Integrated Management Systems Series

IMS: Managing food Safety

Helen Hinch

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IMS:
Managing Food Safety

Integrated Management Systems Series

The Integrated Management Systems (IMS) series of books provides practical guidance and advice on integrating the systems operating within an organization. The IMS series provides a framework into which additional management systems can be incorporated.

Each volume is written by an acknowledged expert in the field. The series editor is David Smith of IMS Risk Solutions Ltd, who has been involved in writing management system standards since the early 1990s and is himself the author of a number of BSI books on the subject.

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IMS: Managing Food Safety

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1. Introduction

About this book

This book is about product control in the food industry and the characteristics which cause its management to differ from product control in other industries. The food industry is unique in that it distinguishes between product safety and product quality. Product safety is the control of adverse health effects that may be transmitted to the consumer via food. Due to the overriding importance of such product safety, systems have been devised for its exclusive control. Product quality refers to the parameters in food that affect its acceptability which are not included in the definition of food safety.

This book does not assume that an IMS (integrated management system) is already in place, or even that such a system is planned for implementation in your organization. Neither does it assume that a formal quality management system is in place, such as ISO 9001 or any other formal management system dealing with, for example, environment or occupational health and safety. This book will demonstrate the advantages in managing food safety systems as part of an IMS, no matter which food safety systems are deemed necessary in your organization. This guidance is not mandatory, and is given for use in the installation of a food safety system to stand alone if so desired. Because the IMS is based on a framework that is relevant to all applications, this book starts off with a brief outline of the principles of an IMS and its principal features. This enables subsequent chapters to be seen in the context of the overall system covering all activities of the organization. This is followed by a description of food safety control and the hazard analysis and critical control point (HACCP) system and how these relate to food quality and quality management systems. The significance of other management systems is then discussed in relation to their inclusion in the integrated system.

The principles of an integrated management system

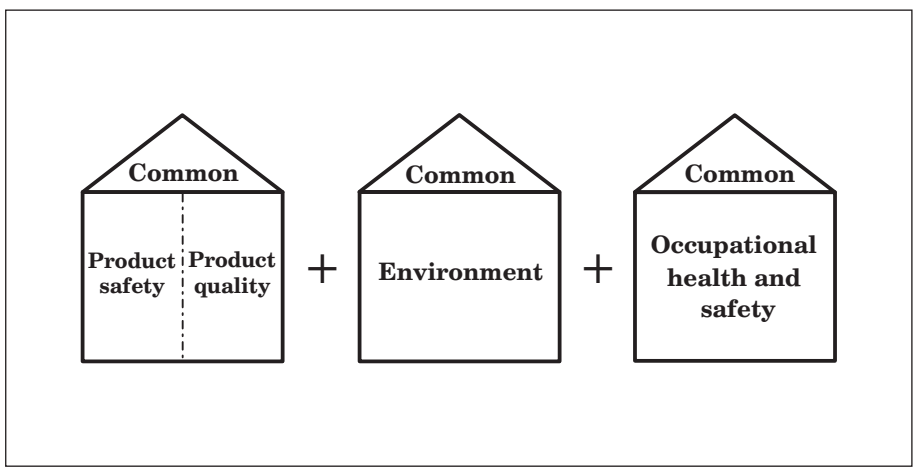
It is not the purpose of this book to describe how to install an IMS – that is described in other books in this series – but it is appropriate to give an outline of the thinking behind the development of an IMS and its implementation.

Virtually all management systems standards have certain elements in common. Whilst their subjects may be diverse – quality, the environment and so on – they all demand statements of policy, documentation, planning, operational control etc. If each standard is treated separately this can lead to much duplication of effort and even conflict in areas of overlap. Recognizing the common elements as part of an integrated system can avoid duplication, as well as providing a ready made framework into which additional management systems can be incorporated as the need arises. It also serves to underline the fact that all management systems have a common purpose in promoting the business of the organization.

The most efficient strategy for managing systems in any organization is through an integrated management approach. The concept of an integrated management system for use in industry has been described in the first book of this series, *IMS: The framework* and its operation in the second book, *IMS: Implementing and operating*. The integrated management system is designed around a common core of management standards, which may be added to or adjusted to meet the requirements of each individual organization.

