. Dry with paper towel. Clean and sanitise cutting boards, countertops and utensils before and after preparing food.	Store raw meat, fish and seafood below ready-to-eat foods and produce in the refrigerator. Store in containers that prevent dripping.	Avoid serving raw cookie dough, raw milk, raw commercial juices, sprouts and other raw products with a history of causing foodborne illness. Cook raw chicken and ground meats to required internal temperature (160°F/71°C for ground meats; 165°F/74°C for chicken). Verify temperature using independent thermometer; do not rely on the appearance of the meat to determine 'doneness.'	Thaw/defrost frozen foods in the refrigerator, in cold running water (placing food in airtight container) or in the microwave. Maintain refrigerator temperature at or below 40°F/5 °C (ideally measured by an independent thermometer and checked once every3 months). Avoid over packing refrigerators.

(Continued)

Table 18.1 (Continued)

		Category			
		CLEAN	**SEPARATE**	**COOK**	**CHILL**
Good Consumer Practices	**INSTITUTION**	Wash hands for 20 seconds with warm, clean water and soap. Use of a nail brush is recommended. Dry with paper towel. Clean and sanitise cutting boards, countertops and utensils before and after preparing food. Wash and scrub all raw produce except leafy greens, stem vegetables, and floral vegetables. Do not wash prewashed leafy greens.	Store raw meat, fish and seafood below ready-to-eat foods and produce in the refrigerator. Store in containers that prevent dripping.	Cook raw chicken and ground meats to required internal temperature (160°F/71°C for ground meats; 165°F/74°C for chicken). Verify temperature using independent thermometer; do not rely on the appearance of the meat to determine 'doneness'. Avoid serving raw cookie dough, raw milk, raw commercial juices, sprouts and other raw products with a history of causing foodborne illness.	Thaw/defrost frozen foods in the refrigerator, in cold running water (placing food in airtight container) or in the microwave. Marinate raw meats in the refrigerator. Maintain refrigerator temperature at or below 40°F/5°C (ideally measured by an independent thermometer and checked once every 3 months). Avoid over packing refrigerators.

Source: Adapted from Leighton and Sperber (2015) and North American Industry Classification System (2017).

18.7 Case Studies

By way of illustration of the benefit of an organised approach, two case studies are presented, one fictional and one real.

18.7.1 Fictional Case Study: Microbiological Food Safety

Background

A 'typical' suburban family has been stricken by a number of illnesses during the past several years, most or all of which may have been foodborne illnesses resulting from foods prepared in their home. The Knight family – father, mother, daughter, and son – can recall three recent episodes in particular that seem to have been food related:

1) Three of the family members began vomiting within 2 hours of eating a meal that included Himalayan Nut Pilaf. The only member who did not become ill had not eaten the pilaf.
2) All family members experienced repeated diarrhoea within 14 hours of eating a winter holiday meal that included a dressed and roasted 4 kg goose. Because this meal was a family tradition, all members ate heartily.
3) Two family members and three of four visiting neighbours experienced simultaneous vomiting and diarrhoea within 1 day of feasting at an outdoor summer barbecue that included grilled chicken and Caesar salads.

Origin of the Knight Family Home Food Safety Programme

The Knight family's growing awareness that some of their memorable bouts of illness might have been associated with food handling practices was gradually reinforced with information gained by each family member from different sources. The mother's suspicions were raised while watching a public television programme about the causes and nature of foodborne illnesses. Both children learned simple facts about safe food handling in their school's health classes. In particular, they learned about the importance of proper refrigeration temperatures and learned more about foodborne illness symptoms than they imagined possible after Googling 'diarrhoea, eating chicken'.

Retrospective Analysis of Previous Illnesses

The Knight family began to discuss their new found information about food handling practices and began to develop hypotheses about the unexpected and, at the time, mysterious illnesses that had affected them and their neighbours. Additional online searching and attempted reconstruction of events surrounding the potentially incriminated meals and suspect foods led them to the following conclusions:

1) It seemed rather clear that the first series of illnesses involved the Himalayan Rice Pilaf, as it had not been eaten by the only family member who was not ill. The mother recalled cooking the rice the evening before the pilaf was prepared and served. She spooned the hot cooked rice into a rectangular plastic storage dish, which she covered and placed in the refrigerator door. It is likely that the episodes of vomiting were caused by the growth of *B. cereus* in the rice, which required many hours to cool below ambient temperature. *B. cereus* spores are normally present in rice. The spores survive the cooking process and are able to grow rapidly if the rice is not consumed or adequately chilled within several hours. During growth, *B. cereus* produces a heat-stable emetic toxin which induces vomiting within several hours of consumption.
2) The dressed/stuffed goose served for the holiday meal had been purposely roasted at an oven temperature lower than the recommended 163°C in order to retain the succulence of the meat. The father learned online that *Clostridium perfringens*, also a spore-forming microorganism, was often the cause of diarrhoeal illness in meat and poultry products, particularly those involving dressing/stuffing or gravy. It can grow very rapidly at temperatures up to about 50°C in foods that are roasted too slowly or held too long during serving. Following growth, it produces spores in the food. After consumption, the spores germinate in the host's intestine and produce toxins which cause diarrhoea typically within 8 to 24 hours. In this episode, the family's illnesses could have been caused by the growth of *C. perfringens* in the dressing/stuffing during slow roasting, or in the gravy, which had been made from the goose drippings/juices and held for many hours at ambient temperature during the long holiday meal.
3) Reconstruction of the third illness episode led to two plausible causes; perhaps both were involved to differing extents in the five illnesses. The same tongs had been used to handle raw and grilled chicken pieces. It is possible that grilled chicken could have been recontaminated with *Salmonella* or *Campylobacter,* both common contaminants of raw poultry. It is perhaps more likely that the Caesar salad was the cause of the illnesses, as it was made with two potential sources of contamination. Whole chickens were cut on a cutting board that was given only a cursory wipe (not washed

and disinfected) before being used to cut salad ingredients. Furthermore, the salad dressing was prepared with fresh, raw egg yolks, which have frequently been responsible for illnesses caused by *S.* Enteritidis, and it was not refrigerated once made. *Salmonella* infections typically are characterised by vomiting and diarrhoea, while *Campylobacter* infections do not always involve vomiting. Therefore, it is more likely that the illnesses were caused by *Salmonella*, though it could not be determined whether the raw egg yolks or raw chicken were responsible for the contamination. In any case, both are serious food handling mistakes which need to be prevented.

Knight Family Food Safety Team and Action Plan

Equipped with this knowledge about foodborne illnesses and their likely mistakes that caused the illnesses, the Knight family agreed to work together to avoid future occurrences. Each member assumed responsibility for specific aspects of the resulting family action plan:

- One of the two children volunteered to become the team leader, wanting to be the keeper of the collected data, which could later be used in a school project. This also meant taking responsibility for monitoring refrigerator temperatures at least weekly and making adjustments when necessary.
- The father agreed to monitor cooking and roasting temperatures as necessary, and to supervise prompt and proper refrigeration of foods.
- The mother agreed to monitor food handling practices and to regularly clean and sanitise kitchen counters to minimise opportunities for food contamination.
- The other child agreed to continue online monitoring of safe food handling information and to inform the entire family about useful practices.

Whilst this case study is a mostly fictional example of a family and its home food safety plan, the authors believe that it can be effectively used to promote the possibilities of improving safe food handling practices in the home, the ultimate link in the food supply chain.

18.7.2 Real Life Case Study: Allergen Food Safety

Raising Peanut-Allergic Children: A Mother's Perspective

Melanie Lundheim (in her own words)

This case study is an example to illustrate application of food safety management and is provided without any liability in its application and use.

Siblings Put Peanut Allergies Behind Them

Peanuts can no longer kill my kids. On January 3, 2014, Soren and Tessa Lundheim graduated from a 6-month peanut oral immunotherapy (OIT) programme. Since this time, the quality of our lives has dramatically improved.

Before Peanut OIT Treatment: Life Was Nerve-Wracking

Before treatment, invisible traces of peanut could – and did – trigger life-threatening anaphylactic reactions in Soren and Tessa. From a young age, they were well aware they could die from exposure to peanut if they weren't careful. Many a time, they were star

advocates for their own safety, turning down offers of peanut-containing treats, asking about ingredients in foods served to them, and making sure they had their life-saving medications with them at all times.

Despite my husband Andy's and my best efforts to keep Soren and Tessa safe inside and outside the home, they have had numerous anaphylactic reactions to peanut between them over the years.

Soren's Peanut Exposures : Pre-Peanut OIT

At age 5, Soren cried out to me for help just minutes after I tucked him into bed. When I got to his room, I saw that he was having so much trouble breathing, his upper lip was blue. Thinking at first he was having an asthma attack, I gave him his inhaler. Then his lips swelled up like a special effect in a movie. In a panic, I gave him a dose of antihistamine before injecting him with epinephrine – following his emergency protocol backwards even though I should have known to inject him first.

The instant I picked up the phone to dial 911 that unforgettable evening with Soren, Andy was miraculously on the line calling me from a nearby Home Depot store. I told Andy that Soren was having anaphylaxis and I had to hang up so I could call for an ambulance.

Amazingly, Andy beat the paramedics to our house and was able to ride with Soren to the hospital for observation while I stayed with Tessa.

A couple of months later, Soren had another anaphylactic reaction at school, followed by a second, 'biphasic', reaction about 20 minutes later in the ambulance en route to the emergency room.

These were Soren's only anaphylactic episodes in his first 12 years of life, before undergoing peanut OIT. Whilst we don't know for sure where Soren's exposures came from, we can only assume peanut was the trigger given the severity of his reactions.

Tessa's Peanut Exposures : Pre-Peanut OIT

Tessa has had more anaphylactic episodes inside and outside of school than we can count. Visits with the school nurse, as well as the paramedics, had practically become routine for her before undergoing peanut OIT at age 10.

Her reactions typically started with tingling in her ears, followed by wheezing, sneezing, upper-body flushing and feelings of impending doom. Then she'd get an uncontrollably runny nose and full-body hives.

Fortunately, Tessa's emergency medicines, including epinephrine, antihistamine and her asthma inhaler, alleviated her anaphylaxis, and her reactions didn't escalate to closing of the airways, cardiac arrest or death.

Keeping Soren and Tessa Safe at School

Still, Soren and Tessa were so vulnerable to peanut before undergoing peanut OIT, they qualified for protection under Section 504 of the Rehabilitation Act of 1973 at school. Their school district partnered with Andy and me to create and implement Section 504 plans for our kids. District administrators and we used the plans to ensure caregivers knew how to prevent, recognize and respond to peanut exposures in Soren and Tessa. These caregivers included teachers, school nurses, coaches, administrators, recess and lunch aides, chaperones, substitute teachers, custodians, volunteers, bus drivers and others.

The Five Stages of Grief, Adapted to Dealing with Peanut Allergies

We're grateful that most people in our lives have been supportive in helping keep Soren and Tessa safe. A few, however, have expressed resentment toward us for requiring peanut-allergy accommodations over the years.

Rather than get too upset about this behaviour, I compare learning about peanut allergies to learning about death. The news can make people – myself included – undergo the five stages of grief:

- First, denial that peanut allergies are real and severe enough to be life-threatening. 'Peanuts are harmless! Are you making this up?'
- Second, anger. 'Accommodating kids with peanut allergies is a pain!'
- Third, bargaining. 'Isn't there a cure for these kids, or an easier way to deal with their allergies?'
- Fourth, grief, either in the form of feeling sorry for peanut-allergic children, sorry for oneself for having to deal with peanut allergies, or both. 'Why us?'
- Fifth, acceptance: 'These children have life-threatening peanut allergies. Their allergies are real and we must help keep them safe.'

Peanut Allergy Impacts on Kids' Social Lives

Understandably, friends were reluctant to invite Soren and Tessa to their homes for play dates and birthday parties. Some feared inadvertently exposing Soren and Tessa to peanuts, causing anaphylactic reactions and having to administer shots of epinephrine.

Similarly, my husband and I were reluctant to let our kids go to new places. Why risk it? Yet, as our kids grew older, we were starting to feel isolated from our community – as though our kids had the plague. It was no way to live.

The Promise of Peanut OIT and Finding Treatment

Fortunately, peanut OIT was showing promise as a peanut-allergy treatment for Soren and Tessa. But it was only being performed in clinical-trial settings at first. Given our kids' history of asthma, as well as prior anaphylactic reactions to peanut, they didn't qualify for the trials. Outside of trial settings, peanut OIT was only available from doctors outside of our state at the time.

Desperate to get my kids desensitised to peanut so they could live more normal lives, I enrolled them in a reputable doctor's peanut OIT programme 250 miles – a four-and-a-half hour drive – away from our hometown.

During Peanut OIT Treatment – Well Worth the Effort

Under their doctor's expert care, Soren and Tessa started peanut OIT with a dose of 1/250 000th of a peanut on July 9, 2013. During weekly peanut-updose visits over the course of nearly 6 months, they worked their way up to the final dose of 21 peanuts, which they consumed under their doctor's observation on their January 3, 2014 peanut OIT graduation day.

Despite the long drive, we looked forward to every peanut-updose appointment in the doctor's office. Each made Soren and Tessa less vulnerable to peanut, and thankfully, all visits were covered by our medical insurance.

Peanut OIT didn't go without incident. Our kids experienced mild symptoms on occasion, such as tingling in their throats or onset of hives shortly after taking their doses. They had a few more severe reactions during treatment as well, triggered by heightened

activity during their doctor-prescribed hours of inactivity that – to this day – they must strictly observe after taking their morning peanut doses. While undergoing peanut OIT, the doctor closely monitored our kids, down-dosing them as required, such as during illnesses.

