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Moving on from HACCP

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12.1 Introduction

Throughout the world, food manufacturing, distribution, retailing and food service is becoming a highly complex business. Raw materials are sourced on a global scale and an increasing number of processing technologies are used to provide a wide variety of products to the consumer. In addition, consumers' expectations are changing, with a desire for convenient foods with less processed, fresher and more natural characteristics.

Against this background of change, there has been a permanent improvement in the performance of the food industry at large, associated with unprecedented efforts by private and public organisations to create an environment that fosters better prevention and control of foodborne hazards. In this context, the Hazard Analysis Critical Control Point (HACCP) system is now widely accepted as the most effective means of ensuring that a high standard of food safety is maintained.

However, common experience shows that food systems are still vulnerable to disturbance when challenged by internal or external factors such as equipment breakdowns or new hazards. Public and private organisations have been thrown into disarray when faced with recent food scares, such as *Escherichia coli* O157:H7, bovine spongiform encephalopathy (BSE) or the crisis related to the presence of dioxin in animal feeds that affected several countries in the European Union in 1999. The debates and controversies raised by endocrine-disrupting chemicals or genetically modified organisms (GMOs) have also shown the vulnerability to disturbance or failure that has many consequences. Failure of food systems may result in a serious threat to public health, but also has economic or legal consequences and the potential for financial loss to businesses and countries. The major outcome of these failures is the scepticism of the public at large about the security of the systems responsible for producing, manufacturing and safeguarding food safety. This is regardless of the improved level of safety actually achieved.

Several factors may contribute to this perceived vulnerability.[1] All are derived from the central position that food plays in everyday life. The vulnerability of the food supply affects the welfare of citizens, consumer choice and food price, the income of farmers, manufacturers and others and the strength and international competitiveness of national agro-food economies. Any disturbance in consumer confidence feeds back to all links in the chain.

Food may contain many different hazards. Food-borne microbial pathogens are highly changeable and adaptable; foodstuffs can also carry a number of chemical/toxicological risks, which lead to new areas of concern, such as endocrine perturbation or allergenicity.

Risks or perceived health risks linked to food are becoming increasingly unacceptable to society. As, in reality, food becomes safer, the public at large becomes less tolerant of the remaining and occasional risks. This trend is enhanced because the general public feels more and more alien to the preventive or control activities of experts, where decisions appear to be made in isolation by technological (e.g. the food industry) or administrative (e.g. the public agencies having jurisdiction) organisations. This results in a new perception of food safety risks as an 'outrage'. An outrage is seen where the level of risk is controlled by others who may be coerced by industry and linked to other untrustworthy sources. The public wants outrage risks to be taken more seriously.[2] Despite substantial progress in food science and food control, the current technological or administrative approaches pay little attention to the perception of outrage, thus magnifying any residual risk.

Other forms of vulnerability are associated with the production, manufacturing or distribution of food. These sourcing systems are characterised by the following features.

- Their interdependence (e.g. high integration, specialisation, global susceptibility to one single adverse event, series of connected responsibilities)
- Their fragility (e.g. existence of several weak points in commercial and business processes)
- Structural obsolescence
- The possibility of drift in specifications and the application of control and quality assurance schemes
- The existence of weak segments whose failure may adversely impact on the activity of all other segments
- Their 'black-box' nature (e.g. lack of a global and transparent presentation of food safety assurance and management; this is often a feature of the systems used or may happen by accident)
- Managerial shortcomings (e.g. uneven allocation of resources, complexity of technical regulations, poor internal or external communication, lack of

consistent, comprehensive and flexible food safety programmes and structures).

Over the past decades, industry and regulators have focused mainly on scientific and technological advances aimed at preventing or controlling hazards in food. Today, the analysis of major food safety problems teaches us that many of these problems have their origins in organisational deficiencies. Increasingly complex food systems are vulnerable because a global organisation for approaching food safety issues is not growing at the same rate as the food business is changing or consumer concerns are growing.

The principal lesson to be drawn from this overview is that the challenges of providing food safety have changed. The main challenges for the total food chain are to maintain the highest standards of safety, to meet new challenges and reduce the vulnerability of food systems in order to restore and develop public trust. Meeting this challenge basically requires more effective use of HACCP, as discussed by the previous chapters of this book. Running alongside is the need to develop a broader approach to food safety management extending beyond HACCP. This chapter outlines a framework for this approach and considers its rationale, its components and some of the tools that may be used. Although the primary focus will be on microbiological issues, the principles are equally applicable to control of chemical or physical contaminants.

12.2 Future trends

It is widely recognised that HACCP has the potential to provide enhanced assurance of product safety by focusing resources on the control of raw materials and other key steps in the supply chain. However, as a rationale or for prediction of future trends, it is important to understand what HACCP can actually do for food safety improvement and to recognise that the approach has some limitations that need to be overcome.

12.2.1 Strength and limitations of HACCP

HACCP originated in the food industry. It is a system owned by food producers, presently widely accepted and utilised across their industry. Its principles can be applied at all stages of the food chain, although some difficulties may require specific adjustments to the system (e.g. in the primary production, at the slaughterhouse, or even in the home). It has also become a cornerstone of many national regulations and international recommendations related to food control. It can never be overemphasised that HACCP was primarily designed as a tool to establish or improve product/process control activities and provide assurance that operators focused control of their processes where product/process sensitivity and/or food safety requirements were greatest. HACCP was derived from the armoury of reliability tools, in particular from HAZOP (Hazard

Analysis and Operability) type studies and FMEA (Failure Mode and Effect Assay). Both are derived from engineering quality management systems that look at a product, its components and manufacturing and ask what can go wrong within the total system. In this respect, the HACCP study is designed to identify hazards and find potentially hazardous conditions that may exist in a product or process (contamination, development or persistence of hazards) in order to eliminate or control them and their causes. This leads to all the process stages being controlled in the most effective way.[3]

There is no need here to describe HACCP in detail, as this information is available in the preceding chapters of this book. Suffice it to say that HACCP requires users to foresee where problems may occur and to take steps to reasonably ensure that they will not. Under the HACCP concept, potential problems are identified and steps are taken to analyse likely causes and to develop and implement preventative measures at the stages involved. Appropriate evidence has to be produced. According to its principles and rules, HACCP focuses on hazard management, through identifying hazards and hazardous conditions during the HACCP study, leading to their assessment and control by its implementation. It can minimise the chances of sporadic problems, while establishing more reliable control. It is a systematic and very effective approach for reducing the probability of unsatisfactory supply chain performance, thus making the process and products safer.