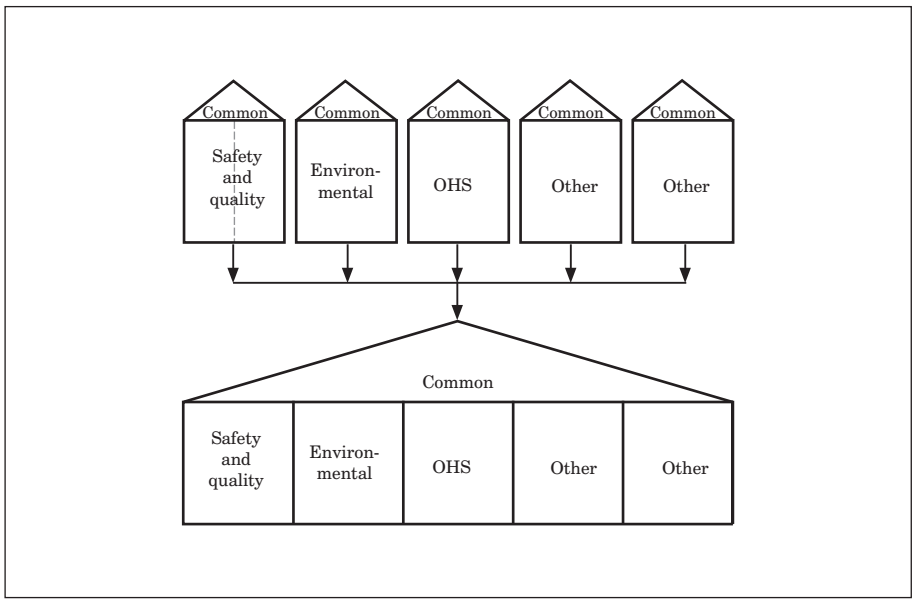
In the food industry, the essential core standards cover the management of product safety and product quality, the environment, and occupational health and safety (see figure 1.1).

Figure 1.1 Core elements of an IMS for the food industry



These can be integrated with each other and with other applicable standards (eg customer satisfaction) as represented schematically in figure 1.2.

Figure 1.2 To show that the common elements of the range of standards required by a food organization can be integrated in an IMS



All organizations within the food industry should include an identifiable system for product safety in their management strategy. Such a system should ensure that raw materials and products are not a potential health hazard while under the direct control of the organization or at any later stage in the food chain. In many countries this is now a legal requirement.

The management of food safety is closely related to the management of food quality, as shown in figure 2.2, nevertheless, many food organizations control them under two separate systems. The most frequently used are ISO 9001:2000 for food quality and the HACCP system for food safety. This book discusses the advantages of combining food safety and food quality into one management system and the integration of that system into an IMS.

Apart from product safety and quality, other core elements of an IMS for the food industry are the management of environmental issues and occupational health and safety. Environmental management is essential throughout the food industry but particularly in the primary production sector. Occupational health and safety has a special significance for the food

industry because raw materials, and sometimes the products, may be vectors of diseases which can be transmitted to the workers. Conversely, if infected with food-related pathogens, food handlers can transmit them to the products and to other workers. Therefore, environmental management and occupational health and safety are essential support systems to the safety and quality control of food industry products. Integrating the systems avoids duplication and streamlines management, just as operating a joint product safety/quality system gives maximum efficiency at the centre of the management structure.

This book focuses primarily upon food safety and the HACCP system in particular.

The basic IMS framework

The IMS framework has been described in earlier books in this series and will not be repeated in detail here. The outline (to be considered in more depth later in this book) is as follows:

- management system – establishing the system and seeking continual improvement;
- policy;
- planning;
- implementation and operation;
- performance assessment;
- improvement;
- management review.

These main headings will be instantly recognizable in relation to any management system. The full framework is reproduced as appendix 1.

2. Managing food safety

The global food market

Because food is marketed globally, the standard of product control in different countries has a potential worldwide impact. Therefore, in order to ensure acceptable levels of safety in all products, national and international food authorities should undertake – and food industries should accept – comprehensive responsibility. The most important responsibility is that end products will not compromise the health of any group of consumers within the world population; with a second responsibility that products will maintain the required quality until the end of their guaranteed shelf life, wherever they may be sold. These responsibilities continue beyond the point of sale and require the provision of advice and instructions to customers on storage and preparation, appropriate to the foods purchased. These responsibilities also apply to suppliers of ancillary goods and services to the food industry.

To provide an internationally recognized standard for food safety control and to facilitate international trade, the Codex Alimentarius Commission (CAC) has published a series of codes of practice and guidelines for planning and operating a food control system based on hazard analysis and critical control point identification. The CAC implements the WHO/FAO (World Health Organization and Food and Agriculture Organization) joint food standards programme. The HACCP system is supported internationally by the International Commission on Microbiological Specifications for Foods (ICMSF) and the International Standards Organization (ISO) through ISO 15161:2001, *Guidelines on the application of ISO 9001:2000 for the food and drink industry*. A standard is currently being prepared which will set out the requirements for managing a food safety system based on the CAC guidelines for HACCP (ISO/CD 22000, *Food safety management systems — Requirements*).

The international retail sector of the food industry launched the Global Food Safety Initiative (GFSI) in 2000. Under this initiative, food safety audit schemes, which meet specified criteria, are approved by the GFSI for the use of retailers and others. (GFSI 2003) In the food safety legislation of the European Union, Directive 93/43 EC (1993) on the hygiene of foodstuffs specifies the use of a HACCP-based system to control the safety of food. The HACCP system is increasingly specified in national food legislation while the publications on HACCP by the CAC, and the recognition of HACCP by international organizations, have ensured its worldwide acceptance.

Food safety, suitability and quality

Food is judged on a number of criteria and the terminology used in relation to food safety has changed in recent years. Food safety continues to be defined as the assurance that food will not cause adverse health effects to the consumer when it is prepared and/or eaten according to its intended use (CAC 2001a). The definition proposed for food safety in the working document for the forthcoming ISO/CD 22000 standard has the same meaning, although it is expressed differently. It also has an additional note that the term food safety is applied to the occurrence of hazards and does not include other human health aspects such as nutrition (ISO/CD 22000).