After Peanut OIT Treatment - Freedom at Last!

Peanut OIT is not a cure for peanut allergies. Even though Soren and Tessa graduated from peanut OIT treatment, they must consume their doctor-prescribed doses of peanut every day, indefinitely, to maintain desensitisation. They're also encouraged to consume peanut-containing foods throughout the day.

Soren doesn't mind the taste of peanut, so he occasionally exceeds his minimum daily peanut dose. Understandably, Tessa still dislikes peanuts, no matter how much I try to disguise the flavor in candied peanuts, ice cream, brownies, smoothies or other concoctions.

Soren's and Tessa's commitment to completing their doctor's peanut OIT programme has been worth every peanut dose and every mile of the commute for treatment.

Post peanut OIT, Andy and I can send Soren and Tessa off to school without fear that they'll be exposed to invisible traces of peanut on surfaces, sports equipment, art supplies or in cafeteria foods they consume. We no longer have to read package labels to see if foods were made on equipment or in a facility that processes peanut. Whilst it's still necessary for me to educate others in charge of Soren and Tessa how to prevent, recognize and respond to anaphylaxis in them, doing so has been less stressful ever since they've been desensitised to peanut.

Friends now invite Soren and Tessa to their homes without worry of exposing them to peanut. They can go on field trips without dedicated chaperones, or me, at their side. At restaurants, cafeterias, donut shops and ice cream parlors, they get to choose any item on the menu. They can eat DQ® Blizzard® treats, peanut-containing candies and assorted chocolates, just like their friends who don't have peanut allergies. It's so freeing!

Over the holidays, we're able to attend family parties without having to ask hosts to put the bowls of peanuts away or tell us about ingredients used in the foods being served. Best of all, we can breathe easier knowing that life-threatening peanut allergies are in the past for Soren and Tessa.

18.8 Conclusion

Food safety is multisectoral and multidisciplinary (WHO 2016b). It requires collaborative efforts from government, the agri-food industry, educators, and consumers to assure safe food at the point of consumption. The important role of consumers requires them to be informed about common food hazards and safe food handling practices. They need to read food labels and follow instructions provided for safe cooking and storage. Education campaigns are important in communicating best practice advice to consumers and home food preparers. The case studies in this chapter demonstrate the ways that consumers can get involved in understanding and contributing to the safety of foods that they serve and consume. Application of good consumer practices in the home and other venues where food is prepared and consumed is an important element of the shared responsibility for food safety.

19

Food Safety in Foodservice Operations

19.1 Introduction

The term *foodservice* relates to a wide variety of business types with diverse operations and processes and equally wide-ranging sets of challenges. Foodservice businesses cater for individuals and groups of consumers in work, study, leisure and pleasure, residential, healthcare. and custodial settings, as well as when they are out and about and on the move. They have to be able to respond to the needs of diverse consumer groups, including not just the general population but also vulnerable groups who may be at higher risk of contracting a foodborne illness or suffering an allergic reaction to food ingredients.

Foodservice kitchen facilities are often small and cramped but may be home to a huge variety of ingredients and recipe processes. Added complications arise for temporary, mobile, or 'pop-up' facilities, where food preparation may be done with limited access to running water for washing and hygiene facilities. Overall, the foodservice industry is highly complex and one size definitely does not fit all when it comes to food safety management systems and procedures.

Historically, attitudes to HACCP-based food safety management systems have varied in foodservice businesses and much has been made of the challenges of applying such systems in foodservice (World Health Organisation [WHO] 1999; Taylor 2001; Taylor and Taylor 2004). This has resulted in adapted and simplified programmes being developed specifically for foodservice settings, examples being *Assured Safe Catering* (Department of Health [UK] 1993) and *Safer Food Better Business* in the United Kingdom (FSA [UK] 2007) and *Managing Food Safety* in the United States (FDA 2006a), which also has an accompanying regulators' manual (FDA 2006b). These simplified approaches have provided valuable information and guidance to foodservice businesses about how to meet their food safety obligations; however, critics have suggested that, in some cases, these approaches are an oversimplification of food safety requirements, and there is no doubt that they would not be suitable for larger businesses (e.g. large or chain restaurants, institutional catering, etc.). Recent regulatory guidance in the European Union (EU) has underlined the importance of risk-based flexibility for certain food businesses (including some foodservice businesses) and recognised the important role of prerequisite programmes (PRPs) within these types of operation (European Commission 2016).

Foodservice business proprietors certainly do not want to make their consumers ill; however, historical data suggests that this area of the food industry is linked to a high proportion of foodborne illness cases and outbreaks (Greig et al. 2007;

Food Safety for the 21st Century: Managing HACCP and Food Safety Throughout the Global Supply Chain, Second Edition. Carol A. Wallace, William H. Sperber, and Sara E. Mortimore.

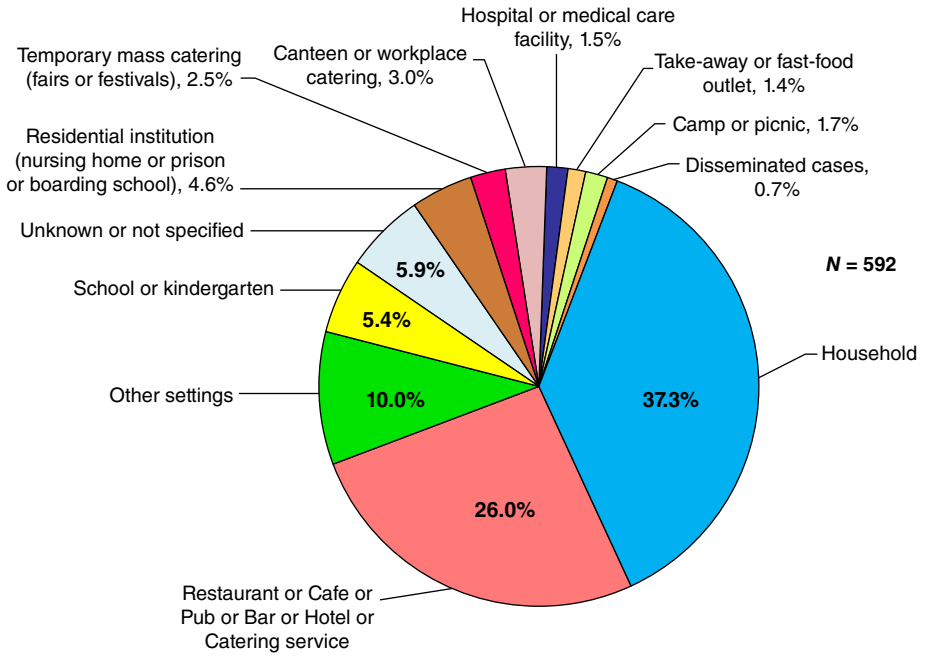

Figure 19.1 Distribution of strong-evidence outbreaks by settings in the EU, 2014. Data from 592 outbreaks are included: Austria (13), Belgium (16), Croatia (25), Denmark (31), Finland (16), France (122), Germany (28), Greece (1), Hungary (13), Ireland (3), Latvia (3), Lithuania (11), the Netherlands (6), Poland (71), Portugal (6), Romania (13), Slovakia (8), Slovenia (4), Spain (143), Sweden (14), and the United Kingdom (45). Other settings (n=59) include: farm (3), mobile retailer, market/street vendor (1), multiple places of exposure in one country (1), and other settings (54). Unknown or not specified (35) include: unknown (16) and 19 outbreaks for which information on the setting was not provided. *Source*: EFSA and ECDPC (2015).

Rocourt et al. 2003). Figure 19.1 illustrates recent data on foodborne illness in the EU where there was strong evidence for the setting most likely implicated in the outbreak (European Food Safety Authority [EFSA] and European Centre for Disease Prevention and Control [ECDPC] 2015); this demonstrates that foodservice settings were involved in more than 42% of the 592 outbreaks reported.

Whilst there are certainly many foodservice businesses that take food safety seriously, these foodborne illness statistics tell us there is much more to be done. Clearly problems remain in assuring the effectiveness of some foodservice food safety management systems and lessons can be learned, both from understanding what went wrong in previous outbreaks and from sharing best practices from businesses who have stringent systems in place. This chapter aims to highlight the complexity of the foodservice industry, presenting information on food safety challenges in a range of settings and discussing how these are being overcome with practical food safety management approaches.

19.2 Mapping the Foodservice Landscape

Foodservice settings exist wherever people may need or want food. Many businesses, such as restaurants, are well-established in physical premises that are or can be

made suitable for food preparation and consumption. Others are more transient, such as mobile food vans/trucks and food stalls at festivals and markets; these may have good facilities to allow hygienic operation but, in some cases, facilities may be more basic, meaning that operating safely is more of a challenge. The huge variety of different types of operations makes it difficult to develop a meaningful classification system for the foodservice landscape, and this is made more difficult by the overlap between different types of operation within individual businesses and different business settings. The North American Industry Classification System (NAICS 2017) breaks down 'Foodservice and Drinking Places' into five main categories: special foodservices (contractors); caterers; mobile foodservices; drinking places (alcoholic beverages); and restaurants and other eating places. Some of these categories are further subdivided into several additional subcategories. Choi and Almanza (2012) also provide a detailed categorisation of foodservice business types that would be widely recognised (Table 19.1).

Table 19.1 Mapping the foodservice industry.

Category	Establishment description	Notes
1. Full-Service Restaurants (Independent):	Serves food and beverages with a full menu providing waiter/waitress service; patrons pay their bills after they consume their food and beverages	Includes restaurants of various sizes and cuisines, (e.g. chef-patron, larger independents, fine dining, etc.)
2.Full-Service Restaurants (Chain):	The same as independently owned full-service restaurants with the additional requirement of a minimum of five independently housed establishments operating in at least two geographically distinct municipalities	May include franchise operations as well as group-owned facilities.
3. Limited-Service Restaurants (Independent):	Serves limited menu items and no waiter/waitress service; patrons typically pay their bills before they consume their food and beverages	Includes quick-service independents with take-away and sit in options (e.g. fish & chip shops, hamburger, and kebab restaurants)
4. Limited-Service Restaurants (Chain):	The same as independently owned limited-service restaurants with the additional requirement of a minimum of five independently housed establishments operating in at least two geographically distinct municipalities	Includes quick-service chain restaurants (e.g. chicken, hamburger restaurants); may include franchise operations as well as group-owned facilities
5. Cafeteria:	Serves a variety of prepared foods and beverages; self-service allows patrons to select food from displayed items in a cafeteria line	May also include order at counter for table delivery in addition to self-service
6. Institutional:	Serves food to educational establishments (e.g. schools, colleges), day care, hospitals, retirement homes/centres, nursing homes, and prisons	Large institutions (e.g. universities may fall into this category or may have multisite cafeteria (5), limited service (3 and 4), retail (7) and catering-based (10) options available on campus)

(Continued)

Table 19.1 (Continued)

Category	Establishment description	Notes
7. Retail:	Establishments that offer prepared food items from display areas and groceries which require minimum handling at the establishment.	Examples include prepared take-out foods served in garage forecourts and general grocery stores.
8. Taverns and Bars:	Bars, taverns, nightclubs, or drinking places primarily engaged in preparing and serving alcoholic beverages for immediate consumption	These establishments may also provide limited foodservice. Businesses offering a wider menu of food items (e.g. café-bars, bar-restaurants, pub-menus) would normally be considered within the full-service categories (see 1 and 2).
9. Mobile Facilities:	Food vans and trucks which generally have built-in food preparation and service facilities; would also include roadside stalls and carts selling ready-to-eat food on a regular basis (i.e. not temporary) and which may or may not have some built-in food preparation facilities	These businesses may use a regular pitch or may move between locations such as fairs and markets (see also below). Note: Food provision in mobile locations such as cruise ships and ferries would normally be considered under the restaurant and cafeteria categories (1–5) rather than mobile facilities.
10. Mobile Catering[a]:	These establishments generally have equipment and vehicles to transport food to events or prepare food at an off-premise site	May engage in providing single-event-based foodservices (e.g. weddings) or may provide a regular delivery-service of ordered items (e.g. workplace sandwich buffet delivery, etc.)
11. Delivery only:	Establishments that offer limited food items and beverages, based on delivery only	Includes pizza delivery services, etc.
12. Temporary:	Establishments that operate for a period of no more than 14 consecutive days in conjunction with a single event or celebration	Includes fairs, festival events, farmers' market events, etc.; operations likely to be pop-up stalls or restaurants but may include food vans and trucks (see also 9)

[a]*Note*: the term *catering* is also used more widely in line with its general definition as 'the activity of providing food and drink to a group of people'. This means that in some countries the term is used interchangeably with *foodservice*.

Adapted from Choi and Almanza (2012); North American Industry Classification System (2017).

Table 19.1 illustrates the sheer complexity and variety of types of foodservice operation. It is clear that some businesses fit neatly within one category, but other businesses may span several categories depending on their specific operations.