However, whilst industry and government bodies have published their expectations of what HACCP will achieve and there is genuine commitment to its use as a key food safety tool, there are a number of inherent limitations in the approach. In particular, although HACCP is a systematic and practical approach to hazard control in food manufacturing, it has not been designed for, nor is able to guide, managerial decisions about:

- the nature of hazards whose elimination, or reduction to an acceptable level, is considered essential to the production of a safe food and to maintenance of consumer confidence, i.e. the identification of hazards and assessment of their public health significance,
- the definition of an acceptable level of hazard(s) in a food after processing, relative to the level desirable for consumer health protection (or a level of risk that a society considers as acceptable or tolerable). There is no means for the HACCP system to check whether its outcome or objectives (design or adjustment of products, processes and control measures) are appropriate to the needs of society in public health terms. It does not consider these versus other considerations, such as technical feasibility or the cost of achieving control. The hazard analysis stage is very weak.

Clearly, such managerial decisions are 'outside' the HACCP process and the necessary linkage of HACCP to public health requirements has been generally overlooked.[4] To be meaningful and effective, HACCP needs to be driven by an understanding of the relationship between the reduction of risk in a food process, and the level of food safety required by consumers. In other words, HACCP needs to be directed by consumer requirements for food safety. This is the only means for appropriate identification of the hazards that concern consumers, for the allocation of resources and determination of extent and stringency of the HACCP plan and its control measures. Determination of the outcome in this way would give consistency in evaluating what is acceptable and what is not, allowing for the validation of the components of the HACCP plan, its Critical Control Points (CCPs), their critical limits, controls and monitoring procedures.

Determined in such a way, the outcome may also provide a reference for comparing the objectives of different HACCP plans. To that point, it has to be borne in mind that HACCP originated in the NASA space programme and was originally applied by various parts of the food industry (e.g. canning) and for the control of specific types of hazard (e.g. foreign bodies) to give zero defects. For these applications the objective was chosen prior to development of the plan. For microbial pathogens, a zero defect or zero tolerance level may or may not be appropriate. To design food safety into products and processes and to provide appropriate assurance along the supply chain that food safety requirements are effectively met, implemented HACCP systems should evolve so that they operate with reference to the broader framework of food safety and public health.

12.2.2 The way forward

The future challenge is to improve the management of food safety by providing a clear link between control and public health benefits. If HACCP remains the chosen system then the challenge is to improve its efficacy whilst still keeping its practical nature.[5] There might be several approaches to achieving this, but we firmly believe that there are three crucial components.

The first is government-led and corresponds to the development of a risk-based food safety strategy, with a public health perspective. This approach would include

- determination of the requirements for food safety,
- development and use of specific procedures for risk analysis, extending from scientific understanding and characterisation of the actual risk to the appraisal of managerial options,
- monitoring of the implementation of any measures,
- assessment of their effectiveness,
- review of hazards and measures.

Mechanisms would need to be provided to ensure the involvement and participation of interested and affected parties (the stakeholders) at all stages. The practical implementation of this approach would rely on two basic principles, the limitation of exposure and optimisation by review.

The second is the development of effective food safety management programmes and systems by food business operators. This radical approach should help businesses take account of their role in the food chain and ensure that product safety is given the highest priority. Food safety programmes should help to determine the food safety requirements of each business, identify where improvements are necessary and how any organisational and technical issues can be tackled and the improvements reviewed in the light of changing food safety issues. The systems should incorporate HACCP as a key tool for implementation.

The third is to realise the full potential of HACCP for ensuring that food safety requirements will be met. This involves using (quantitative) risk assessment techniques at the Hazard Analysis stage of the HACCP study. The aim of this is to link the probability of failure (in the process) with the severity of the consequences for public health and to use these findings to apportion safety management resources throughout the different stages and elements of the process.

These three components are considered in turn in the following sections.

12.3 Development of a risk-based food safety strategy

Food safety results from the successful interaction of government agencies, business, private organisations, consumers, and other supporting players. Government agencies are in the best position to influence how the other partners work together. Until very recently, these agencies had a mainly reactive approach to food safety problems and focused their interventions on specific contaminants posing immediate hazards and on preventing poor hygiene in the food chain. As a consequence, food safety problems were dealt with mostly in a pragmatic way. Now because of the complexity of the food safety problem, there needs to be a move from this hazard-based approach towards a more comprehensive, risk-based approach taking a public health perspective. This requires the development of national food safety plans[6] that should encompass the following elements:

- Formulation of a food safety policy and objectives (see the newly introduced concept of 'Food Safety Objectives', in Section 12.3.2)
- Identification of systems and means for ensuring that the objectives are achieved
- Development of supporting food control activities
- Evaluation of the effectiveness of activities undertaken
- A mechanism for review against current needs.[7]

Hence a national plan would provide a framework and infrastructure for the development of horizontal functions. These should include targeted research, data collection and analysis; surveillance and monitoring; management of emergency situations and the building of adequate resources, including personnel; strategies for the reduction and containment of identified risks; and building the confidence of consumers. The international debate until now has focused attention on risk analysis as the foundation for decision making in the process of designing and implementing a food safety strategy.

12.3.1 Risk analysis

Risk analysis is becoming a cornerstone for the development of food safety plans. The technique can legitimise and communicate decisions regarding programme priorities, allocation of resources, levels of protection appropriate to populations, preventive interventions and research. Risk analysis has been described as a process consisting of three components: risk assessment, risk management and risk communication.[8] Although it is oriented towards decision making, which is a managerial activity, risk management always needs to be supported by risk assessment and risk communication and cannot function well in isolation.[9]

An emerging consensus suggests that the risk management process should encompass four elements.

- Risk evaluation, which includes
  - identification of a food safety problem,
  - establishment of a risk profile,
  - ranking of the hazards for risk assessment and risk management priority,
  - establishment of risk assessment policy for conducting the risk assessment,
  - commissioning of a risk assessment,
  - consideration of the results of the risk assessment.
- Risk management option assessment, consisting of
  - identification of available management options,
  - selection of preferred management option,
  - final management decision.
- Management decision on implementation.
- Monitoring and review, including
  - assessment of effectiveness of measures taken,
  - review of risk assessment and/or risk management as necessary.[10]

Risk assessment provides essential factual support for the risk management decision. It is a scientific process aimed at understanding known, or potential, adverse health effects resulting from human exposure to foodborne hazards, how likely they are to occur, and their consequences.[11] It covers documentation and analysis of the scientific evidence to measure the risk and to identify factors that influence it. Risk assessment is the domain of the sciences and uses concepts and information from many fields that is structured and passed to risk managers to assist them in making informed decisions. In this context, it is the duty of the managers and decision makers to create an environment safeguarding the scientific independence and integrity of the risk assessment, while at the same time ensuring that it is documented, structured, transparent, reliable and credible.[12] To do this it is essential that risk assessment is functionally separated from risk management. But to ensure a realistic outcome, a balance has to be found between ensuring the scientific independence, integrity and transparency of the risk assessment and interaction with risk management.