The main cause of illness from food is due to the presence within it of microbiological pathogens or their toxic metabolites. Well-documented breakdowns in food safety have occurred in various countries and there is now a global awareness that the spread of disease through food could result in an international pandemic. But pathogens are not the only adverse health agents that may be found in food. Toxic chemicals and physical contaminants may also cause harm to the consumer and their significance and control is included in the term, food safety. Food safety hazards may occur at any stage in the food chain, and therefore action to meet legal and customer standards should be managed efficiently and diligently throughout the food industry.

The term, 'food suitability', is used by the CAC to denote food which is 'acceptable for human consumption according to its intended use'. The definition implies that the term includes all factors affecting the safety and quality of the food, but the interpretation of the definition is not clear. Therefore in this book the term FSQ (food safety and quality) is used to mean food which is safe and of the quality required. Most authors refer to the factors inherent in food, other than those that affect its safety, as quality criteria. These include microbiological, chemical and physical contaminants, which are non-dangerous to health and operational faults,

throughout the food chain. They are controlled to meet legal or customer requirements. The quality management standard ISO 9001:2000 is used in the food industry to manage quality. By following the guidelines given in ISO 15161:2001, ISO 9001:2000 can be extended to cover the principles and ancillary requirements of the HACCP system and to also manage product safety.

In everyday usage, 'product quality' implies safety as no product would be considered to be of adequate quality if it were not safe to use. Therefore, by extension, it may be said that adherence to ISO 9001:2000 in the food industry implies a safety control system equivalent to the HACCP system.

Food safety control – The HACCP system

Control systems to ensure the safety of food have been devised and revised for many years. The HACCP system was developed in the 1960s from the engineering system – FMEA (failure, mode and effect analysis). FMEA reviews each stage of an operation for potential problems, together with the possible causes and likely effects. The HACCP system is based on the same concept. 'Failures' at each consecutive step of a food handling operation, which could result in an adverse health effect related to the product, are identified as hazards and are investigated by hazard analysis. The steps in the operation at which hazards occur, and where they need to be controlled, are called CCPs (critical control points). At each CCP, controls, also called preventative measures, are put in place to avoid, eliminate or contain the hazards. The controls should be at an appropriate level to contain the hazards. The critical limits of the control, outside which it cannot be accepted to be effective, should be specified and target levels, optimum settings for the control within the critical limits, should be determined to indicate when a control is beginning to deviate from the norm. The controls are monitored, and, if they show deviation beyond the target levels or do not conform to the critical limits, corrective action is taken. Verification of the effectiveness of the controls and the monitoring procedures and validation of the HACCP plan are an integral part of the system.

The HACCP system was originally based on the seven principles shown in figure 2.1. They are conceptual rather than practical and consequently have been interpreted in a variety of ways resulting in a number of variants of the system. The seven principles also omit certain elements that have been found necessary for the effective operation of a HACCP system. These have now been added and they complete the current form of HACCP discussed in chapter 3.

Figure 2.1 The seven principles of HACCP

1. Conduct a hazard analysis.
2. Determine the CCPs.
3. Establish the critical limits.
4. Establish a system to monitor control of the CCPs.
5. Establish corrective actions to be taken, when monitoring indicates that a 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.

(CAC 2001b)

Food quality control – ISO 9001:2000

Because the control of food safety is of paramount importance to human health it has received greater attention than the control of food quality. Also there is a close relationship between the growth of microbiological pathogens and spoilage micro-organisms, and therefore defects caused by the latter can often be eliminated by control measures taken against the former.

It can be seen from Table 2.1 that a food safety system will give significant control over microbiological food quality. The same applies to the elimination of chemical and physical contaminants – controlling those that are toxic and sharp will also give protection against non-hazardous types in the product. However, there are some quality parameters that are not covered by a food safety system; these may include some details of labelling, composition, organoleptic characteristics and unit measurements. Thus operating a HACCP system alone means that there is a limit beyond which control over product quality is lost. There are currently two ways of resolving this. One is by using a separate quality management system such as ISO 9001:2000, but this has involved operating a dual product control system with a considerable degree of duplication and overlap at the interface and possible omissions at the limits of each. The other approach is to add on quality parameters as subsidiaries to the HACCP system. The danger here has been that a two-level system is created in which the quality parameters are not adequately audited and verified. For example, enforcement officers from the department of health are concerned with food safety issues and not with those which affect quality only.