It is difficult to quantify the amount of food that is consumed in foodservice settings. This is partly because food consumption patterns vary hugely in different countries and cultures but also because data may be collected in different ways or not at all. It was estimated in 2005 that nearly half the adults in the United States dined in foodservice facilities nearly every day (National Restaurant Association 2005 cited in Choi and Almanza 2012). More recent US census data estimates a per capita spent of more than US$1900 on foodservice and drinking places in 2015 (US Census Bureau 2015). Further, recent UK data from the 'Food and You' survey provides insight into the proportions of the population eating in foodservice settings in 2016. Fieldwork was conducted in 2016

and consisted of 3118 interviews from a representative sample of adults ages 16 and older across England, Wales, and Northern Ireland. Data show that 96% of respondents ate out, with 43% doing so at least once or twice a week. Younger respondents were more likely to report eating out at least once or twice a week (60% of those ages 16 to 24 and 55% of those ages 25 to 34 compared with 26%–42% of those in the older age groups). There was also some variation by gender; 50% of men ate out at least once or twice a week compared with 38% of women (Bates et al. 2017). Additional UK data is provided by WRAP (2013) on numbers of meals served in various foodservice settings:

- Restaurants: 704 million/year
- Pubs: 871 million/year
- Education (nursery, schools, universities): 1,134 million/year
- Health care (hospitals and clinics): 1,04 million/year
- Hotels: 611 million/year
- Quick-service restaurants: 1,977 million/year
- Services (others): 261 million/year
- Leisure (transport (ships, trains, etc.), museums, stations, mobile caterers, cinemas, etc.): 523 million/year
- Staff catering: 880 million/year

Data such as these demonstrate the huge numbers of meals involved and illustrate the potential for foodborne illness if food safety hazards are not managed effectively. Clearly, the landscape for eating out in foodservice settings is changing, and the foodservice industry continues to evolve in different countries.

It is well-known that in some parts of the world, often in developing countries, street food vendors are commonplace and often provide cheap nutritious and freshly cooked food options for locals and tourists alike. The Food and Agriculture Organisation (FAO) held a Technical Meeting on Street Foods in Calcutta in 1995, where it was pointed out that an important aspect of street foods that deserved particular attention related to their safety (FAO 1997). It was recognised that street foods raise concern with respect to their potential for serious food poisoning outbreaks due to microbiological contamination, improper use of additives (in particular the use of unapproved colourings), and the presence of other adulterants and environmental contaminants. Improper food handling practices were also identified as a serious cause of contamination, as were problems with potable water supply, the quality of raw materials used (for example rotten vegetables or spoiled meat), unsuitable environments for street food operations (such as proximity to sewers and garbage dumps), and inadequate facilities for garbage disposal (FAO 1997). Since this date, numerous studies have been published on standards in specific countries and cuisines regarding street food providers' hygiene knowledge and practices (e.g. Liu et al. 2004, de Silva et al. 2004, Subratty et al. 2004; Barro et al. 2006; Abdallah et al. 2008; Rheinlander et al. 2008; Choudhury et al. 2011), and the microbiological quality of street foods (e.g. Mosupye and Von Holy, 2000; Muleta and Ashenafi 2001; Hanashirio et al. 2005). Further guidance materials and training interventions have also been provided (e.g. FAO 2009), but this remains an area where there are concerns for consumer health protection.

Although foodservice settings and businesses may be different around the globe, there are common issues that affect many businesses. Key issues of importance are around education and training, skills, knowledge and practices of the food handling workforce,

staff turnover, constraints such as space and equipment availability, and lack of time in the food-preparation environment. Added to this, the variation in food safety culture within the many different businesses further illustrates the complexity involved in assuring food safety in the foodservice industry. The following sections highlight the challenges in selected example foodservice settings and consider how different types of businesses are working to overcome their challenges and protect their consumers and businesses from involvement in foodborne illness.

19.3 Quick-Service Restaurants

Quick-service restaurants often, but not always, have a relatively narrow range of menu items that will generally be standardised across branches of the same business chain. The basic concepts of chain quick-service restaurants are consistency, simplicity, and speed, with the aim of providing a quality product every time. Although there may be some local fresh ingredient and product variations, global chains normally aim for the same product to deliver the same experience wherever in the world it is ordered and eaten. This requires a high level of standardisation of ingredients, products, and procedures and means that a staff member should be able to walk into another restaurant of the same brand in any other place and both feel at home with most of the items on the menu and be able to make most of the products. Menus for these types of restaurants tend to have limited complexity to allow for speed of preparation and kitchens are designed for ease of cooking and putting menu items together with limited movement needed from the staff members.

Common misconceptions of quick-service restaurants often relate to perceptions of food quality. People often think that if the food is cheap then shortcuts must have been taken, and so how can it even be created safely? However, the consistency and simplicity of menus means that company standards are highly regulated and this combined with ingredient-buying power, particularly in larger chains, means that high-food safety standards can actually be easier to achieve than in some other types of foodservice business.

19.3.1 Challenges in Quick-Service Chain Restaurants

The challenges start with getting the right team members in place at each location. Difficulties are associated with interrelated factors such as the general employee age and education, high staff turnover, and the geography of the restaurant location, and all these factors can also influence the individual restaurant's financial performance as well as its food safety capability. Many staff members are young people for whom it might be their first job, perhaps a part-time position whist they study at high school or college. Their age may mean that they are paid a minimum wage for a physically demanding position, and difficulties around the geography of the location may mean that, particularly for non-drivers in areas with limited public transport, it is challenging to get to the restaurant at the times needed for shift hours. Added to this is the potential competition for part-time staff from other employers, and this makes it easier to understand the relatively high staff turnover at quick-service restaurants throughout the industry.

High staff turnover makes it difficult for quick-service restaurants to be progressive with new systems and procedures because of the need to be constantly hiring and training new staff. It can be difficult to find new staff members to fit the existing culture and demands, and continuous vigilance and energy is needed to train new employees. Training needs to be broken down into a digestible format, and many quick-service chains use technology such as online training to help get key brand and food safety messages across.

A lack of leadership in a restaurant combined with high staff turnover increases the chance of poor performance, and this can have a knock-on impact on the overall customer experience, and potentially, food safety. Within this context, the restaurant general manager (RGM) has an important role to play and it is crucial to have stable and high-performing individuals in this role. The RGM is the main driver of food safety and brand performance at the restaurant level, and a good RGM means that the necessary targets for food safety, cleanliness, and so on are likely to be met on an ongoing basis. It is certainly best to have a motivated RGM who is a good influence on the rest of the team: 'Our best RGMs have created a family like environment where staff live and breathe food safety culture' (Kathleen Emsley, Taco Bell, personal communication, 2017). As an example, Taco Bell makes sure that new RGMs have appropriate training certification (Servsafe) and that they follow training modules throughout the year with annual recertification, and with performance tied to bonus. In addition, motivational courses are provided to help grow and inspire team members. In larger chains, the regional 'field leaders' also play a hugely important role in ensuring consistent messages about food safety and its importance flow throughout the entire chain. They need to make sure that the food safety message doesn't get lost and that organisational food safety values from the top of the organisation live throughout the culture at all locations. Box 19.1 illustrates the multifaceted approach to food safety training and education at Taco Bell.

Box 19.1 Bringing food safety to life through a multi-prong approach at Taco Bell

- Foundation level – prerequisite programmes and certification
- Education – continuous for all staff levels
- Training – through management meetings
- Communication – timely and constant
- Programmes
  - Programmes are designed to aim for greater than the minimum standards
  - Taco Bell makes sure that its restaurants meet or surpass food safety levels
- Rewards and Accountabilities
  - Bonus tied to food safety at all levels
  - Growth-ready status
  - Need to find the right balance between the rewards and accountability which drives a positive food safety culture

(Continued)

Box 19.1 (Continued)

- Cross-functional effort – quality assurance is responsible for setting standards, but everyone is a part of the process and aware of the why behind decisions.
  - Employees are part of the conversation very early on.
  - Discuss the different risks as we bring in new menu options/ingredients (e.g. how cheese is shredded, are the potatoes frozen, shelf stable sauce, etc.)
- Very clear alignment on zero tolerance for food safety risk from executive leaders to team member

Personal Communication, Ensley 2017.

19.3.2 Ongoing Control of Food Safety in Quick-Serve Restaurants

Following on from the training and education programmes described above are PRPs and the foundation of food safety programmes at the individual restaurant level. Implementation of PRP standards is crucial and effective monitoring is key to food safety assurance. In order to facilitate this in the busy restaurant environment, there is a major trend towards investment in new technology to help with the day-to-day challenges. Digitising data collection and helping with new technologies makes life much easier for restaurant staff (e.g. introducing a tablet helps make things more efficient and accurate and has the potential bonus of feeding back real-time data to head office). An example of how technology is being used in this setting is given in Box 19.2.

Box 19.2 Using Technology for ongoing control of food safety at Taco Bell

Restaurants are required to go through their extensive food safety checklist *twice* a day. This task is laborious, so tablets are used to make the process smoother/faster. Some of the benefits of this approach are:

- Sensors feed the tablet and helps save the manager to have to test the temperature
- Gives corporate the ability to check in on the restaurants
- Labour saving and makes it easier and more preventative in the terms of the maintenance of food safety controls
- Helps get ahead of machines breaking down
- Real time and closed loop
- Might cost more up front but will help later down the line
- Removes guesswork from monitoring and record keeping

The Taco Bell approach has been to digitise as much data as possible to move to a more preventative rather than reactive approach. This includes:

- Daily checklists
- Monthly pest report – reported in real time.
- Special media team in operations – monitoring FB or Twitter for things going on. If anything food safety related comes up it feeds into the food safety team
- Quality assurance hotline data

The important aspect is how all the data comes together so that the food safety and operational leadership team have useful information to base management decisions. This is achieved via the Customer Protection App (CPA):

- Uses an algorithm that if anything critical comes up then it alerts the field, food safety team, and leaders in the organisation
- Time limits are embedded to ensure actions are taken immediately
- Rolled out in June 2016, and whilst it's not completely preventative, it allows the team to track and take action on issues much quicker, even when they are smaller
  - Working towards predictive analytics in the near future; for example, three apparently unrelated issues going on in a restaurant right now might not raise alarm, but the system would be able to catch these problems together again in the future and highlight that it may create a problem.

A similar approach is ongoing in the supply chain with regards to technology, For example:

- Cold Chain Management - sensors that deliver the produce and beef during distribution so that the quality assurance hotline and product manager gets an alert so that if the temps are off during transportation they're notified
- Monitoring chlorine levels in the wash flume. Sensors that would release chlorine into the water intermittently instead of waiting for employees to check the levels and add more chemical.

Personal Communication, Ensley 2017.

In summary, achievement of best practice food safety in quick-serve restaurants relies on having well-trained and committed staff, applying the most stringent food hygiene standards (e.g. strictness around hand washing, sanitiser and glove use, and using technology and digitisation wherever possible to assist in the application of food safety procedures). This approach is easier for staff members to execute their responsibilities, uses real-time data to help prevent larger issues, and gives increased visibility of the food safety system. The importance of traceability and documentation of the food within the restaurant supply chain is also realised through technology solutions.

The food safety culture and commitment to apply company quality values is paramount within the organisation, and systems are further strengthened by external partnerships (e.g. with regulators and competitors being brought together for non-competitive food safety conversations and industry-wide benefit). The ability to compare notes with others in the industry is helpful for benchmarking best practices. This 'real willingness to partner and innovate with regulators and industry is a new trend' (Kathleen Ensley, Taco Bell, personal communication, 2017). There has been a definitive shift over the past 10 years, especially with the introduction of social media. People are constantly communicating, and because all quick-serve restaurants are in the business to protect the public and make sure that they are serving safe food, people are relieved and willing to share, recognising that one person or brand does not have all the answers.

19.4 Institutional Catering

As noted in Table 19.1, the 'institutional' foodservice sector serves food to educational establishments (e.g. schools, colleges), day care, hospitals, retirement homes/centres, nursing homes, and prisons. Although commonly grouped together as a sector, these are often different settings which operate in different ways. Particular establishments or locations may operate using:

- their own kitchen and staff where food is cooked from scratch under the leadership of the head chef or cook;
- a central kitchen (either internal or external to the institution) where food is prepared and delivered to the locations where it may be served. Food delivery may be under hot-holding conditions or there may be reheating at the serving location;
- a number of kitchens and cooking teams across a range of cafeteria, restaurant, and snack-bar locations. Common of larger universities, this type of institutional catering may be run by in-house employed teams, may be outsourced to managed contract catering services, may include a number of franchised brand operations, or may be a combination of these types of operation.

As different as the range of operating conditions within different types of institutions, the consumer group will also differ markedly and in many cases will include high-risk consumers. This makes adherence to good food safety practices within the institutional supply chain a highly crucial part of consumer health protection. Catering for large numbers of consumers within an institution also gives challenges of scale and this means the design of kitchens and operating facilities is important to allow the safe production, holding, and service or large amounts of food.

Because of the scale, operational complexity and consumer groups, it is unlikely that simplified food safety management systems such as Safer Food Better Business (FSA UK 2007, 2016) will be suitable apart from in smaller institutional settings (e.g. small nurseries/day care or small retirement homes). For most larger facilities a HACCP-based food safety management programme will be essential. Successful HACCP systems in these types of operations rely on careful design to cover all possible processes and ingredients in a practical and manageable format. This allows detailed understanding of the operation and identification of hazards and suitable control options. Mortimore and Wallace (2013) include a case study from a complex university catering operation, a key part of which was to understand and map the process activities involved in creating all meal options. Figures 19.2 and 19.3 show, respectively, the overall map of process modules in the HACCP system and an example module. These preparatory documents allowed the catering services team to create the structure of their HACCP system and understand how to control hazards at various stages in the operations. Once implemented, successful operation of the systems, like in any other food operation, relies on a strong food safety culture (Chapter 15).