Risk communication is understood as an exchange of information and opinions between the risk managers, the risk assessors and the other concerned or affected parties (the stakeholders). It must extend over the whole process and is crucial for bringing together the necessary information, bridging gaps in understanding, values and perceptions, for ensuring that public values are considered and, finally, for generating better accepted and more readily implemented decisions.[13] How, and how much, stakeholders are involved will depend on the nature of the study, but however it is done should not compromise the independence and integrity of the risk assessment. It should not hide any responsibilities for risk management.

Providing an outline of developing risk analysis concepts and practices goes far beyond the scope of this chapter and additional information can be found in the literature. The elements of risk analysis in one form or another have been utilised by many government agencies to deal with food safety problems. However, critical evaluations[14,15] have stressed that there is now a need for a more systematic and comprehensive application of risk analysis to food safety strategy and programmes, by both governmental authorities and food companies (see Section 12.4).

12.3.2 Principles for implementation

The food safety risk associated with microbial contamination of foodstuffs can be virtually eliminated by eliminating pathogens. An array of cheap technologies to do this is available, or may soon be. However, a strong school of thought recognises that it might be unrealistic to require all microbiological contaminants to be eliminated from all foods. If we share this view, then the objective becomes risk reduction or minimisation to the level of 'acceptable' or 'tolerable' risk. This should be guided by two principles: limitation of exposure(s) and optimisation, using risk analysis as an essential supporting tool.

The *principle of limitation* suggests that the exposure of individuals to a hazard should be limited, so that no one is exposed to an 'unacceptable' extent. Between unacceptable and negligible exposure, a band of concern over levels or concentrations ('brightlines') can be made based on risk.[13] This concept is intended to convey the idea that there is not an exact boundary between safe and unsafe, but equally it is not intended to indicate that the risk, provided it is low, is acceptable. Rather it serves as a source of information about the level of health protection necessary for any hazard.

There are several examples of its use and usefulness outside the food industry, in sectors such as radiological protection. It is amazing that the scientific and public health community in the field of microbiological food safety[16] has not debated its usefulness. Health-based 'brightlines' should be established during risk analysis, by merging the scientific and analytical process of risk assessment with an analysis of the different options from a societal perspective, taking into account the wishes of stakeholders. Differences between a technical appraisal of risk and the risks concerning stakeholders contribute to the breadth of the brightlines. Thus communication can help decision making on risk reduction and process optimisation. In practice, risk-based brightlines could be expressed as pathogen distributions, levels or frequencies. This is the new concept of Food Safety Objectives (FSOs) proposed for the management of microbiological hazards by the Codex Committee on Food Hygiene; several groups are currently considering procedures for the application of these objectives.[17–19] Multiple brightlines may be established when there is a need to protect sensitive sub-populations, or there may be a range from the upper boundary of 'acceptable' risk down to lower levels where technology and other considerations allow virtually 'zero risk' to be achieved.

The *principle of optimisation* is the essential basis for risk management, because it requires that within the brightlines, exposures should be 'as low as reasonably achievable'. Risk assessment plays a pivotal role in determining actual levels or frequencies in question. Optimisation starts with a scientific characterisation of the actual situation (unrestricted risk assessment), identifying and ranking the most important factors contributing to the risk. This process may eliminate some scenarios and support the development of particular mitigation measures. A restricted risk assessment will allow comparison of mitigation measures for robustness and effectiveness, while providing an essential basis for further considerations, such as cost-effectiveness.[20]

These principles may be implemented by government agencies when considering a food safety problem from production to consumption and establishing the basis for intervention. They may also be applied by food business operators for the management of a specific segment of the supply chain or a process, through a comprehensive food safety programme.

12.4 The Food Safety Programme

Within a food company, food safety is typically cross-functional, including activities that draw on many functions and departments, using different skills and levels in the organisation. It also extends outside an organisation, to suppliers and customers. Because food safety interacts with all aspects of food production and distribution, such as quality, productivity or costs, 'trade-offs' or compromises between areas may create difficult problems.

Expectations of HACCP should not extend beyond what it can realistically achieve. HACCP is only a powerful tool for reliability improvement. To contribute to public health and food safety within a food company, HACCP has to be operated within a longer-term managerial strategy concerning food safety. This is the rationale for integrating the Food Safety Programme (FSP) with other managerial initiatives of a company.

The intent of this section is to provide a 'road-map' for the development of an FSP and it utilises many of the same concepts which underpin other quality tools, such as the Total Quality Management (TQM) approach, the series of standards related to quality management (ISO 9000 series of standards) or environmental management systems (ISO 14000). Detailed guidance may be found in the related literature,[21–26] standards and guidelines for application.

12.4.1 FSP – a managed programme

The Food Safety Programme (FSP) must address the needs and expectations of customers in relation to food safety and be compatible with a company's capability. Total commitment of the senior company management is crucial to successful implementation. The FSP should cover both organisational and technical issues and should be focused where improvements are likely to be necessary. In line with TQM, it is based on the concept of continuous improvement and the participation of all members of the organisation.

Preparation for the programme needs a consistent and disciplined approach. The starting point is the development of a food safety policy and a review of food safety issues. The policy is a means to guide and inspire the development of food safety activities within a company. It is a statement by senior management establishing the overarching goals with regard to food safety performance and the direction for action to maintain and improve its performance. For example, a food safety policy may include core values and guiding principles of food safety, their relationship with other policies and guidance on best management practices and best practicable technology. It should state the company's commitment to compliance with legislation and regulations and provide a framework for prevention and risk reduction. It needs to make provisions for evaluating performance, change and continual improvement. Policy should require the involvement, education and training of internal and external interested parties. Management should ensure that the food safety policy is fully communicated to, understood and supported by all employees.

Under the guidance of the policy, issues should be prioritised so that requirements and actions to achieve full implementation are identified. To meet its commitment, management needs to ensure that sufficient resources are available at the right time and that there are on-going activities to improve the food safety performance of the company. It is particularly important to involve all employees.[27] Communication is a key for success and management should ensure that the importance of food safety for consumers and the company is properly understood at all levels of the organisation. Motivation is of primary importance. To help this, cross-functional teams and teams addressing specific activities (e.g. the HACCP team or teams providing assistance or support to suppliers and customers) should be built to develop the opportunity for everyone to contribute. This implies a clear presentation of the food safety policy and its requirements with adequate supporting information. Within the company both awareness of the FSP and the linkage of company activities to food safety should be developed. Correct presentation should ensure support from everyone in the organisation.