Table 2.1 Relationship between food safety and food quality parameters

Food safety parameters	**Food quality parameters**
Microbiological pathogens, toxins and parasites	Microbiological spoilage
Chemical components and adulteration dangerous to health	Chemical composition and adulteration (non-toxic)
Physical contaminants – dangerous to health	Physical characteristics, unit measurements and contaminants – non-dangerous health
Packaging – protection from contamination by pathogens and other adverse health agents	Packaging – protection from damage, physical and chemical contamination and microbiological spoilage
Labelling – storage and cooking instructions and allergy information	Labelling – composition and nutritional value
Date coding – to ensure the safety of the product when consumed	Date coding – to ensure the physical, chemical and microbiological quality of the food at final sale
Storage and distribution – protection from pathogens and other adverse health agents and prevention of pathogenic growth	Storage and distribution – protection from damage, physical and chemical contamination and the prevention of microbiological spoilage

Food safety and quality control – ISO 9001:2000/ISO 15161:2001

Therefore the food industry requires a product assurance management system which will cover all the acceptance criteria. It should be designed to identify those aspects that are concerned with food safety and should also ensure that quality parameters are adequately addressed. Such a system may be achieved by using ISO 9001:2000 and applying the guidelines given in ISO 15161:2001. These review the requirements of ISO 9001:2000 and map the seven principles of HACCP to the relevant clauses. Implementation is to the ISO standard and thus the HACCP system may be managed within the IMS framework. It is included in the audit and certification processes and there is no gap between food safety control and other quality management responsibilities. For example, all measuring equipment required for food safety monitoring would become part of the calibration programme and raw materials would be purchased to specifications that include quality as well as safety parameters. Furthermore, ISO 9001:2000 is designed to achieve continual improvement, which should be an essential requirement for food safety as well as for food quality, to enable the food industry to keep abreast of increasingly stringent customer demands and legal requirements.

In ISO 15161:2001, the information relating to the HACCP system is presented as notes and comments. A few parameters, such as the sensory

evaluation of food, are discussed, but previous in-depth knowledge of HACCP is required in order to apply the guidelines.

In the draft of ISO/CD 22000 it is proposed that the standard will be cross-referenced to ISO 9001:2000. How far this will make possible the operation of a combined food safety/quality management system with food safety based on HACCP and with efficient coverage of quality control cannot be assessed at present. The system will be controlled by audit and certification processes equivalent to those of an ISO 9001:2000/ISO 15161:2001 system.

Process identification and mapping

The need to identify all processes involved in a manufacturing operation in converting inputs into outputs is one of the principal requirements of ISO 9001:2000, and is an essential element in any IMS. It is only by understanding the processes involved from the top level to the lowest, and the interrelation of those processes, that all risks can be identified and, more positively, opportunities for improvement be identified. By placing the emphasis on processes, rather than procedures, it is possible to gain an overview of the organization and the way it works.

To start identifying the processes and to map them (to show the way in which they relate to each other) is a major task for any organization. It is, however, essential. It is required by the HACCP system (task 4 – H4), by the IMS (0–a) 'The organization should identify the processes needed…' and by ISO 9001:2000/ISO 15161 s4.12 'The organization shall …identify the processes needed for the management system…' Whilst the task is a formidable one for an organization that has not previously defined its processes, companies that have carried out the exercise find that many and unexpected benefits result.

3. The application of HACCP

The modern HACCP system

Since it was first introduced, the HACCP system has been revised repeatedly to meet the needs of the food industry. The areas in which changes have been made are:

- expansion of the seven principles to give more structure and support to the system;
- introduction of microbiological criteria for the evaluation of potential health hazards in food;
- introduction of risk analysis using risk assessment to quantify the hazard analysis and risk management and communication in the implementation of the system;
- formulation of HACCP systems for specific sectors of the food industry, particularly relating to food exports.

To accommodate these developments, the CAC has issued a series of codes of practice and guidelines (CAC 2001a, b, c, d). They are grouped as follows:

- general principles of food hygiene;
- principles of HACCP and guidelines for the application of the HACCP system;
- principles for establishing microbiological criteria for foods and their application;
- principles of microbiological risk assessment and guidelines for their implementation.

The tasks required to plan, implement and maintain the HACCP system are shown in table 3.1.

Table 3.1 An itemized approach to the HACCP system (CAC 2001b)

A. Guidelines for the application of the HACCP system			The use of microbiological criteria and risk assessment in a HACCP system
HACCP Reference	Working reference	Description of task	
Guidelines for the application of the HACCP system	H.i	Prerequisites for the application of HACCP	
	H.ii	Management commitment	
	H.iii	Recommended scope of the HACCP system	
	H.iv	Critical Control Points (CCP) as the central food safety control mechanism in a HACCP system	
	H.v	Recommendation of a separate HACCP system for each specific operation	
	H.vi	Requirement to review and amend the HACCP system when there is a modification to the product or to any process step	
	H.vii	Requirement that the HACCP system is flexible and aligned to the nature and size of the operation	
B. Application of the HACCP system			
Task	Working reference	Description of task	
Task 1	H1	1.1 Assemble and train the HACCP team 1.2 Define the scope of the system	
Task 2	H2	Describe the product	Risk assessment using microbiological criteria as appropriate
Task 3	H3	Identify the intended use	
Task 4	H4	Construct a flow diagram	
Task 5	H5	On-site confirmation of flow diagram	