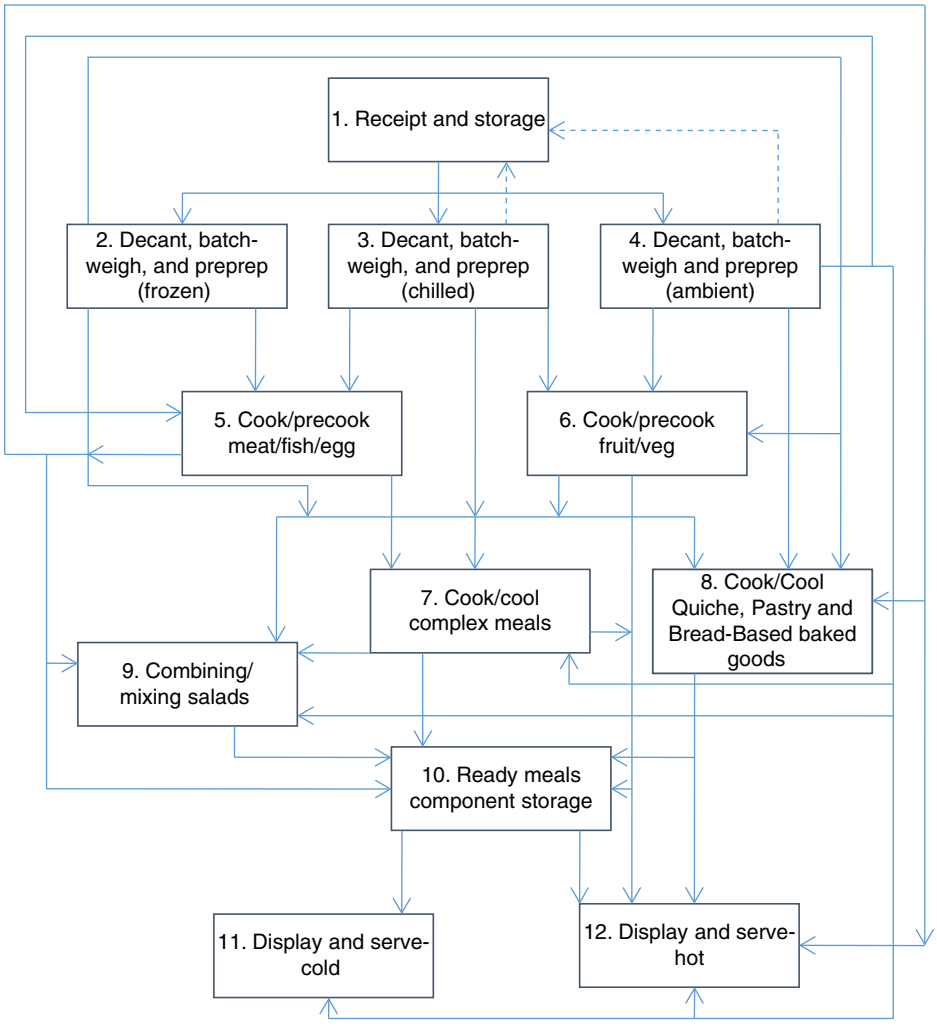

Figure 19.2 Example institutional foodservice HACCP modular system structure: University catering services. *Source*: Mortimore and Wallace (2013). Reproduced with thanks.

19.5 Foodservice SMEs: Owner-led Restaurants, Cafés, and Snack Bars

Moving from the larger operations such as chain quick-serve restaurants and institutional catering to consider foodservice small and medium enterprise (SMEs) and microbusinesses, we see challenges in applying food safety standards and practices. Some of these are similar to issues also seen in larger businesses and already described,

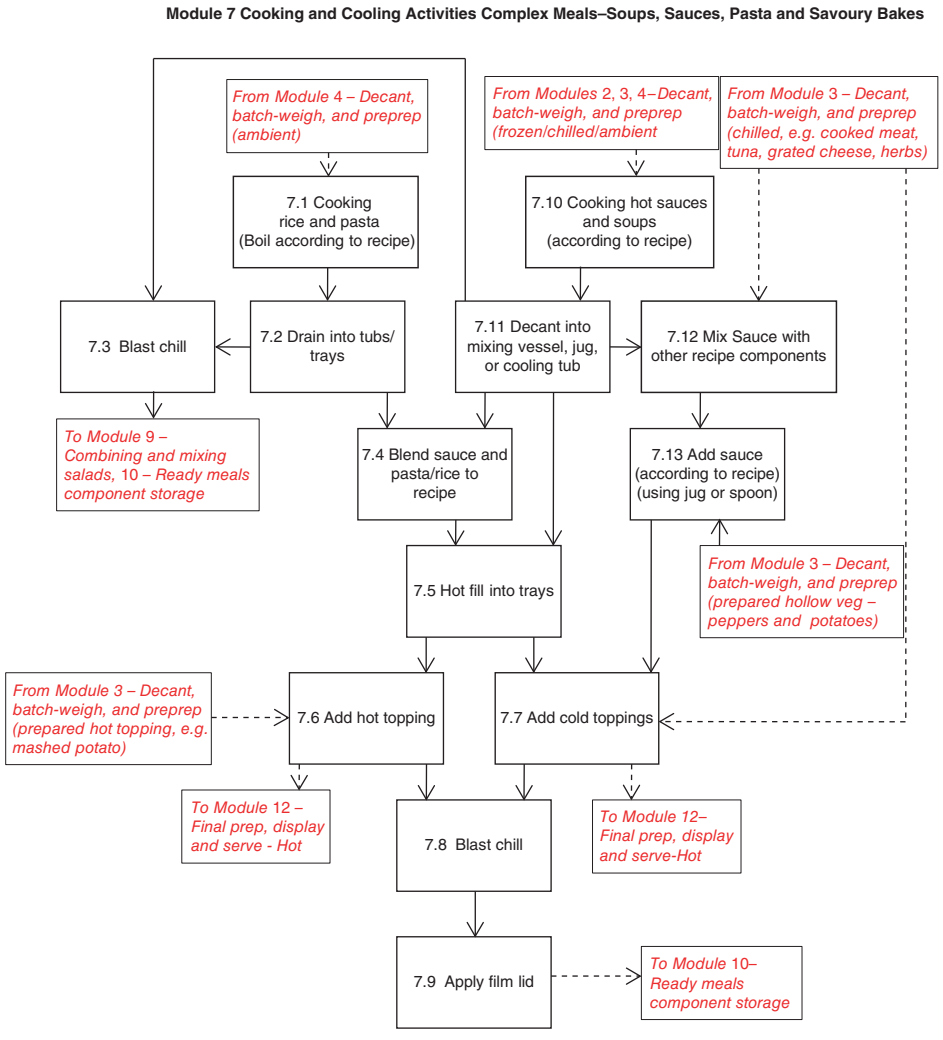

Figure 19.3 Example HACCP module flow diagram
Source: Mortimore and Wallace (2013). Reproduced with thanks.

such as difficulties in hiring, educating, and training staff to perform correct food safety practices. Others may be more focused in SME businesses, such as lack of space, facilities, and resources for safe food preparation, and this may be a particular problem in mobile businesses (see also Section19.7). Like the restaurant general managers in quick-serve restaurants, the owner–operator or manager of SME businesses plays a crucial role in the food safety culture of the restaurant. It is therefore important that this individual has a good understanding of food safety requirements and responsibilities; however, often people set up food businesses with limited knowledge or experience of the food industry and the special considerations needed for consumer safety. There is a role for regulators and industry associations here in promoting the knowledge and expertise required and in helping these individuals to quickly upskill themselves and their teams.

As mentioned in the introduction, the challenges of applying HACCP-based food safety management systems, particularly in very small foodservice businesses, have been highlighted for several years and this has led to adapted and simplified programmes, often with a useful training element, being developed specifically for foodservice settings. This can only be a good thing if it helps SME proprietors and managers to develop appropriate systems to protect public health.

19.6 Fine Dining, Star Ratings, and Celebrity Chefs

In terms of exclusivity and expense, fine dining restaurants, often with prestige star ratings, are at the pinnacle of foodservice outlets, and it might be anticipated that food safety practices would be held at an equally high level. Whilst there are, no doubt, examples where this is the case, there are also incidences where risky practices are employed within food preparation. This can include use of novel and unusual ingredients and cooking methods that are developed for their taste sensations and may have limited or no attention paid to food safety. However, it can also involve high profile/celebrity chefs who believe that food safety practices and regulations are in place to stifle creativity and, perhaps more dangerously, that they themselves are above compliance. Whilst these 'ego chefs' (Schembri 2017) may spend little time cooking, their attitude is often mirrored by the Head Chefs who run the kitchens and then it cascades through the kitchen brigade – a clear indication of poor food safety culture led from the top.

Examples of the practices that result in this type of situation include:

- Chef proprietors and chef directors belittling the presence of food safety professionals, referring to them as, e.g. food police, and being generally dismissive of advice.
- Complex or high-risk menu items with no HACCP or food safety risk assessment in place, such as sashimi, sous vide, steak tartar, and burgers to be eaten less than thoroughly cooked
- HACCP in place but ignored
- Fudged food safety records
- Little understanding of the impact of poor food hygiene standards (e.g. poor hand hygiene, dry/dusty wash hand basins, and no soap or paper towels)
- Low levels of food safety training amongst staff

Food safety professionals have conquered these types of issues by talking to the head chefs and sous chefs at their level, asking for their advice (even when it may not have been needed) on how to make their lives easier, helping them to be compliant with regulations but still enabling them to cook fabulous, exciting, and safe food. Engagement of the team leaders in this practical way has been effective in changing attitudes to food safety. The goal here is for food safety practices not to be seen as an obstacle, and so food safety professionals can assist in identifying new or improved practices that make food safe without limiting creativity.

An example of how this has been achieved has included an overarching generic HACCP plan being put in place to reflect what the chefs needed it to cover as well as being compliant with necessary food safety practices and regulations. In addition, this was supported by specific HACCP plans for complex dishes, validated by microbiological sampling results that demonstrate the novel processes meet safety requirements.

Involving head and sous chefs in this way and helping them to demonstrate safety of their novel processes enabled the HACCP plans to become working documents that were adhered to as a matter of course by the kitchen teams. The chefs designed (in principle) what they wanted the monitoring records to look like and the food safety professional made them fit for purpose. This resulted in greatly improved record keeping as the chefs gained the understanding of 'why we do what we do' and has also been reflected in the hygiene standards throughout.

As a spin-off from their successful restaurant operations, some fine-dining chefs achieve celebrity status through television and public appearances and provision of cookbooks. This would seem to be a good opportunity to share best food safety practices with consumers and, indeed, many are viewed as role models by consumer audience members; however, studies of practices displayed by celebrity chefs on television shows have found that poor food safety practices are commonplace, particularly around cross-contamination, checking of doneness and treatment of leftovers (Mortimore 1995; Mathiasen et al. 2004; Borda et al. 2014; Maughan et al. 2016; Woods and Bruhn 2016). Interestingly, Woods and Bruhn (2016) also investigated the attitudes of culinary students towards celebrity chefs' practices and how this related to their own practices and intentions (Table 19.2). These chefs of tomorrow were clearly not impressed with practices of current celebrity chefs who were examined in the study, with 74% of the culinary students believing that celebrity chefs are not good role models, whilst 100% wanted to set a good example themselves. The statements in Table 19.2, excerpted from Woods and Bruhn's (2016) wider list of items on attitudes to professional food safety practices, give a clear indication that culinary students understand that poor food safety practices are being displayed by celebrity chefs in television shows.

Table 19.2 Culinary student attitudes toward professional and celebrity chefs' food-safety practices ($n = 54$).

Statement	Agree, % (*n*)	Disagree, % (*n*)	Not sure, % (*n*)
If I'm doing a demo for TV, I believe it is important to exhibit safe food-handling behaviours.	98% (53)	2% (1)	0% (0)
I think that chefs are role models for consumers.	78% (42)	20% (11)	2% (1)
All chefs should set a good example, whether they are on TV or not.	91% (49)	7% (4)	0% (0)
Celebrity chefs are good role models.	2% (1)	74% (40)	24% (13)
I want to set a good example for others.	100% (54)	0% (0)	0% (0)
If I'm not a television chef, I don't think I need to worry about setting a good example.	2% (1)	98% (53)	0% (0)
Chefs can help reduce the incidence of foodborne illness.	96% (52)	0% (0)	4% (2)
Television chefs sometimes fail to give consumers the information they need so that they can safely prepare the dish they are demonstrating.	96% (52)	2% (1)	2% (1)
Television chefs don't have time to wash hands and utensils, cutting boards, when they cook on TV.	24% (13)	69% (37)	7% (4)
I don't expect celebrity chefs to follow food safety recommendations when they cook on TV.	24% (13)	70% (38)	6% (3)

Adapted from Woods and Bruhn (2016).

Many celebrity chefs from television shows and popular food blogs also write cookbooks which are popular with home consumers. This would seem to be a further opportunity to act as food safety role models by providing appropriate food handling and cooking advice. However, a recent study by Levine et al. (2017) in the United States found that of 1497 recipes containing raw animal ingredients that could be measured with a digital thermometer, only 123 (8.2%) included an endpoint temperature and of these, only 89 (72.3%) gave a correct temperature for the ingredients concerned. Further, the study noted that when no endpoint temperatures were included in recipes, authors often provided subjective and risky recommendations, whilst positive food safety behaviour messages were included in only 5.1% (90 of 1749 recipes). Levine et al. (2017) concluded that further research is needed on the effect of their results on consumer behaviour and the development of interventions for writing recipes with better food safety guidance. This would seem to be an area with significant potential for communicating safe food-handling practices to consumers and celebrity chefs could take on an important public health protection role by both their actions on television shows and by providing correct guidance in their cookbooks.