Management should ensure that all employees develop a positive, proactive attitude towards food safety issues. Emphasis should be placed on prevention, and not only on control activities. To support this, the Food Safety Programme should provide evidence of reasonable care and regulatory compliance. Most importantly, it must provide a climate for continuous improvement. As a whole, the Food Safety Programme should contribute the development of a food safety-conscious culture within the company, providing consumer satisfaction and increasing the company's competitiveness.

12.4.2 Stages and components

The Food Safety Programme can be developed through a series of stages,[28] as illustrated in Fig. 12.1.

Preparation

Preparation is the initial stage. Its aim is to establish the company's position with regard to food safety and determine the needs and opportunities for establishing an FSP. This should include the following elements.

1. An inventory of constraints, including the level of protection required by public health authorities (legal and regulatory requirements) and other professional or contractual requirements.
2. Identification of food safety issues relevant to the company's products and processes.
3. Identification of the impact of products and processes on food safety, including a comparison of the company's performance and internal criteria with consumers' concerns and needs and external standards and regulations. The degree of practical control of food safety achieved by current safety practices and procedures should be considered, not only for normal or abnormal conditions, but also for potential 'emergency' conditions. Contractual and liability issues should also be considered.
4. A review of past problems or shortcomings and information gained from investigation of previous non-compliance or incidents.
5. Identification of opportunities for improvement or change.
6. Consideration and description of accepted risks (see below, product/process planning and Section 12.5).

The preparation phase continues with the identification of company or structural barriers and enablers. Barriers may include poor organisation, inadequate resources, cultural and technical factors and marketing constraints. Enablers may include a motivated workforce, and the identification of areas for improvement, and for programme implementation (e.g. organisation, resources, technology, motivation and training of the workforce).[27] It concludes with the

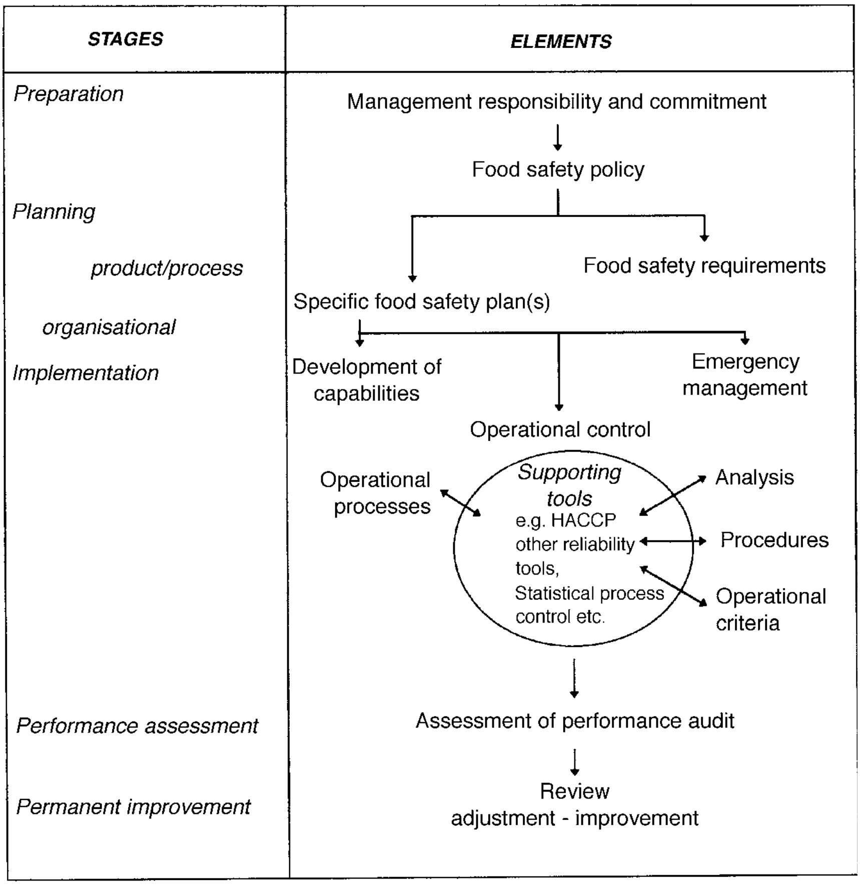

Fig. 12.1 The Food Safety Programme.

development and communication of a food safety policy and the commitment of resources for planning and implementation by management.

Planning

Planning is the activity that ensures a logical and structured approach to changes and improvements. It covers organisational planning and product/process planning.

Planning should make provision for the preparation of specific food safety plans or the improvement of existing ones, and establish the company's requirements for food safety, including new and existing products and processes. It should address the specific designs, practices, resources and sequence of activities relevant to the safety of products or processes; a HACCP plan is an example. It needs to assign responsibility, authority and resources, and identify those specific actions, procedures and lines of communication necessary to gain support and commitment from all personnel. Organisational planning should also include the development of mechanisms for assessing performance and continuous improvement. Requirements should be expressed as a set of measurable quantitative or qualitative requirements for the product and process. Food safety requirements should cover all significant aspects of food safety and be based on the company's preferred level of protection, to meet public health requirements and protect the company from the adverse consequences of unsatisfactory performance. The current capability and any improvements to the technological or control within the supply chain, plus envisaged product developments or new markets, must be covered and may lead to periodic review and revision.

Company food safety requirements may be expressed in several forms, such as rules to be followed, procedures to be implemented or attributes to be met (e.g. a target level for a certain contaminant in a food). Where they are not directly measurable, a company should consider developing measurable indicators of performance (e.g. rate of failure associated with a particular hazard) to allow for the assessment performance versus requirements. Food safety requirements may exist at several levels. At the highest level there are global requirements for a broad system within a multi-site company. Lower down there are site-specific requirements for a local business and below them requirements for a product or process design or operational requirements, covering a group of steps, or even a single step, in a production process (e.g. a known reduction or inhibition of specified microorganisms).

The consideration of risk plays a major role in product or process design and the determination of its food safety requirements by a company. A clear statement of requirements is necessary to provide a basis for decisions and to determine what is acceptable and what is not with regard to food safety performance. At a company level, consideration of risk includes two interacting dimensions. One is consumer oriented (the consumer risk) and corresponds to the unacceptable probability of illness resulting from consumption of an apparently safe food product, leading to public health problems and possible litigation. The other is company oriented (the producer risk) and refers to the unacceptable chance that a process step does not consistently produce foods meeting specified requirements for safety or may be falsely rejected by QA. Even if there is no increase in risk to the consumer this may result in claims, loss of confidence, loss of image, or loss of market.