Task 6 Principle 1	H6	6.1 Conduct a hazard analysis of all potential hazards at each process step 6.2 Set preventative measures (controls) for each hazard	Risk assessment using microbiological criteria as appropriate
Task 7 Principle 2	H7	Determine CCPs	
Task 8 Principle 3	H8	Establish the critical limits for each CCP	
Task 9 Principle 4	H9	Establish a monitoring system at each CCP	
Task 10 Principle 5	H10	Establish corrective action for each CCP	
Task 11 Principle 6	H11	Establish a verification procedure	
Task 12 Principle 7	H12	Establish documentation and record keeping	
C. Additional elements for the HACCP system			
HACCP reference	Working reference	Description of task	
Additional element	H13	Training	
Not specified by the CAC	H14	Establish supporting systems (laboratory accreditation, supplier assurance audits, preventative maintenance, visitor control)	

Guidelines for the application of the HACCP system (H.i – H.vii)

The CAC guidelines for the application of the HACCP system state: 'Management commitment is necessary for implementation of an effective HACCP system' (H.i). No one involved in food safety would disagree with this. Unless the entire management hierarchy of an organization fully supports the introduction of the HACCP system and continues to take a proactive lead in its implementation and maintenance much of the benefit will be lost. A major recommendation in the introduction to the implementation of HACCP (H.ii) is that an organization should first ensure that its operations meet the standards of hygiene given in the *Recommended International Code of Practice for the General Principles of Food Hygiene in Basic Texts on Food Hygiene* (CAC 2001a). Their function is to ensure that those areas of food hygiene, which are general to the whole of an operation or organization, are controlled efficiently. The HACCP system deals effectively with the facets of

food hygiene which apply to a specific step in an operation, but it becomes unwieldy and repetitive if all the generic factors are included at each CCP. Therefore, procedures should be in place to ensure that there is no gap in the standard of overall food safety throughout an operation and organization. CAC 2001a provides for this, but to be effective the general principles need to be managed efficiently. As they are not an integral part of the HACCP system, provision should be made within the HACCP plan to ensure that they are addressed, implemented, maintained, controlled and reviewed. The HACCP plan documents the full complement of tasks to be undertaken in order to ensure the efficient functioning of the HACCP system within an organization. It addresses the scope of the system and specifies which requirements are included for each operation.

The guidelines recommend that all food-handling operations within an organization be included in the HACCP system and that the impact of the raw materials on the safety of the product be evaluated (H.iii). The food industry should also carry responsibility for any adverse health effects which its products may have on the public. Therefore, the possible abuse of the safety of the product, the susceptibility of the consumers to food-related diseases and the epidemiological risk that the foods may carry should be considered when planning the HACCP system (see microbiological criteria, chapter 4).

The importance of the CCPs, the focus of food safety control in the HACCP system, is emphasized (H.iv). It is recommended that the operation be redesigned if a hazard is identified but is not controlled at a specific critical point in the process. Each operation should be analysed separately within the HACCP system of an organization (H.v). This is to avoid the possible omission of a hazard in a generic plan or its misinterpretation at a specific CCP. The necessity to review the HACCP system and to make revisions to the HACCP plan when changes are made to the product or process is addressed in H.vi. The guidelines conclude with a recommendation that the HACCP system be designed to suit the application (H.vii). The flexibility of HACCP has been a contributing factor to its universal use, but the lack of a single management standard against which to assess individual systems has resulted in variation in the success of its application.

The first five tasks in the application of the HACCP system (H1 – H5)

The first of the five preliminary tasks involves assembling a multi-disciplinary team to give expert advice on the scope of the system and specific areas

relating to potential adverse health effects in the end product (H.1.1). It is recommended that, if there is a lack of expertise within the organization, external advice is sought. Gaze (2003) suggests that the skills of a quality assurance/quality control expert, a production specialist, and an engineer should be represented on the team along with key operators. Specialists from other departments are co-opted as necessary. It is recommended that the team does not exceed six persons, including the team leader. Emphasis is placed on the practical expertise of the individual team members as they will be responsible for planning the system and taking an active part in its implementation and maintenance. The first task of the team is to determine the scope of the HACCP system (H.1.2), i.e. to identify the products and operations of the organization that will be included in the system and to determine the type of hazards to be analysed. The hazards associated with the HACCP system are grouped as microbiological, chemical and physical in relation to the safety of the final product. As discussed in chapter 1, food safety and food quality defects often result from the same hazards and the HACCP system within an organization can be extended to cover the latter as well as the former.

Having agreed the scope of the system, the second task (H.2) requires the team to describe the products that will be controlled within it: either the output of an intermediate stage of processing; or final products for dispatch to the end consumer. Where more than one product is included in the overall HACCP system it is recommended that each should be considered separately. This ensures that all team members are familiar with the full production range. Details of all relevant aspects of each product should be included as the team determines the criteria on which the acceptability of a batch or lot is based. The use of risk assessment and acceptance criteria to evaluate toxic chemicals and radiation in food is well established, but the microbiological disease potential of food is more difficult to predict. Micro-organisms are dynamic and their behaviour may vary at each stage of processing with different types of equipment or if operational faults occur. It is also difficult to predict the degree of pathogenicity that will be imparted through a food because its constituents may vary in their physico-chemical characteristics and these can affect microbiological survival and growth. Each person has an individual susceptibility to disease agents which does not remain constant throughout life. Therefore, the HACCP team not only needs to describe the product but also to identify its intended use, indicating the sectors of the public for whom it is intended (H.3). If the product is intended for consumers known to be vulnerable to food-related diseases, such as babies and immuno-compromised groups, this factor should be included when considering the microbiological criteria. The CAC defines a microbiological criterion for food as 'the acceptability of a product or a food lot, based on the absence or