19.7 Mobile Foodservice: Market Stalls, Food Vans/Trucks, Festivals, and Pop-Up Facilities

A further and highly complex area of foodservice is that of mobile operations. As shown in Table 19.1, these can include catering at one-off temporary events or regular pitches; they can involve foodservice from market stalls and pop-up facilities or from mobile facilities such as food vans and trucks. Increasingly we are seeing consumers who are desirous of procuring foods from these smaller enterprises. In previous chapters, we considered the changing consumer demographics, specifically, the perception that small and local might be better (i.e. healthier). Those of us in the business know that this is not necessarily the case, and unless the proprietors have the required food safety knowledge, then there could be a high likelihood of failure in this category. In the case of food trucks, which are not only becoming more and more popular, but also more gourmet, the food safety challenges are similar to the larger foodservice establishments but with one addition – they are highly space constrained which means that a high-degree of know how in preventing cross-contamination is needed. The design of the facility will have limitations so operator hygiene practice will be key to success.

Guidance for achieving food safety at these types of events and in mobile food businesses is provided by various sources but can be sporadic. An early example of guidance for mobile events in the United Kingdom was the *Industry Guide to Good Hygiene Practice: Markets and Fairs Guide* (Chadwick House Group Ltd. 1995). Developed in collaboration with NABMA and the Environmental Health Officers at Sheffield Council, these guidelines are still widely in circulation today, albeit distilled down into more succinct form on many council Web sites as the original document is now out of print. This industry guide provided guidance on how traders should carry out a hazard analysis, identify critical control points and ensure that safety controls are in place, maintained, and reviewed. More recently, the UK Chartered Institute of Environmental Health produced *CIEH National Guidance for Outdoor and Mobile Catering* in 2010. Also useful in this field is guidance for sellers of street food (e.g. FAO 2009). Additional local and

national guidance is likely to be available in many countries and the WHO publication *A Guide to Healthy Food Markets* (WHO 2006a) also offers some useful advice at the international level. Because of the increasing popularity of mobile food provision, we see further work and guidance as a necessity for consumer health protection.

19.8 Conclusions

It can be argued that there has been a gradual convergence of global food safety expectations and standards in the manufacturing sector over the past number of years. This has largely been driven by the globalisation of the supply chain alongside the public and private sectors willingness to work collaboratively towards a common goal. This gradual shift is not so true in the foodservice environment, with the exception of the large multinational quick-service restaurant chains and some larger institutional settings. There is still a wide range of social customs in terms of preferences for out of home eating. Many and varied challenges remain, not least in the small and independent foodservice operations where the knowledge and skills level of the many thousands who work in this industry often needs improvement. The differences in food cultures around the world will likely have a greater influence in the foodservice sector such that the development of a food safety culture will prove to be more of a challenge. However, the pace of change in terms of technology is making an impact in many areas and here too it is emerging as an influential factor.

Sites such as iwaspoisoned.com make the claim that they are pushing the industry towards safer dining by crowd sourcing data. This is a site that posts information from consumers around the globe, and it makes for a fascinating read. This is not the only likely influencer in this space because there are many other sources of information that are readily available to the global food tourist – not least the now well used TripAdvisor® site, although this latter example is likely to include more comments on perceived food quality and service than foodborne illness. As food safety professionals know, untrained individuals will often be convinced an illness results from a specific item of food they have consumed, often the last item or something they have eaten when away from home. However, with knowledge of likely types of foodborne illness and causal organisms, the actual item of food or meal where it was consumed may be different. This means that data from consumer-reporting sites needs to be treated with caution, but nevertheless, there is a role for big data in identifying trends in foodborne illness.

Foodservice food safety challenges will continue to be a concern for many years to come, but the need to protect reputation both locally and globally is something that can be leveraged by consumers who want to trust that what they eat is safe, whether at home or when eating out.

Epilogue

At time of writing we are not yet a quarter way through the 21st century, and have barely scratched the surface of the third millennium. As we reflect upon the rapidly changing world, the pace of change continues to increase, which makes it difficult to imagine what the world will be like at the end of this century.

We do know that **supply chains** of the future will be majorly influenced by technology. 'Smart' factories where increased digitalisation will result in systems and components exchanging information to control and regulate themselves - predictive maintenance and leaner production with fewer people as a result (MacPherson 2017). Driverless trucks, drone deliveries, the decline of retail stores, and increase in ecommerce is a given. The impact of digitalisation and artificial intelligence will not eliminate people but will require different skills. All of this has implications – positive and challenging – for food safety.

Supply chains of the future will also be influenced by **climate change**. Climate change not only in relation to global warming, but also the increasing weather variability which is perhaps more important with regards to food availability and, as a consequence, food commodity pricing. This requires that food systems develop resilience to fluctuations (Benton and Thompson 2016) which from a food safety perspective will require us to be on the alert for new and unforeseen challenges, such as the increases in economic adulteration through scarcity and price inflation, the transference of disease from one part of the globe to another or even the emergence of new pathogens.

Technologies beyond biotech. Less-developed nations are starting to embrace technology to feed their hungry populations and export surplus. In the last few years we have seen incredible developments. Increased efficiencies in agriculture through better animal nutrition and use of technology is only a part of the story. The advent of big data, predictive analytics, the Internet of things, robotics, 3D and 4D printing, DNA and isotope traceability, genetic engineering, genome editing and sequencing, and more (Chester 2017) is starting to take hold and will create impacts we can only start to imagine. Water scarcity will require innovative solutions, not just in reducing water usage and recycling water but also in thinking about sources of water differently such as the ability to capture water from condensate in the desert. We will have to recognise that feeding more people cannot come from increased deforestation or from ploughing up grassland. We need to use land more efficiently, growing more on farms we already have and making use of urban spaces and vertical farming systems. We may even need to change diets (e.g. eating less animal protein) and reduce the use of food crops and

Food Safety for the 21st Century: Managing HACCP and Food Safety Throughout the Global Supply Chain, Second Edition. Carol A. Wallace, William H. Sperber, and Sara E. Mortimore.

food farming land for biofuels (Foley 2014). Many challenges for food safety that we have not seen before are likely to come out of these developments but also a great many solutions.

Changing demographics will have as big an impact on food safety as does changing technology. In many parts of the world there is a growing demand for 'real' foods, made by small and local producers and including entrepreneurial start-ups. Whilst these are not going to impact the global food security of growing populations, in communities where they exist they are often perceived as being more 'wholesome' through their shorter, 'cleaner' ingredients listings and local/reduced 'food-miles' status. Those of us working in the food safety field know all too well that many of these smaller entrepreneurs lack the essential knowledge required for safe food production, but the typical consumer, whilst often well-educated and able to afford the typically higher prices associated with these types of products, does not have that insight. Bespoke diets based on DNA analysis and the desire for less processed foods which are 'free from' is also a trend in the Western world but a real polarity when compared with the hunger or food insecurity statistics that are not only related to impoverished countries but also increasingly a concern in the Western world.

We see the rise of different food delivery and purchase systems, the advent of the 'Grocerant' where foods are served in the retail store as a way of providing an enhanced experience and to draw customers (who are dwindling because of ecommerce) into the buildings, alongside restaurants who provide home delivery through operations such as 'Uber' and 'Deliveroo'. These new ways of getting foods to consumers in themselves give rise to new food safety challenges related to distribution. Salad crops are being grown in-store and on restaurant roofs to compete with farmers' markets and to assure the customer of the freshest possible quality. New ways but perhaps based on older values where customers felt closer to the producer and had a higher level of trust as a result.

Continued need for expert knowledge. Many of these changes in supply chains, technologies, and purchasing demographics are positive and to be welcomed; however, we need to continually consider the need for food safety systems and procedures to protect public health. These remarkable and rapid changes will require even more attention from microbiologists, toxicologists, food safety specialists, and regulators to assure the safety of the growing and changing food supply chains.

Culture and people factors in the food space are acknowledged as being significant to food safety and our understanding of the role of food safety culture is likely to evolve into further cross functional engagement not only for food safety assurance but for global food security. This is not just in the behaviour science sense, agri-*culture* is the world's largest endeavour, and according to *National Geographic* (2014), one in eight people go to bed hungry every night whilst only 55% of global crops go to nourish people. A quarter of the world's population regularly eat insects, whilst 48 million Americans rely on food assistance. Developed and developing nations have problems with malnutrition, not just because of hunger but to overconsumption of cheap but high-calorie foodstuffs. This impacts both obesity levels and the availability of essential nutrients. National culture plays a major role in what we eat, how food is grown, how food is prepared, and how food is wasted. Household food waste in the United Kingdom in 2015 was estimated to be 7.3 million tonnes (Quested and Parry 2017). In the United States it was estimated that in 2010 consumers spent more than

US$900 million on tomatoes that went uneaten (McMillan 2014), and there are many more similar facts and figures that tell the same story. With food security an increasing concern, waste at this level is unacceptable This is a food culture where we must and can do better.

Food for thought as we close . . . .

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Appendix 1

Manufacturing HACCP Case Study

This case study is a HACCP Plan for the Rice and Pasta Meals section of Riviera Risottos Ltd. It is an example to illustrate application of food safety management and is provided without any liability in its application and use.

HACCP Plan

HACCP Team

R. Arborio – technical manager (HACCP team leader)
L. Grain – production manager
C. Basmati – engineering supervisor
M. Wild – production supervisor
T. Jasmine – technical consultant

Scope

The manufacture of ready-to-eat hot and cold prepared meals including products relating to special dietary needs requirements for the following sectors:

- Retailer private label products
- Riviera Risottos–branded products

Terms of Reference

- The HACCP plan will cover all relevant microbiological, physical, and chemical hazards to include allergens and compounds that cause intolerant reaction.
- This HACCP plan covers all processes from raw material intake to chilled storage of finished products before dispatch.

Food Safety for the 21st Century: Managing HACCP and Food Safety Throughout the Global Supply Chain, Second Edition. Carol A. Wallace, William H. Sperber, and Sara E. Mortimore.

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 on site but are strictly controlled. Ingredients are sourced through approved suppliers globally.

All cooked prepared meals are heated to pasteurisation temperatures, then blast chilled, stored chilled, and distributed chilled. The shelf life of the products is determined by prescribed storage and usage conditions and is verified during production trials and confirmed microbiologically.

Fit for purpose food-grade packaging is used including foil and crystalline polyethylene terephthalate (CPET) microwavable food trays. All packaging carries full ingredient breakdowns, nutritional information, allergen information, heating and storage instructions, and shelf-life information.

Intended Customer Use

- The products are intended for the general population which may include high-risk groups.
- Some products may contain allergens so are not suitable for the whole population.
- All allergens are stated on pack, and all packs carry the relevant warnings
- Products may be consumed cold or reheated as per instructions.
- All products should be held under refrigerated storage before use.

Envisaged Consumer Misuse

- Temperature abuse
- Consumed after the manufacturer's recommended shelf life has expired.

Prerequisites

This HACCP study operates in conjunction with the following site prerequisite programs under the Codex principles for food hygiene:

- **Establishment design and facilities –** The site is located on a 7-acre site on the edge of an industrial food park. The production facilities are housed in a purpose-built factory unit opened in October 2007.
- **Control of operation –** Control of food hazards, key aspects of hygiene control systems, incoming material requirements, packaging, water, management and supervision, documentation and records, and recall procedures.
- **Establishment maintenance and sanitation –** Maintenance and cleaning, cleaning programmes, pest control systems, waste management, and monitoring effectiveness.
- **Establishment personal hygiene –** Health status, illness and injuries, personal cleanliness, captive uniforms, personal behaviour, and visitors.

- **Transportation:** General, requirements, use, and maintenance.
- **Product information and consumer awareness –** Lot identification, product information, labelling, and consumer education.
- **Training, awareness and responsibilities –** Training programmes, instruction and supervision, and refresher training.

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 because 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 2009b).

HACCP Review

The HACCP plan will be reviewed annually and updates made to the plan as required.

A HACCP study will be carried out before a new product is launched, or a plant trial is done for proposed new products, if there is a new process involved or if a new raw material is to be introduced to the factory. All new products go through separate product safety assessment process and authorisation sign-off.