The control or minimising of consumer safety risk should be the primary consideration of a business. It must provide the level of control of food safety risk that is 'accepted' or 'tolerated' by society at large, or to express this positively, to the level of consumer protection that should be guaranteed. The minimum level (LOP) is usually fixed by public authorities, and may be developed through a government-led risk analysis process (see Section 12.3) leading to the proposal of specific 'Food Safety Objectives (FSO)'. These identify the level, frequency or concentration of a hazard in a food that is tolerable to provide a specified level of protection, i.e. the level of control that should be achieved. Hence an FSO provides a basis for a company to determine its own minimum food safety requirements. However, a company may in practice wish to operate to another (lower) level of risk, perhaps defined by the rate of failure it will tolerate in the marketplace. This may take into consideration additional factors such as the reputation (or loss of image and position) of the brand or consumer perception. In any case, the level of risk accepted by a company should always be lower, never higher, than the level determined by reference to public health authorities in their Food Safety Objectives.

Food producers have traditionally considered and managed the risks of their products using an empirical, experience-based, qualitative approach. Today, there is a need to rationalise decisions about food safety requirements using a more formal, quantitative approach within the framework of risk analysis. Its purpose is to ensure that industrial risk management is linked to the consumers' perspective on public health risk and to facilitate communication of decisions regarding food safety requirements and their basis inside and outside the company, especially to consumers.

The framework identifies significant aspects of food safety and places them in a risk context, by assessing information on potential hazards, exposure assessment and hazard characterisation, followed by risk characterisation. Based on actual practices within the factory (unrestricted risk assessment), this analytical process allows appreciation of the risks actually taken by a company and how these match with, or differ from, the risks deemed 'tolerable' by public authorities, society or even the company. As such it supports the sound identification of food safety requirements in a prospective manner. Participation of staff in the technical and analytical stages of risk assessment and in decision making ensures understanding and communication throughout the food business.

For efficient development, risk assessment should be introduced according to a 'tiered' or 'phased' approach. At the preparation and planning stages of the food safety programme, risk assessment needs only to be developed on a general or global basis ('screening' risk assessment). This characterises the present situation, placing it in a comparative context for establishing priorities, and determining overall requirements. Later on, at the implementation stage, a more detailed, operational level of risk assessment should be developed to assess the impact of any deficiencies on a given process and develop preventive or corrective actions and limits necessary to meet food safety requirements. Risk assessments may be conducted both prior to the development of a specific food safety plan (e.g. the HACCP plan) and as one of its vital elements.

Implementation

Implementation of the food safety programme is done through specific activities using appropriate tools. Management should coordinate this and ensure consistency of results, decisions and actions with regard to food safety requirements. Implementation needs capabilities, procedures and systems to be developed, so that operational control can be established.

Developing capabilities within the factory requires the allocation of human, technical and financial resources. The workforce should gain an increased awareness of food safety requirements and develop an understanding of their importance. Good communication, recognition of work well done and encouragement to make suggestions will lead to motivation and improved food safety performance of staff. Identification of the knowledge and skills necessary will lead to the development of an ongoing training and education programme. It should be oriented towards helping the workforce understand their roles and responsibilities and perform tasks in an efficient and competent fashion. The development of technical capability might also include medium- or long-term changes in premises, equipment or control technologies within the financial capability of the company.

The establishment of operational control is crucial to ensuring that food safety performance is consistent with an organisation's policy and requirements. The impact of manufacturing operations and activities on food safety must be determined. And controls must be identified to ensure that these activities are carried out to ensure compliance with the food safety requirements. This implies a thorough understanding of all stages of the production cycle from raw material sourcing through to finished products and their use, including understanding of product–process interactions, key product or process parameters, monitoring and verification procedures, and where and which improvements are necessary to comply with requirements.

A detailed analysis may be necessary to identify which factors affect safety, which preventive or control measures should be implemented to ensure compliance with food safety requirements, and which operational criteria are necessary for control and monitoring. This is the same scope and functions that HACCP methodology has developed in the food sector.

The food safety programme provides a framework to create a favourable environment for the use of HACCP. The quality of HACCP plans will be improved by the use of risk assessment tools and techniques (see Section 12.5) during the hazard analysis stage.

Preparation for emergency situations is becoming more and more important; companies need to be able to respond in a consistent and timely manner to unexpected incidents or situations, to minimise their impacts on food safety. A company should develop an emergency plan covering organisation, responsibility and authority. It should outline any services required and their coordination, and contain information on hazardous materials, possible contaminants or hazardous situations with their impact and actions to be taken. This should be covered in a training plan with periodic testing for practicality and responsiveness. Risk assessment, used in a predictive manner, should play a crucial role in emergency planning. Firstly, it can be used to predict the robustness of the food manufacturing system (its stability or capability to function without disturbance) and its ability to run under emergency conditions without overwhelming the company and having an adverse impact on food safety. Secondly, it can be used to predict the likely impact of an incident on public health, allowing the company to provide a response that is proportionate to the risk. Much remains to be done to reduce the vulnerability of food systems. A good start would be an effective system for exchange of information within the food industry and between the latter and public authorities.

Performance assessment
Assessment of performance is a key activity that ensures a company is performing according to its intended food safety programme and plan(s). Management should ensure that performance is regularly monitored against food safety requirements. Performance indicators should show the reliability of data and test results (e.g. laboratory accreditation schemes, management of the hardware and software capability, etc.) and may include audits of the food safety programme to determine if it conforms to planned arrangements. Audits will show if it is properly implemented and maintained and will identify any weaknesses, causes of unsatisfactory performance or drifts that need appropriate correction.

Review, adjustment and improvement
These processes should ensure that changes in the food safety 'context' are taken into account in a timely manner. The review should cover new or emerging hazards, changing consumer expectations, changing regulations, changes in products or activities of the company, lessons learned from incidents, and advances in food science and technology, and should ensure that assurance of food safety is not compromised. In particular, the findings and conclusions of audits and reviews should be documented, with the necessary corrective actions and their completion identified.

12.4.3 Integration with other management programmes

There is a need for a company to develop an overall vision of its managerial goals. Food safety management is not a standalone activity; its management should be intimately integrated with other activities within the overall managerial strategy. Sub-systems that are independent of the overall management of an organisation, or not in line with it, will not operate successfully and may not even survive.[22] The integration of the food safety programme with other management systems in an overall managerial strategy is illustrated in Fig. 12.2.