presence, or number of micro-organisms including parasites, and/or quantity of their toxins/metabolites, per unit(s) of mass, volume or lot' (CAC 2001c). A food organization requires information on the microbiological criteria of raw materials, intermediate and end products to assess the level of risk of hazards identified in the hazard analysis of the HACCP system. Such information has been applied qualitatively to hazard analysis since the HACCP system was first introduced, but with the development of the global market for food, quantitative data is required to ensure that no products represent a risk to public health. The use of microbiological criteria in assessing food safety risks is discussed in chapter 4.

Having described the products to be included in the HACCP system, the team then constructs schematic representations of the processes by which they are produced (H.4). These flow diagrams or process flow charts show the stages of the operations in sequence. Each of the operations included in the HACCP system needs its own flow diagram and should contain detailed information about the parameters that are used to control the process at every stage. To avoid errors or omissions the final preliminary step in the HACCP system needs on site-confirmation of the flow diagrams.

The seven principles for the application of the HACCP system (H6 – H12)

Having established the food safety characteristics of the products and their mode of production, the team is required to list all potential hazards at each stage of the corresponding process (H.6.1). The list should also include hazards from primary production and stages of processing prior to those carried out within the organization, as these may affect the safety of the product via raw materials and ingredients. Hazards, which may occur during subsequent stages of processing and distribution to the point of consumption, should be listed as these may influence decisions taken regarding the safety of the product during processing by the organization. Once the list is compiled the team analyses the hazards to determine those which need to be prevented, eliminated or reduced to an acceptable level in order to ensure the safety of the final product. Hazard analysis is carried out most effectively by using risk assessment techniques as described in chapter 4.

When the hazard analysis is complete and the microbiological risk of each hazard has been assessed the team can determine the preventative measures to be used to control each hazard (H.6.2). Concurrently, the team will identify those steps in the operation at which hazards may occur that, unless controlled, will have a potential adverse food safety effect in the final

product – the CCPs (H.7). Determination of the CCPs throughout the operation is central to the HACCP system. Establishing the CCPs is essential to deciding on the type of controls (preventative measures) that are to be used. It also affects the determination of the critical limits (CLs) of the control (H.8). The CLs set the acceptable range for the control. A target level may be specified within the critical limits. This is the optimum at which the control should operate. Deviation from the target level can be used as an early warning that the control is not functioning satisfactorily and preventative action may avoid the control exceeding the range of the critical limits. The preventative measures used to control the potential hazards at each CCP should have measurable parameters by which they are monitored and their efficiency and effectiveness assessed (H.9).

The monitoring system should use physical and chemical measurements if practicable. These give rapid results and permit immediate adjustments to be made to the control to keep it within the predetermined critical limits. Indirect assessment of the microbiological quality of the product can be obtained from such measurements. Where microbiological analysis is necessary, modern techniques, which reduce the length of time required to complete the tests, should be used. The results from such tests are less retrospective and therefore of greater value than those obtained by classical methods. Some monitoring processes operate continuously and, linked to appropriate recording devices, give a total review of the status of the preventative measure, i.e. its effectiveness in controlling the hazard at the CCP. Others, however, require intermittent readings to be taken. The team should determine the frequency of monitoring the preventative measure taking into account the rate of product throughput at that operational step, the reliability of the control and of the monitoring device. As part of the monitoring system it is necessary for the team to establish corrective action procedures for the preventative measures at each CCP (H.10). When the critical limits of a preventative measure are exceeded, action should be taken to restore the control to its target level and to ensure that a defective product does not reach the consumer. All staff working with the product at a given stage of the operation should be aware of the corrective action procedures to be followed for CCPs at that stage. It is particularly important that staff know to whom they should report out-of-line results. Once the HACCP system has been planned and is being implemented it is necessary for the team to establish a verification programme to determine that it is functioning effectively (H.11). The programme should ensure that all facets of the HACCP system are verified over a specified period. The frequency of verification for each section should be set according to the need to keep the system operating efficiently. There are various activities which may be used

in the verification programme. The CAC recommends auditing, data analysis, random sampling and testing and specifies the following activities:

- review of the HACCP system and its records;
- review of deviations and product dispositions;
- confirmation that the CCPs are under control.

Performance assessment should clearly be part of any management system, and the general requirements for an integrated management system are described in section 4 of the IMS framework (see appendix 1). The provisions described here for the HACCP system meet the requirements described in the framework.

Throughout the development of HACCP, the documentation required for planning, implementation, maintenance and verification has not been formalized; this helps to maintain flexibility in the application of the system. The CAC recognizes that 'efficient and accurate record keeping is essential' but states that it should be aligned to the size and type of the operation (H.12). The documented progress of a HACCP system is referred to as a HACCP plan. The HACCP plan is compiled as the system is devised. It is a portfolio of the design of the system and includes the operational details for implementing, maintaining and verifying it (see figure 5.2). Each process within the system may be summarized in a HACCP control chart. This is a matrix which summarizes the elements of HACCP for one process as shown in figure 3.2. All documentation referred to in the chart should be referenced using a system which is consistent throughout.