References

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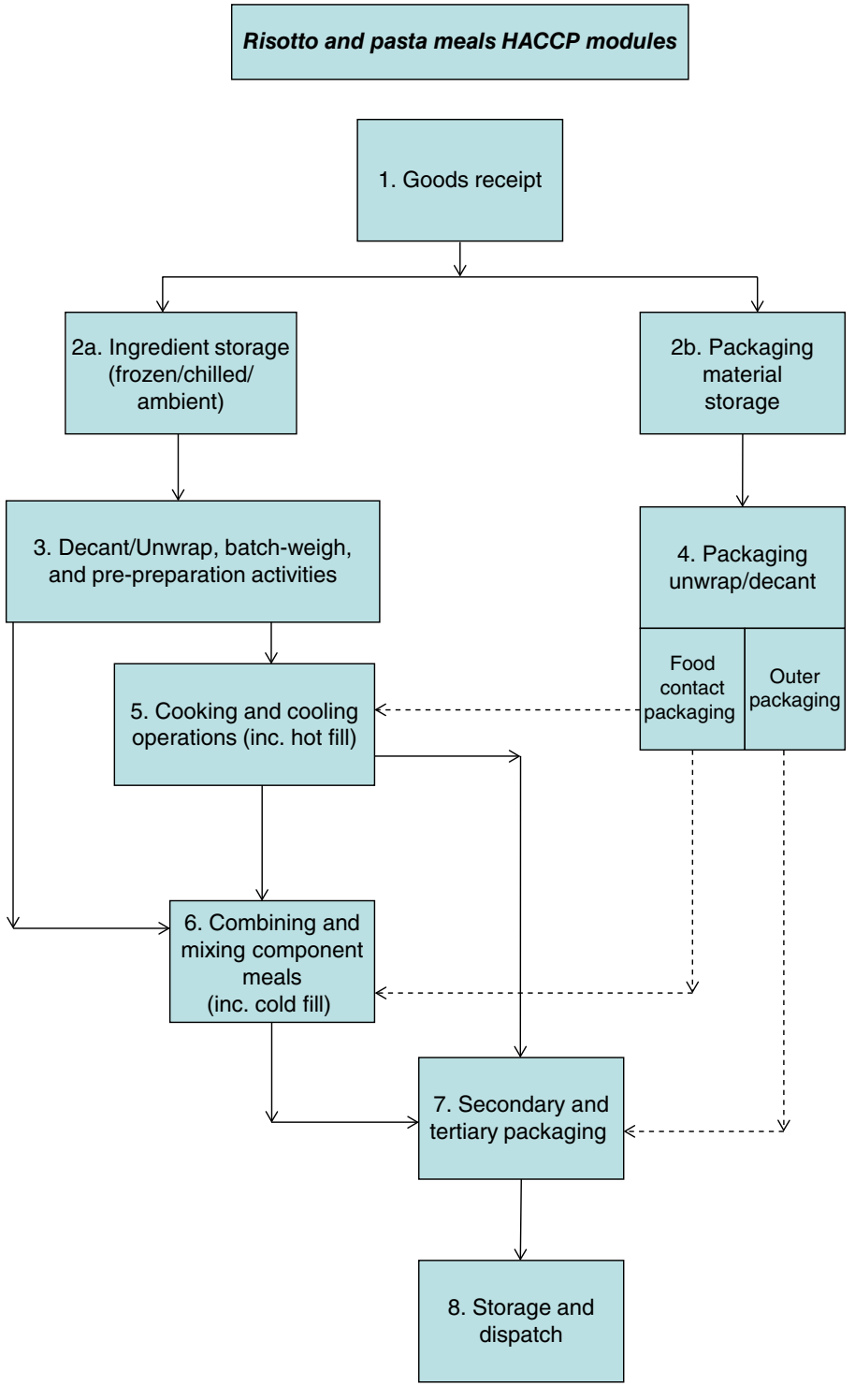
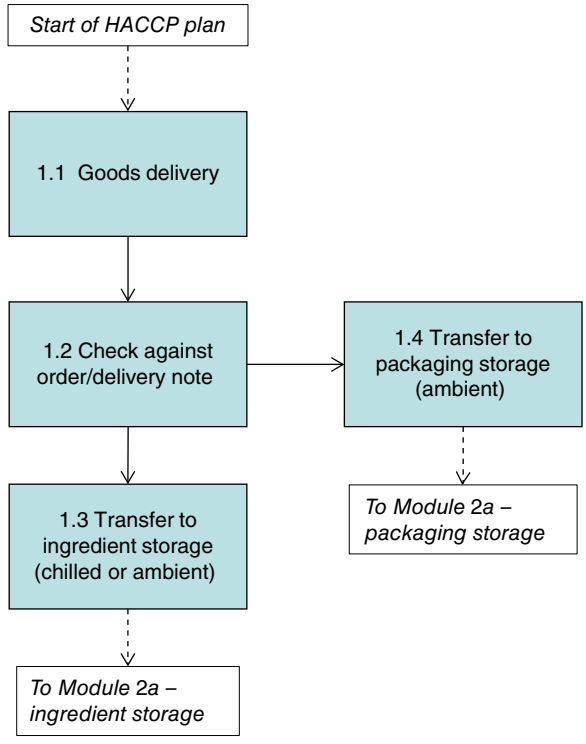
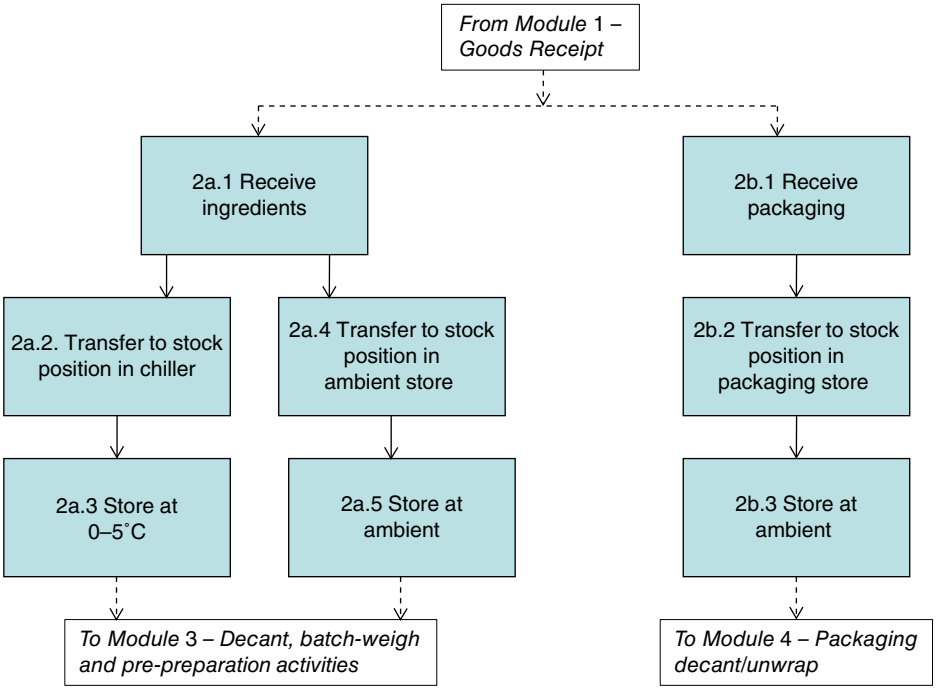

Risotto and pasta meals HACCP modules
1. Goods receipt
2a. Ingredient storage (frozen/chilled/ ambient)
2b. Packaging material storage
3. Decant/Unwrap, batch-weigh, and pre-preparation activities
4. Packaging unwrap/decant
Food contact packaging
Outer packaging
5. Cooking and cooling operations (inc. hot fill)
6. Combining and mixing component meals (inc. cold fill)
7. Secondary and tertiary packaging
8. Storage and dispatch

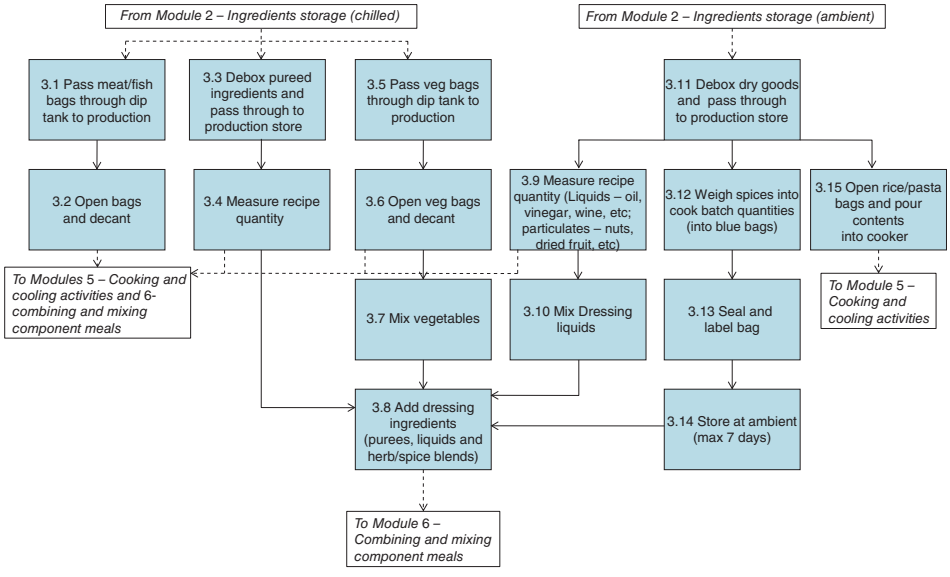
Module 1 Goods Receipt



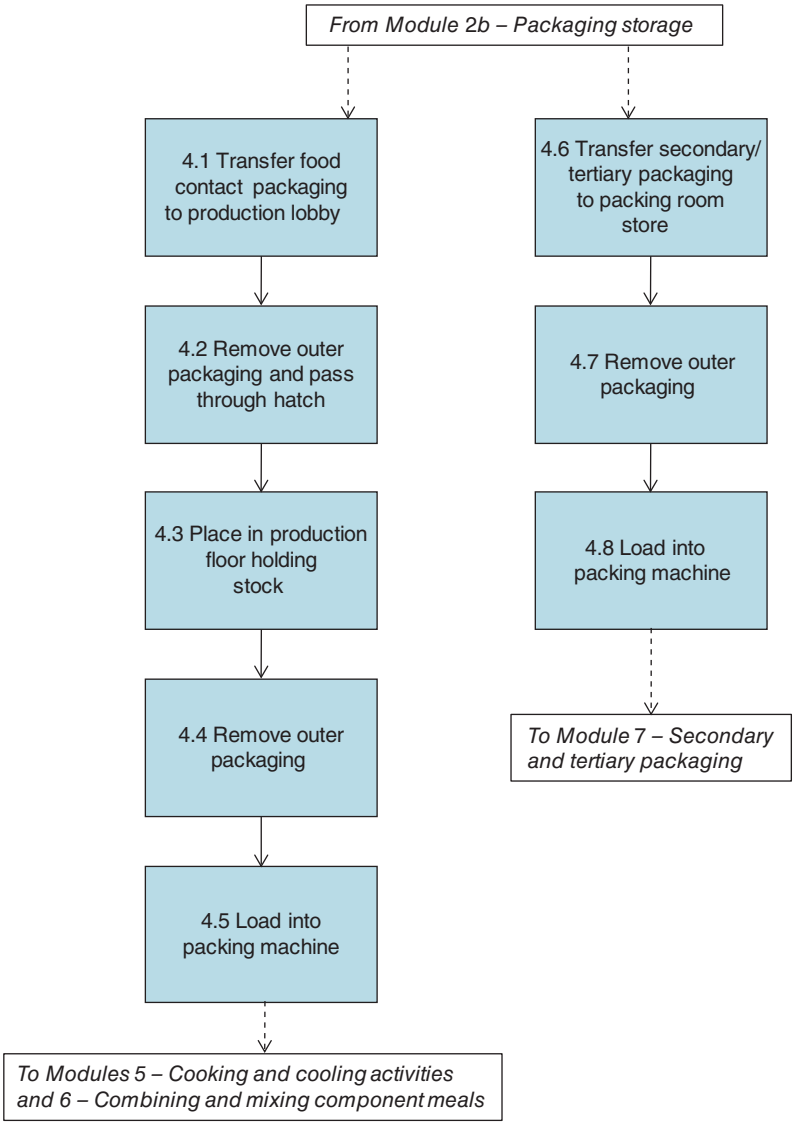
Module 2 Materials Storage



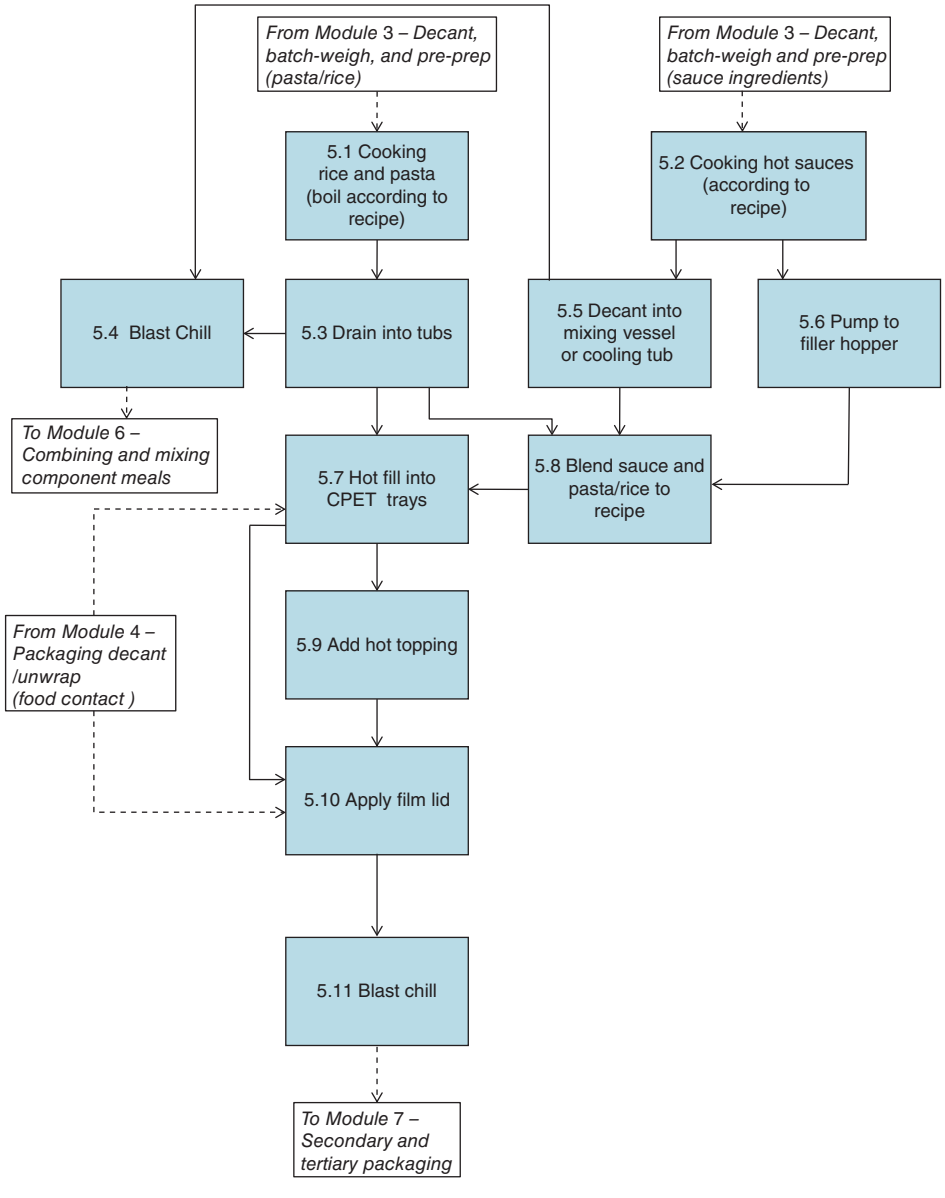
Module 3 Decant, Batch-weigh and Pre-Preparation Activities