As previously stated, the TQM approach provides a recognised road-map. Within its framework, a company should endeavour to manage risks in a consistent manner. Industrial risks may be categorised into four areas, apart from food safety:

- Quality (the risk of delivering a product that does not conform to implied or expressed customer specifications or is unsafe)
- Occupational safety (risk of workplace injury)

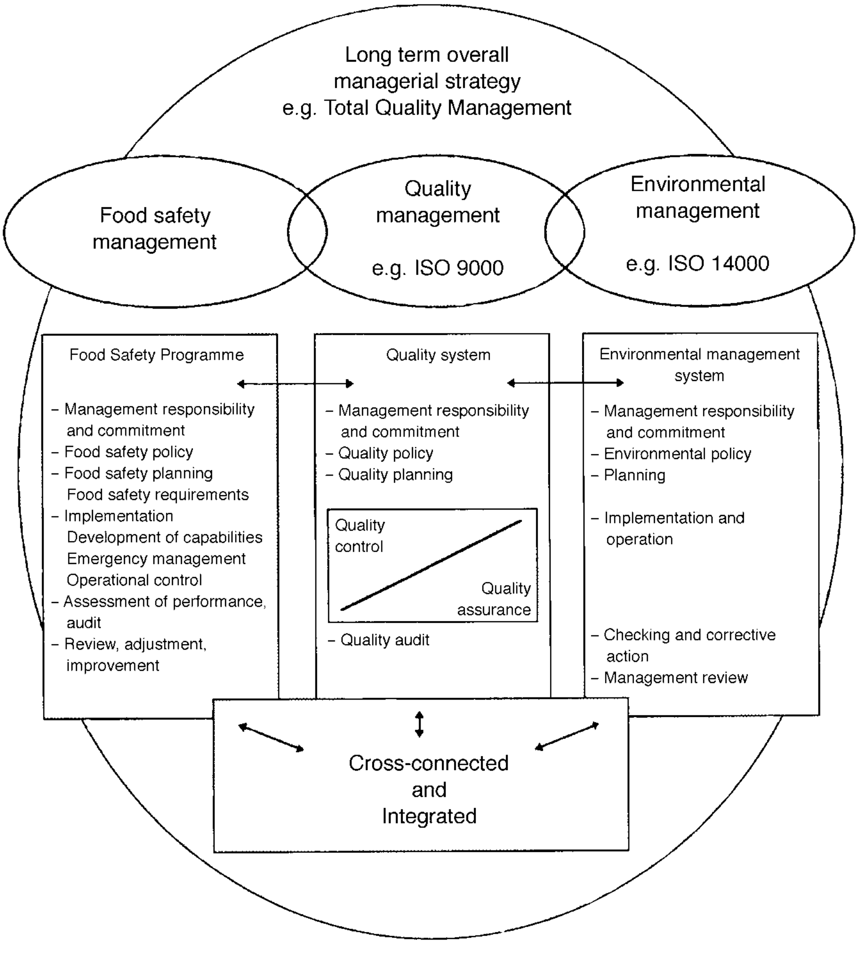

Fig. 12.2 An integrated approach to the management of key issues.

- Environmental impact (risk of damaging the environment during production through pollution, or inefficient use of energy or natural resources)
- Security (risk of being subjected to criminal activities during production).

Harmonisation of approaches and systems in these four key areas plus food safety, and their integration into an overall managerial strategy, are the only means for long-term success.

Because it incorporates the same concepts as TQM and quality or environment management systems, the food safety programme can be readily integrated with these programmes, where they exist. It should not be established independently, and must be part of the quality management system that addresses activities, procedures and processes closely related to food safety. Nevertheless the development of a complete food safety programme will show that a company has taken a comprehensive and consistent approach to dealing with food safety issues, its goals are clearly established and communicated, and operational activities are effective and meet food safety requirements.

This integrated approach resolves the problem of integrating HACCP with ISO 9000 quality systems. Present attempts have taken two main directions: expanding the HACCP methodology to incorporate some managerial activities organised and documented according to ISO 9000 requirements, or using the quality system to manage the HACCP system. Neither route is entirely satisfactory, because to keep HACCP strong and practical it should not be misused. Second, because food safety is crucial to accomplishing an organisation's strategy, its proper management should receive full consideration and it should not be considered a subset of another management system.

For practical implementation, there needs to be correspondence and compatibility of the food safety programme with environment management systems (ISO 14000) and quality systems (ISO 9000) (Fig. 12.2). ISO 9000 standards are under revision, to be brought in line with the ISO 14000 series. Therefore the food safety programme and the two other management systems may be easily integrated in the future. But HACCP needs to maintain its pragmatic value to establish operational controls and in this context the use of risk assessment is the novelty. It can be viewed as the 'Ariane thread' ensuring a consistent progression between the food safety programme and public health (Fig. 12.3).

12.5 HACCP revisited: introduction of risk assessment techniques

The future challenge facing managers and food business operators is to establish a clear link between operational controls and public health requirements, based on risk assessment, while keeping the practical nature of HACCP. Even though they incorporate the best scientific information, technical know-how and expertise, most current HACCP analyses are mainly qualitative. These HACCP studies have facilitated understanding and ownership by the workforce of the HACCP methodology and programmes. The practical strength of the system probably accounts for its current worldwide acceptance.

Today, however, the increasing complexity of food safety requires a better understanding of how the processing steps, their control and inherent variability and the possibility of failure interact to affect the safety of the food produced. This clearly demands revisiting the Hazard Analysis stage of the HACCP methodology. This would be improved by the introduction of a more quantitative, probability-based approach to evaluate the reliability of processes and align process controls to public health requirements. This is risk assessment.

The opportunity for incorporating risk assessment techniques into HACCP could deliver several benefits. Risk assessment offers identification of relevant hazards, a quantitative appraisal of the likely level of hazard(s) in food, while