The concept of continual improvement lies at the heart not only of quality systems such as ISO 9001:2000 but of any modern management system. As described in section 5 of the IMS framework (see appendix 1) this is achieved through 'the use of the policy objectives and preventative actions and management review'. All such activities should be seen not merely in the negative sense of preventing nonconformities but as a positive means of continual improvement throughout the organization.

There are many variations in the detail of HACCP control charts produced by different authors. It is recommended that each HACCP team should include the items which they consider most suitable for their system. In the HACCP control chart shown in figure 3.2, the CCP column includes control points (CPs). These are stages in the process where there is a control in place but it is not critical to the safety of the final product. It provides an intermediate control which is considered necessary for that process.

Support systems for the HACCP system (H.13 – H.14)

CAC (2001b) addresses the need for a programme of training to be undertaken by an organization establishing a HACCP system (H.13). The training should include all personnel who are working with the system, although the depth of instruction will vary for different groups. It is recommended that the training should include courses on the establishment of a HACCP system as well as procedures and work instruction for the stages of the operation at which CCPs occur.

The recommendations of the CAC for the establishment of a HACCP system are shown in Figure 3.1. It is deemed necessary by other authors that support systems should be added to the HACCP system by the organization (Mortimore and Wallace, 1998). These include laboratory accreditation, supplier audits and preventative maintenance (H.14). To retain flexibility, the CAC has avoided a prescriptive approach, but this allows considerable latitude in the interpretation of the recommendations. The development of ISO/CD 22000 will ensure that HACCP systems are efficiently and effectively managed. In countries that have incorporated the HACCP system into their food law, third party auditing is by the national regulatory authority. Some private food control companies include HACCP auditing among their services, but the approval they give is limited to their commercial status. The standing of private companies is enhanced by their amalgamation into national bodies and in turn by these combining to form international consortia. The use of internationally accepted standards and accreditation by international organizations is gradually reducing the degree of variation in the interpretation of the HACCP concept that was a feature of its early application.

Figure 3.2 Example of a HACCP control chart (CAC 2001b)

HACCP control chart

Process _____

Reference and issue no. _____ Approved _____ Date _____

Process flow		Hazards micro-biological, physical, chemical	CP CCP	Preventative measures (controls)			Monitoring			Corrective action	Personnel responsible
No.	Step			Identification and procedure	Target level	Critical limits	Procedure	Frequency	Records		

4. Food risk

Risk and risk analysis in the food industry

Some form of risk is present in every operation undertaken by an organization. In this book, however, the term 'risk' is used to denote the chance or possibility that something of an adverse nature, caused by a hazard present in food, will affect either the health of the consumer or the acceptability of the product. A wider view of risk is given in appendix 4. Food hazards are grouped as microbiological, chemical or physical. In each of the three groups the hazards fall into two main categories. In one category there are those hazards that have the potential to cause an adverse effect on the health of the consumer, and in the other those which, if not controlled, will affect the quality of the product. Some hazards may cause more than one type of risk in food. For example, rodent droppings may be classed as microbiological with the potential to cause disease and also, as a physical hazard because, if visible, they will be classed as foreign matter. When this double effect occurs the hazard should be controlled under the heading of the more serious risk to the consumer, but the second effect should also be documented.

Across all the groups of food hazards, those which have an adverse effect on health, present the greatest risk. Within the groups, risks to the consumer from microbiological pathogens and their toxins are currently receiving attention from regulatory authorities, international health and agriculture organizations and food research institutes. Chemical risks to human health via food have also been intensively investigated and are similarly addressed by food organizations and are controlled by specific legislation in many countries. Physical hazards are usually covered by general laws for the control of food contamination. When contamination by a physical hazard occurs it is usually an isolated incident which can be traced to a breakdown

in good manufacturing practice (GMP) or good hygiene practice (GHP). Examples of physical hazards are bone splinters in meat products or glass shards in products packed in glass containers. Both hazards could cause lacerations, damage to teeth and choking.

The process of risk analysis, by which risk is assessed, managed and communicated, is well established in many areas of commerce and industry, but its application to food control is currently being developed. The FAO/WHO are addressing the issue through JEMRA (Joint Expert Meetings on Microbiological Risk Assessment) together with the CCFH (Codex Committee on Food Hygiene). Similarly, the FAO/WHO set up the IPCS (International Programme on Chemical Safety) in 1972 to investigate levels of chemicals in food and a great amount of evidence has been compiled by the various expert committees appointed (FAO/WHO 2002). Recently, the European division of the International Life Sciences Institute, ILSI Europe, has published a comprehensive report on Risk Assessment of Chemicals in Food and Diet, with a special section on risk characterization, under the project Food Safety in Europe (FOSIE) (Barlow et al 2002, Renwick et al 2003).