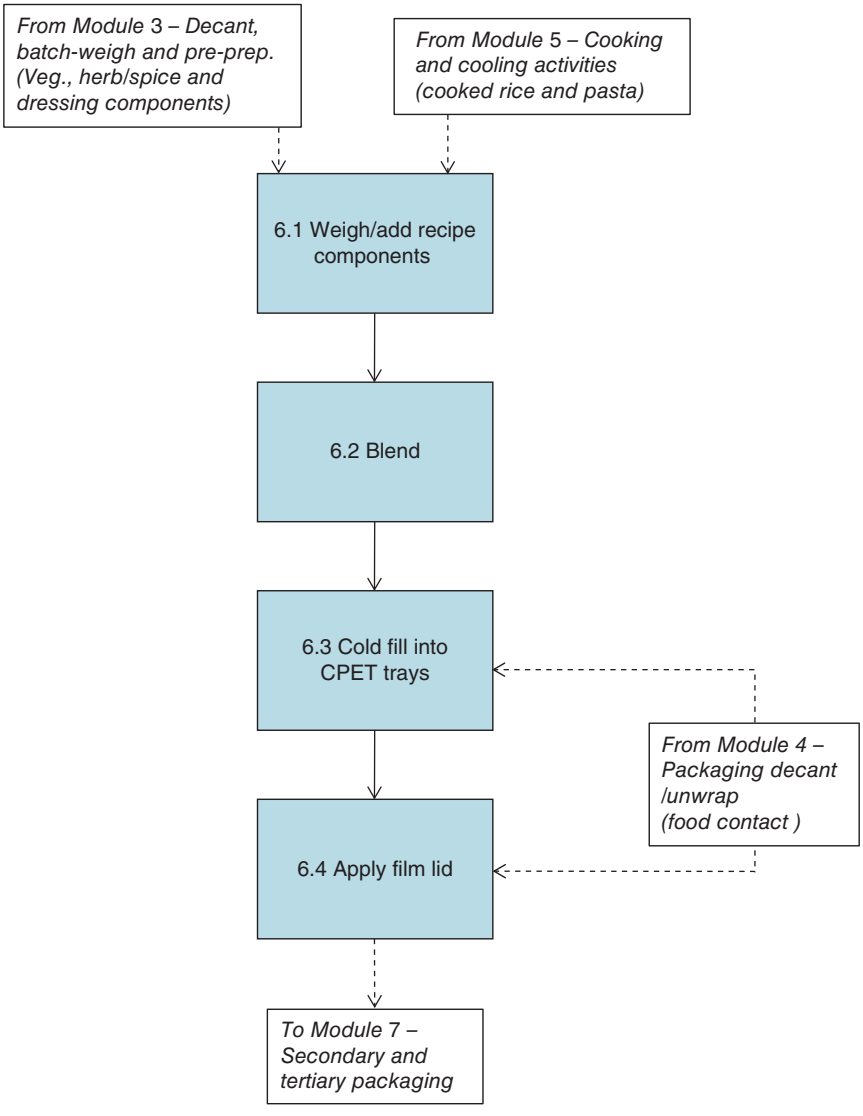
Module 4 Packaging Decant/Unwrap



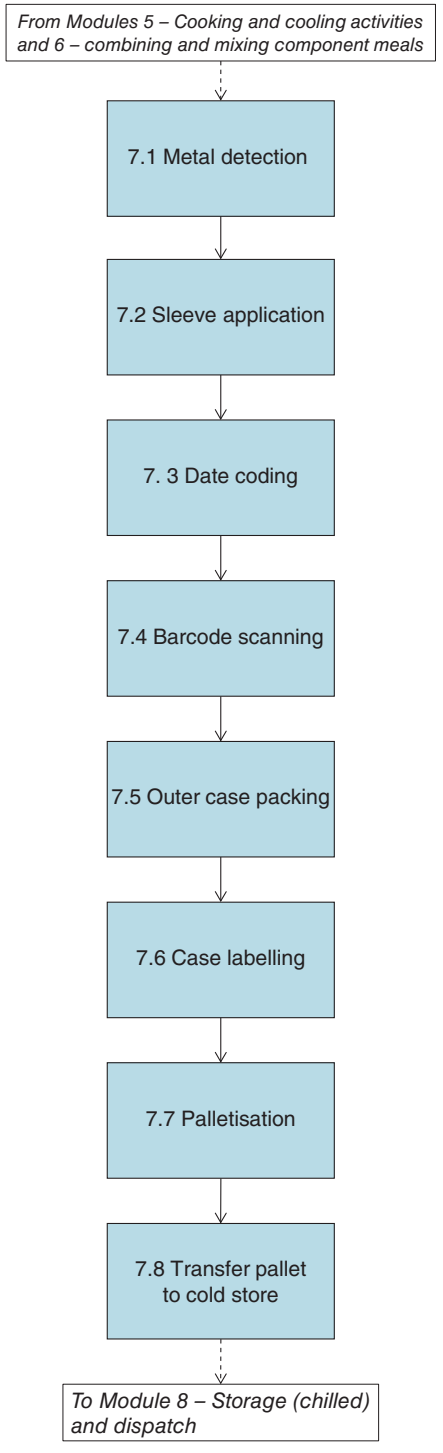
Module 5 Cooking and Cooling Activities (inc. Hot Fill)



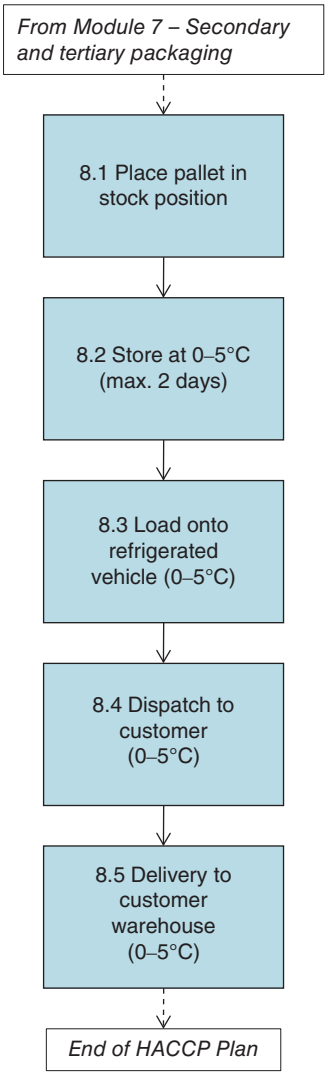
Module 6 Combining and Mixing Component Meals (Salads)



Module 7 Secondary and Tertiary Packaging



Module 8 Storage and Dispatch



Process Step	Hazard	Hazard Analysis			Control measure	Justification
		Likelihood	Severity	Significant hazard?		
Module 1: Goods Receipt						
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 already performed.
	Growth of microorganisms due to temperature abuse of refrigerated goods in transit	Low	Low	No	Rejection of material outside of specified limits – target <5° C; <7° C maximum.	Some history of minor out of specification temperatures recorded at receipt on rare occasions but risk of growth deemed to be low since no more than 2° C above target limit.
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 strict prerequisite programmes and labelling, which rely on knowledge of all allergens in materials supplied as per specifications and allergenic ingredients list. Any substitution of ingredients could endanger existing control measures; however supplier quality assurance relationships are closely managed under prerequisites.
1.3 Transfer to ingredient storage (chilled or ambient)	Possible growth of pathogenic microorganisms	Low	Low	No	Rapid transfer. Managed by prerequisite programmes.	
1.4 Transfer to packaging storage (ambient)	No hazard identified	n/a	n/a	n/a	n/a	

Process Step	Hazard	Hazard Analysis			Control measure	Justification
		Likelihood	Severity	Significant hazard?		
Module 2: Materials Storage						
2.a.1 Receive ingredients	No hazard identified	n/a	n/a	n/a	n/a	
2.a.2 Transfer to stock position in chiller	No hazard identified	n/a	n/a	n/a	n/a	
2.a.3 Store at 0–5° C	No hazard identified	n/a	n/a	n/a	n/a	Temperature control and stock rotation is part of prerequisite programmes.
2.a.4 Transfer to stock position in ambient store	No hazard identified	n/a	n/a	n/a	n/a	
2.a.5 Store at ambient	No hazard identified	n/a	n/a	n/a	n/a	
2.b.1 Receive packaging	No hazard identified	n/a	n/a	n/a	n/a	
2.b.2 Transfer to stock position in packaging store	No hazard identified	n/a	n/a	n/a	n/a	
2.b.3 Store at ambient	No hazard identified	n/a	n/a	n/a	n/a	
Module 3: Decant (unwrap), Batch-weigh, and Prepreparation Activities						
3.1 Pass meat/fish bags through dip tank to production	No hazard identified	n/a	n/a	n/a	n/a	
3.2 Open bags and decant/unwrap	No hazard identified	n/a	n/a	n/a	n/a	Allergens managed by strict prerequisite programmes, including dedicated containers and segregated storage area, plus labelling.
3.3 Debox pureed ingredients and pass thought to production store	Contamination with packaging	Low	Low	No	Prerequisite programmes and work instructions.	Unlikely to harm consumer.

3.4 Measure recipe quantity	No hazard identified	n/a	n/a	n/a	n/a	Allergens managed by strict prerequisite programmes, including dedicated containers and segregated storage area, plus labelling.
3.5 Pass veg bags through dip tank to production	No hazard identified	n/a	n/a	n/a	n/a	
3.6 Open veg bags and decant/unwrap	No hazard identified	n/a	n/a	n/a	n/a	Allergens managed by strict prerequisite programmes, including dedicated containers and segregated storage area, plus labelling.
3.7 Mix vegetables	No hazard identified	n/a	n/a	n/a	n/a	
3.8 Add dressing ingredients (purees, liquids and herb/spice blends)	No hazard identified	n/a	n/a	n/a	n/a	Allergens managed by strict prerequisite programmes, including dedicated containers and segregated storage area, plus labelling.
3.9 Measure recipe quantity (Liquids – oil, vinegar, wine, etc.; Particulates – nuts, dried fruit, etc.)	No hazard identified	n/a	n/a	n/a	n/a	Allergens managed by strict prerequisite programmes, including dedicated containers and segregated storage area, plus labelling.
3.10 Mix dressing liquids	No hazard identified	n/a	n/a	n/a	n/a	
3.11 Debox dry goods and pass through to production store	Contamination with packaging	Low	Low	No	Prerequisite programmes and work instructions.	Unlikely to harm consumer.
3.12 Weigh spices into cook batch quantities	No hazard identified	n/a	n/a	n/a	n/a	
3.13 Seal and label bags	No hazard identified	n/a	n/a	n/a	n/a	
3.14 Store at ambient (max 7 days)	No hazard identified	n/a	n/a	n/a	n/a	
3.15 Open rice/pasta bags and pour contents into cooker	No hazard identified	n/a	n/a	n/a	n/a	Allergens managed by strict prerequisite programmes, including dedicated containers and segregated storage area, plus labelling.

Process Step	Hazard	Hazard Analysis			Control measure	Justification
		Likelihood	Severity	Significant hazard?		
Module 4: Packaging Decant/Unwrap						
4.1 Transfer food contact packaging to production lobby	No hazard identified	n/a	n/a	n/a	n/a	
4.2 Remove outer packaging and transfer through hatch	No hazard identified	n/a	n/a	n/a	n/a	
4.3 Place in production floor holding stock	No hazard identified	n/a	n/a	n/a	n/a	
4.4 Remove outer packaging	No hazard identified	n/a	n/a	n/a	n/a	
4.5 Load into packing machine	No hazard identified	n/a	n/a	n/a	n/a	
4.6 Transfer secondary/tertiary packaging to packing room store	No hazard identified	n/a	n/a	n/a	n/a	
4.7 Remove outer packaging	No hazard identified	n/a	n/a	n/a	n/a	
4.8 Load into packing machine	No hazard identified	n/a	n/a	n/a	n/a	
Module 5: Cooking and Cooling Activities (including Hot Fill)						
5.1 Cook 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.	