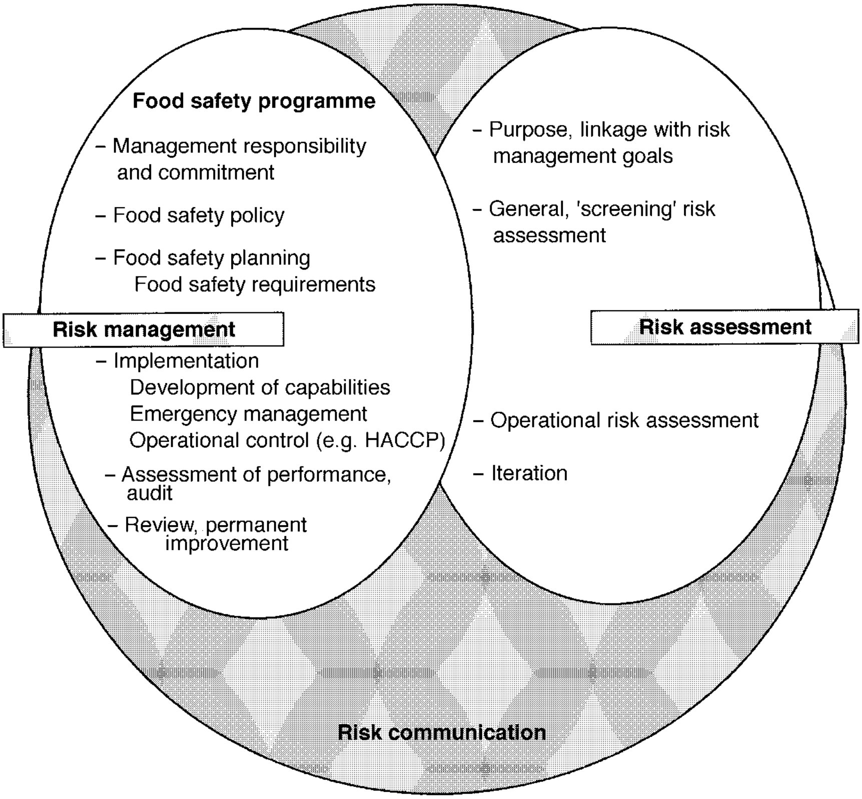

Fig. 12.3 Integrating risk analysis with the food safety programme.

taking into account the variability of raw materials and manufacturing. The better the determination of the level of hazard, the more product/process control requirements can be targeted, all refinements that are missing from the current HACCP system. Key advantages of the quantitative approach would be the ability to link the HACCP plan and controls to public health impact and to measure the level of confidence that the managers (and the evaluators) may have in the operational results.[4]

The usefulness of risk assessment techniques is not limited to improving operational HACCP plans. Risk and especially risk assessment should be considered in the preparation and planning of a food safety programme (Fig. 12.3). Risk assessment may differ in its scope and range depending only on where it is used. In preparation and planning, risk assessment needs to be conducted in a general, 'screening' manner to identify significant hazards and establish priorities for action, so that overall food safety requirements consistent with public health expectations are developed. In the development of a HACCP plan, its purpose is to introduce a probabilistic, quantitative approach based on hazards and their control, taking into account process variability, so that critical control points (CCPs) can be more accurately identified and specified. This requires an operational, process-oriented approach to risk assessment. In other words, a food safety programme can be meaningful only if it incorporates risk assessment activities prior to establishing operational controls.

The following sections will consider the evolving approach towards quantitative risk assessment and how this might be combined with HACCP.

12.5.1 The evolving approach to risk assessment

Risk assessment consists of hazard identification, exposure assessment, hazard characterisation (including dose–response assessment) and risk characterisation.[29] Within this framework, quantitative risk assessment involves the development and use of dynamic risk models and covers the stages of characterisation of the system, model development, analysis, risk estimation and description, and risk assessment.

Characterisation of the system to be studied

This includes[30]

- finding out whether particular microorganisms in a food may be associated with adverse health effects and determining the factors that affect their ability to be transmitted (conditions for survival, persistence, multiplication, inactivation or destruction; vectors and potential spread) and to cause adverse effects in the host (virulence, pathogenicity factors and their variation and evolution);
- characterisation of the source of materials and the process, including product flows (e.g. manufacturing and distribution within the food chain and specific stages in a process); determination of factors that may potentially go wrong and the relationship between the hazard, process, product contamination, and the level of hazard in the product;
- characterisation of the population according to its sensitivity to the hazard and its likely exposure to the product; identification of more sensitive sub-populations and their characteristics, factors that influence susceptibility to the hazard and the severity of disease, as well as consumption patterns and habits;
- characterisation of the disease, involving determination of the different outcomes and the dose–response relationship.

This information should provide an insight into the inherent variability of the different factors, their importance and the likely distribution of their values.

Development of a conceptual risk model

The risk model should integrate and structure the information mentioned above. It should cover both the main variables and their variation – statistical (probability distribution of values, conditions, individuals) and dynamic (evolution of microbial populations, of process parameters, such as pH or temperature). It may incorporate mathematical sub-models, such as microbial predictive models and dose–response models, to provide direction for the analytical phase of the risk assessment.

Analysis

This stage refers to consideration of information from the exposure assessment and dose–response data. Today, a particularly promising tool for this is the 'Monte Carlo simulation'.[31] It can be used to simulate the interactions of the pathogen, the food, a population of consumers and exposure scenarios. Each probability distribution within the model is randomly sampled to reproduce the shape of the distribution and produce a large number of possible scenarios ('iterations' or 'trials'). The simulation determines the combined impact of the probability distribution of variables on the probability distribution of the possible outcomes. Therefore it represents a distribution of risk, based on combining the probability of values occurring. At present a variety of commercially available software products facilitate the calculations.

Risk estimation and description

This refers to risk characterisation and integrates key aspects of the analysis to provide an allocation of risk and a description of the factors that have the greatest impact on the risk. It includes a quantitative measure of the relationship between process targets and their variability and the overall performance of the system with regard to risk. Statistical techniques such as rank correlation (e.g. Spearman rank correlation, tornado diagrams) and sensitivity analysis have proved particularly useful.[32]

Unrestricted/restricted risk assessment

Risk modelling and analysis may first be used to characterise an existing situation or process and provide a baseline. This is 'unrestricted' risk assessment. Using this baseline it is possible to change the input parameters to take account of values resulting from different control interventions or measures and then observe the changes in the risk estimate. This is the 'restricted' risk assessment, which allows for evaluation and comparison of the effectiveness of control strategies and measures. Restricted risk assessment can also provide an objective input into analyses of cost-effectiveness,[20] allowing managers to make informed decisions about practical changes.

12.5.2 Incorporating quantitative risk assessment techniques into HACCP

Several investigators are presently demonstrating that it is possible to develop risk assessment models, and to use them to refine the hazard analysis stage of HACCP studies.[32–35] The process may appear rather sophisticated and demanding in terms of information and data, time and statistical expertise. However, a quantitative, risk-based approach represents the only way to realise the full potential of a food safety programme. The advantages warrant the increased work and any adjustments indicated can be implemented incrementally.

This process starts with a description of the structure of the system, including raw materials, final product and intended use, process steps and product flow and data on current product and process specifications.

The hazard analysis stage begins with hazard identification, a qualitative procedure aimed at identifying which microbial hazards are relevant to the product and process. Microbiological knowledge is required for this and a more informed, systematic procedure is desirable.[36] Hazard identification may be improved by the government-led collection and collation of information (e.g. research results, epidemiological studies), development of global risk assessments by public health authorities, aimed at assessing and ranking the food-borne health risks in a population, and communication of the information to business organisations and operators. Good communication will ensure the active exchange of information on the characteristics of realistic hazards, in particular quantitative changes in risk associated with the variability of microbial populations (e.g. resistance to external factors such as temperature).