5.2 Cook hot sauces (according to recipe)	Survival of pathogenic microorganisms due to inadequate heat processing	High	High	**Yes**	Approved cooking methods - times and temperatures.	
5.3 Drain into tubs	No hazard identified	n/a	n/a	n/a	n/a	
5.4 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.
5.5 Decant into mixing vessel	No hazard identified	n/a	n/a	n/a	n/a	
5.6 Pump to filler hopper	No hazard identified	n/a	n/a	n/a	n/a	
5.7 Hot fill into CPET 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 (e.g. blending and hot-fill operation is unavailable), work procedure is to blast chill.
5.8 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 (e.g. blending and hot-fill operation is unavailable), work procedure is to blast chill.
5.9 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 (e.g. blending and hot-fill operation is unavailable), work procedure is to blast chill.

Process Step	Hazard	Hazard Analysis			Control measure	Justification
		Likelihood	Severity	Significant hazard?		
5.10 Apply film lid	No hazard identified	n/a	n/a	n/a	n/a	
5.11 Blast chill	Germination and outgrowth of spore forming pathogens	Low	High	No	Rapid chilling of individual units.	Likelihood is low in this case due to the size of the individual units – time to cool is <20 minutes compared with the larger vessels being chilled at step 5.4.
Module 6: Combining and Mixing Component Meals (Salads)						
6.1 Weigh/add recipe components	Cross-contamination with allergens into wrong products	Low	High	No	Prerequisite programmes and labelling.	Allergens managed by strict prerequisite programmes; at this stage the programmes include production scheduling for products containing specific allergens and deep cleaning after these products.
	Cross-contamination with pathogenic microorganisms – vegetative or spore formers – from environment or utensils	Low	High	No	Prerequisite programmes.	High standards of hygiene for production environment and utensils.
	Germination and outgrowth of spore forming pathogens	Low	High	No	Immediate through process.	Process area for module 6 operations is held at <10° C. As all components are chilled then limited opportunity for temperature rise into danger zone.
6.2 Blend	Cross-contamination with allergens into wrong products	Low	High	No	Prerequisite programmes and labelling.	Allergens managed by strict prerequisite programmes; at this stage the programmes include production scheduling for products containing specific allergens and deep cleaning after these products.

	Cross-contamination with pathogenic microorganisms – vegetative or spore formers – from environment or utensils	Low	High	No	Prerequisite programmes	High standards of hygiene for production environment and utensils.
	Germination and outgrowth of spore forming pathogens	Low	High	No	Immediate through process.	Process area for module 6 operations is held at <10° C. As all components are chilled then limited opportunity for temperature rise into danger zone.
6.3 Cold fill into CPET trays	Germination and outgrowth of spore forming pathogens	Low	High	No	Immediate through process.	Process area for module 6 operations is held at <10° C. As all components are chilled then limited opportunity for temperature rise into danger zone.
6.4 Apply film lid	No hazard identified	n/a	n/a	n/a	n/a	
Module 7: Secondary and Tertiary Packaging						
7.1 Metal detection	Presence of metal (from previous steps or ingredients) not identified leading to hazardous metal inclusion in product	High	High	**Yes**	All product passes through a functioning metal detector.	No subsequent step to remove this hazard.
7.2 Sleeve application	Presence of unlabelled allergens if wrong sleeve applied	High	High	**Yes**	Bar-code scanning of all products to ensure correct sleeve on product.	Historical evidence of product going into wrong sleeve. Although additional prerequisite programme controls in place for receipt of printed sleeves and machine change overs, the HACCP team felt this is still an area of concern. All products also include 'may contain' statements.
7.3 Date coding	Incorrect shelf life could lead to microbiological growth (*Listeria monocytogenes*) during shelf life	Low	High	No	Documented procedure for labelling of products as part of prerequisite programmes and legal control.	Unlikely that incorrect shelf life could be applied.

Process Step	Hazard	Hazard Analysis			Control measure	Justification
		Likelihood	Severity	Significant hazard?		
7.4 Scanning all products – barcode scanner	Presence of unlabelled allergens if scanner fails to pick up wrong sleeve applied	High	High	**Yes**	All product passes through functioning scanner device.	Scanner will pick up wrong cartons that may be received in mid-stack from printer or that may have become stuck in machine at change over.
7.4 Outer case packing	No hazard identified	n/a	n/a	n/a	n/a	
7.5 Case labelling	No hazard identified	n/a	n/a	n/a	n/a	
7.6 Palletisation	No hazard identified	n/a	n/a	n/a	n/a	
7.7 Transfer pallet to cold store	No hazard identified	n/a	n/a	n/a	n/a	
Module 8 Storage and Despatch						
8.1 Place pallet in stock position	No hazard identified	n/a	n/a	n/a	n/a	Prerequisite programmes manage temperature of all chillers, cold stores, and vehicle refrigeration.
8.2 Store at 0–5° C (max 2 days)	No hazard identified	n/a	n/a	n/a	n/a	,,
8.3 Load onto refrigerated vehicle (0–5° C)	No hazard identified	n/a	n/a	n/a	n/a	,,
8.4 Despatch to customer (0–5° C)	No hazard identified	n/a	n/a	n/a	n/a	,,
8.5 Delivery to customer warehouse 0–5° C	No hazard identified	n/a	n/a	n/a	n/a	,,

HACCP Control Chart

Process step	Hazard	Control measure	Critical limits	Monitoring	Monitoring responsibility	Corrective action	Corrective action responsibility	Record
5.1 Cooking rice and pasta	Survival of pathogenic microorganisms due to inadequate heat processing	All cooked components cooked to min time and temperature	All product achieves core temperature 72° C minimum	Temperature checks with calibrated probes	Cooker operator	Continue to heat until required temperature (72° C minimum) is reached	Production manager	Cooking records
5.2 Cooking hot sauces	Survival of pathogenic microorganisms due to inadequate heat processing	All cooked components cooked to min time and temperature.	All product achieves core temperature 72° C minimum	Temperature checks with calibrated probes	Cooker operator	Continue to heat until required temperature (72° C minimum) is reached	Production manager	Cooking records
5.4 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 minutes)	All product to be cooled below 5° C within 120 minutes	Centre temperature checks with calibrated probes at entry and exit from chiller Residence time checked and recorded	Cooker operator	Discard batch. Investigate and repair any fault with blast chiller	Production/ technical/ engineering managers	Production records

Process step	Hazard	Control measure	Critical limits	Monitoring	Monitoring responsibility	Corrective action	Corrective action responsibility	Record
7.1 Metal detection	Presence of metal (from previous steps or ingredients) not identified leading to hazardous metal inclusion in product	All product passes through a functioning metal detector	Absence of all metal above 7 mm – ferrous, non-ferrous, and stainless; correctly functioning metal detector and rejection mechanism in place and working continuously	Check detection and rejection mechanism with test strips – 2.5 mm all types – placed in centre of product	Line operator	Recheck product since previous satisfactory check	Line manager	Production records
7.4 Barcode scanning	Presence of unlabelled allergens if scanner fails to pick up wrong sleeve applied	All product passes through a functioning scanner device	Scanner functioning at all times	Check with packaging samples – start-up and half hourly	Line operator	Recheck product since previous satisfactory check	Line manager	Production records

Appendix 2

Global Food Safety Resources*

Intergovernmental Organisations

The United Nations – www.un.org
The World Health Organisation (WHO) of the United Nations – www.who.int
The Food and Agriculture Organisation (FAO) of the United Nations – www.fao.org
The Codex Alimentarius Commission (CAC) – www.codexalimentarius.net
The Codex Committee on Food Hygiene (CCFH) – http://www.fao.org/fao-who-codexalimentarius/committees/committee-detail/en/?committee=CCFH
The World Organisation for Animal Health (OIE) – www.oie.int
The World Trade Organisation – www.wto.org
The European Food Safety Authority (EFSA) – www.efsa.europa.eu
The Pan-American Health Organisation (PAHO) – http://www.paho.org

Governmental Organisations

US Department of Health and Human Services (HHS) – http://www.hhs.gov
US Centers for Disease Control and Prevention (CDC) – http://www.cdc.gov
FoodSafety.gov (a gateway to food safety information provided by US government agencies) – https://www.foodsafety.gov/
US Food and Drug Administration (FDA) – http://www.fda.gov
US FDA Center for Food Safety and Applied Nutrition (CFSAN) – https://www.fda.gov/aboutfda/centersoffices/officeoffoods/cfsan/
US Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) – http://www.fsis.usda.gov
USDA Agricultural Research Service Pathogen Modelling Program – https://www.ars.usda.gov/northeast-area/wyndmoor-pa/eastern-regional-research-center/residue-chemistry-and-predictive-microbiology-research/docs/pathogen-modeling-program/pathogen-modeling-program-models/
US National Institute of Food and Agriculture (formerly CSREES) – https://nifa.usda.gov/

* All websites were viewed in August 2017.

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US National Advisory Committee on Microbiological Criteria for Food (NACMCF) – http://www.fsis.usda.gov/About_FSIS/NACMCF/index.asp
US Department of Homeland Security (DHS) – http://www.dhs.gov
Food Standards of Australia and New Zealand – http://www.foodstandards.gov.au
New Zealand Food Safety Authority – http://www.nzfsa.govt.nz
UK Food Standards Agency – http://www.food.gov.uk
UK Department for Environment, Food and Rural Affairs (DEFRA) – www.defra.gov.uk
UK Department of Health – www.dh.gov.uk

Nongovernmental Organisations

Food Allergy Research and Education (FARE) – http://www.foodallergy.org
Anaphylaxis Campaign – http://www.anaphylaxis.org.uk
Global Harmonisation Initiative – www.globalharmonization.net
Center for Science in the Public Interest – http://www.cspinet.org
Wildlife Conservation Society (WCS) – http://www.wcs.org
Global Avian Influenza Network for Surveillance – Final Report – http://mpaenvironment.ei.columbia.edu/files/2014/06/avianFlufinalReport.pdf
World Population Balance – http://www.worldpopulationbalance.org
Partnership for Food Safety Education – http://www.fightbac.org/
Stop Foodborne Illness – http://www.stopfoodborneillness.org/
Global Food Safety Initiative (GFSI) – www.mygfsi.com

Public–Private Partnerships

Safe Supply of Affordable Food Everywhere, Inc. (SSAFE) – http://www.ssafe-food.org
Global Initiative for Food Systems Leadership (GIFSL) – http://www.foodsystemsleadership.org

Trade Associations

Academy of Nutrition and Dietetics (Eat Right; formerly Home Food Safety) – http://www.eatright.org/resources/homefoodsafety
UK Food and Drink Federation – http://www.fdf.org.uk/
Food Safety Magazine (free subscription) – www.foodsafetymagazine.com
Food Safety News – http://www.foodsafetynews.com/
American Meat Institute Foundation (AMIF) Washington, DC – http://www.amif.org
Grocery Manufacturers Association. Washington, DC – http://www.gmaonline.org
International Life Sciences Institute (ILSI) – www.ilsi.org
North American Millers' Association (NAMA) – www.namamillers.org
International Food Information Council (IFIC) – http://www.foodinsight.org

The Consumer Goods Forum (formerly CIES) Annual Global Food Safety Conference – http://www.tcgffoodsafety.com
British Retail Consortium – www.brc.org.uk
The Global Food Safety Partnership – https://www.gfsp.org/

Professional Associations

Commonwealth Scientific and Industrial Research Organisation (CSIRO), division of Agriculture and Food – https://www.csiro.au/en/Research/AF/Areas/Food
International Commission on Microbiological Criteria for Foods (ICMSF) – www.icmsf.org
European Federation of Food Science and Technology – http://www.effost.org
The Society for Food Hygiene and Technology – http://www.sofht.co.uk
European Hygienic Engineering and Design Group – http://www.ehedg.org
International Union of Food Science and Technology (IUFOST) – http://www.iufost.org
Institute of Food Science and Technology (IFST) – www.ifst.org
Institute of Food Technologists (IFT) – http://www.ift.org
International Association for Food Protection (IAFP) – http://www.foodprotection.org
Royal Society for Public Health – www.rsph.org.uk

Academic Institutions

Food Research Institute, University of Wisconsin – http://fri.wisc.edu
Food Allergy Research and Resource Program, University of Nebraska – http://www.farrp.org
Center for Food Safety, University of Georgia – http://www.ugacfs.org
National Center for Food Science and Technology, Illinois Institute of Technology – http://www.ncfst.iit.edu
National Center for Food Protection and Defense, University of Minnesota – http://www.ncfpd.umn.edu
Center for Animal Health and Food Safety, University of Minnesota – http://www.cahfs.umn.edu
Netherlands Organisation for Applied Science and Research (TNO) – https://www.tno.nl/en/focus-areas/healthy-living/food-nutrition/
Food Safety Consortium, University of Arkansas – https://www.uark.edu/depts/fsc/
International HACCP Alliance, Texas A & M University – http://www.haccpalliance.org
Center for Infectious Disease Research and Policy, University of Minnesota – http://www.cidrap.umn.edu
Center for Research on Ingredient Safety, University Michigan – http://cit.msu.edu/cris/index.html
International Institute of Nutritional Sciences and Applied Food Safety Studies, University of Central Lancashire, UK. – www.uclan.ac.uk/iinsafss
Salus Food Safety Culture Science Group – http://salusfoodsafetyculturesciencegroup.com/

Consulting Organisations and Laboratories

Leatherhead Food Research Association – www.leatherheadfood.com
Campden BRI – www.campdenbri.co.uk
Mérieux NutriSciences – https://www.merieuxnutrisciences.com
Deibel Laboratories – www.deibellabs.com

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Note: Italicized *b*, *f* and *t* refer to boxes, figures and tables, respectively.

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