The next activity in hazard analysis involves determining the conditions leading to the presence, contamination, survival or growth of each hazard and its impact on the level in the final product or percentage of non-conforming products. Here, one approach to introducing quantitative, probabilistic techniques may be the use of reliability tools such as Event Tree and Fault Tree analyses. Detailed descriptions of these tools may be found in the literature.[37–39] An Event Tree is a diagram illustrating the consequences of an event chain (where an event is a deviation in a manufacturing process). A Fault Tree diagram describes the causes of the deviation. Combining the two will allow systematic description of circumstances under which a system could fail and understanding the effects of chains of events, expressed in terms of frequency or probability. Once the diagrams have been outlined, the next task is to evaluate evidence on the probability of each event (i.e. the 'risk'). This may be given qualitatively, using expressions such as 'low', 'medium', or 'high' risk, or by a numerical ranking system, using for instance 10 for high risk, down to 1 for low risk. This is suggested by Failure Modes, Effects and Criticality Analysis (FMECA), another reliability tool currently used by industry. FMECA is an extension of Failure Modes and Effects Analysis (FMEA) from which HACCP originated. It is amazing that these tools seldom appeared in the classical descriptions of HACCP, which focus on general or specific hygienic practices. Introducing quantitative approaches into HACCP may be viewed as simply re-sourcing it!

Semi-quantitative evaluation provides a means of assessing the impact of failures and prioritising problems and may prompt the development of more advanced quantitative techniques. When more precise risk assessments are necessary, more accurate quantitative information needs to be sought, to determine the distribution of the probabilities of each adverse event occurring (probability distribution function). Software packages for stochastic simulation (e.g. Monte Carlo) give probability estimates and may provide a means of identifying potential critical points in a complex system[38] allowing better alignment of system capability.

Where a desired outcome has been identified (e.g. attainment of a food safety objective), another approach may be used to consider the effects of variations in materials and process specifications, or hazards, and their variability at all stages. This approach determines the impact of variations on the occurrence of non-conforming product.[40] To do this requires collecting additional information on the level and statistical distribution of microorganisms in the raw materials and at different process steps and in the final product, and next on how this is affected by the distribution of parameter values unique to each process stage (e.g. duration of lag phase, sensitivity to thermal processes, pH variation, time/temperature variation in a thermal process, etc.). This information is used to construct a risk assessment model, using a flow diagram for mapping the process and adding the parameters and their variability to the model. Sub-models may be utilised to refine the approach, such as microbial predictive or lethality models or heat transfer and other process models. The latter should take account of the variability of product dimensions and thermophysical properties, including product temperature at start of cooking and cooking conditions.[41]

After defining the features and variability in the basic model, it becomes possible to use simulation, e.g. Monte Carlo, to determine the impact of the distribution of variables on the predicted outcome. The main advantage of introducing a probabilistic approach is that it provides a rational and transparent way to address variability. Use of a qualitative approach tends to consider average or mean values, based on experience, or will default to the worst-case scenarios. Both approaches are unsatisfactory, the first because a system based on mean values may fail when confronted with extreme circumstances and the second because it may be over-conservative.[4] An approach based on probability considers the whole range of distribution of values, their chances of occurrence, and how they impact on overall variability in the system. This allows interventions to be directed towards reducing the variability and elimination of high-risk scenarios (e.g. poor microbiological quality of raw materials). It also allows the accurate establishment of critical process limits in order to reduce the risk of unsatisfactory performance and ensure conformance with specifications. With good knowledge, process parameters may be used to set processes closer to the edge and maintain safety levels (e.g. using lower heating temperatures in minimally processed foods) and to predict the impact of process changes on the risks of making non-conforming products (e.g. from changes in the quality of raw materials, product dimension or heating conditions, etc.).[41]

Incrementally it will become possible to refine and extend modelling activities to give a complete risk model covering consumer sensitivity and dose–response modelling.[42] Using this type of model, the results of the preceding simulations (e.g. level of hazard or rate of failure) can be correlated with their public health outcomes (e.g. probability of infection, probability of disease occurring). This is particularly important because it can be used to gauge the technical performance of an industrial system analytically and not only from a public health perspective.

It allows businesses to effectively apportion the impact on public health of process design and the stages used in processing and make informed decisions on management of product safety. Where trade-offs with other considerations can be foreseen, the management of compromises, based on a quantitative risk assessment, can balance public health requirements against other considerations such as technical feasibility, market necessities or cost. In the absence of quantitative information about risk, such trade-offs are nothing more than 'a matter of gut feeling'.[43] For informed and justifiable decisions, the whole process needs to be supported by effective communication within the company and its trading partners. Within the food industry, movement towards this approach is a must. The pace at which changes can be implemented, and the final success, depend only on the commitment of senior management of food businesses to improving food safety.

12.6 Summary

Food safety is a basic demand of the consumers. It can be considered as the price of admission to market in the sense that no other feature on which companies compete, such as satisfaction, service, nutrition, innovation, quality and cost, can be valued in the marketplace unless there is customer confidence in the safety of the food. In addition, trading conditions and legislation require food businesses to demonstrate their commitment to food safety issues.

The proposed approach to determining food safety requirements should ideally start with the development of a national food safety plan. It should be based on a government-led risk analysis process, identifying public health based food safety objectives, such as maximum contaminant levels and the level of consumer protection to be achieved. In response, the food industry should organise itself to provide greater evidence that procedures to ensure food safety are present and adequately managed. Integrated food safety management programmes should be widely developed and linked to management of other key issues such as quality and environmental impact within the long-term management strategy. In the context of the food safety programme, better control should be exercised over industrial processes to increase their reliability and the relevance of controls to ensuring public health goals. To that aim, HACCP should evolve, to include quantitative risk assessment techniques at the hazard analysis stage.

Whereas these principles and their application will probably not pose much of a problem to large food businesses, which have the necessary resources and expertise, it has to be appreciated that these changes would increase pressure on smaller, less developed businesses (e.g. the small and medium-sized enterprises, so-called SMEs). They would have unique needs for specific assistance and guidance. This should be provided by governmental authorities and professional organisations, and interpretation of the risk-based HACCP system should be kept flexible to allow them to apply it. To benefit all food producers and consumers, it is essential in particular that scientists from academia, government, professional organisations and industry work together to provide the necessary information, advice and technical support.

The increasing complexity of food safety and the significant changes occurring in the global economy present a unique opportunity and challenge. Going beyond HACCP towards a risk-based food safety management programme will be crucial for companies wishing to move from a regional or national scale to an international one. It is likely that only companies that recognise this need will be successful on the international marketplace during the twenty-first century.

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