The work carried out by the FAO/WHO on the use of risk analysis to promote food safety has largely been designed to create a system for national and international regulatory bodies. As yet risk analysis has been little used in the food industry, but it has benefits which should be incorporated into the safety system of all food organizations, even those manufacturing so called low risk products. These benefits include the use of information drawn from national and/or international data banks, thus introducing into HACCP a scientific and systematic method of assessing product risk at all stages of processing. The information is quantitative, or ranked if qualitative, which makes possible the prediction of risk throughout the process. An important benefit is that decisions taken regarding the level of risks should be transparent and not influenced by commercial considerations. In adapting risk analysis for use with food it has been stressed that risk assessment should be conducted separately from the two subsequent steps – risk management and risk communication. Risk assessment requires a scientific input from a microbiologist and a chemist with expertise in the field relating to the product and the process and the ability to collect and interpret relevant scientific data. It also requires information about the raw materials, previous processing and subsequent treatment of the product after completing this stage of processing and finally being eaten. Historical and current information from engineers and technical managers is also required but the decisions taken should be science-led and independent.

The three steps of risk analysis have been adapted for use with food as shown in table 4.1

Table 4.1 The process of risk analysis in relation to food safety (FAO/WHO 2002)

Risk analysis applied to food safety	
Risk analysis The process of determining, for each hazard under review, the probability of its occurrence and the severity of its effect on consumers – risk assessment. The actions required to control each hazard are decided upon and implemented – risk management. Information on these together with the potential outcome from each hazard, if not controlled, is communicated to all persons concerned – risk communication.	
Preliminary risk management activities	The reasons for undertaking the risk assessment – statement of purpose, and an initial assessment of the potential severity of the hazards at each product/process step under review – risk profile is carried out. The decision to perform a full risk analysis or to work from the risk profile is then taken.
Statement of purpose	The reasons for carrying out the risk assessment should be clearly defined.
Risk profile	This is a preliminary review of the level of risk associated with the hazard. It contains all the steps of risk assessment but is carried out using published data to assess if the severity of the risk requires a full risk assessment being performed.
Risk assessment:	An investigation carried out to identify and characterize each potential hazard in the product/process step under review. Risk assessment should be carried out independently of risk management and should include hazard identification, hazard characterization, exposure assessment and risk characterization.
Hazard identification	In a HACCP system, hazard identification is determined from the flow diagram(s) and will already have been carried out when compiling the risk profile for each hazard. If the full risk assessment is to be made additional information may be required.
Hazard characterization	The evaluation of the agent causing the adverse health effects associated with each hazard. The characterization will include quantitative and qualitative information.
Exposure assessment	The quantitative and/or qualitative assessment of the likely intake of the hazards under review from contaminated food by various groups in the population.
Risk characterization	The process, of determining the probability of the occurrence and severity of potential adverse health effects in a given population. It is based on hazard identification, hazard characterization and exposure assessment.
Risk management	The management of the risk to ensure that it is controlled at an acceptable level. It requires management to evaluate the risk, implement suitable controls and to monitor and review the controls put in place.
Evaluation of risk management options	Having characterized the risk, the management evaluates and establishes the preventative measures to be taken against the potential outcome.
Implementation of risk management decisions	The preventative measures are implemented and monitored. Records are kept of all the monitoring processes.
Monitoring and review	This is necessary to determine the efficiency and effectiveness of the preventative measures in place and to provide evidence on which to base a programme of continuous improvement.
Risk communication	For the food safety and quality control system to operate effectively, efficient and interactive communication between the technical and managerial staff and the food operatives is essential. Risk communication is not shown as a separate item in the *Draft Principles and Guidelines for incorporating microbiological risk assessment* (FAO/WHO 2002).

Microbiological risk assessment

This is a short introduction to microbiological risk assessment (MRA) and it is recommended that the reader wishing to undertake such analysis consults the texts referenced. MRA is being used increasingly by health authorities to determine the level of risk associated with specific foods under given conditions and it is the preferred approach to food safety legislation by the European Union. Collating and interpreting data on a national and international scale for all food-borne pathogens and their toxins are continuous tasks. Information should be continually compiled as new evidence emerges. To carry out a microbiological risk analysis requires knowledge of the microbiology of the raw materials, the process and the product. It also requires information on the possible adverse health effects of the final product on consumers in general and on vulnerable groups in particular.

Some distinctive approaches to risk assessment in food have been published (CAC 2001d), Mortimore and Wallace 1998; Mitchell 2000, Voysey 2000, FAO/WHO 2002). It is agreed, however, that, before beginning a full risk assessment on a food product, a preliminary review of the level of potential risk should be conducted. Voysey (2000) gives a technique for carrying out such a review termed a 'risk profile'. Having decided from the risk profile that a full risk assessment is required, a statement of purpose should be prepared. This should include the specific reason for carrying out the risk assessment and the form in which the conclusions (output) of the assessment will be made. The output should identify the food product, the microbiological disease agent and the form in which the information will be expressed in the final report. The information may be expressed in various ways such as an estimate of the prevalence of a particular form of illness or an estimate of the annual rate of the illness (incidence of human illness per 100,000) or an estimate of the rate of illness and severity per eating occurrence (CAC 2001d, Voysey 2000).

MRA (microbiological risk assessment) comprises four components to be addressed: hazard identification, exposure assessment, hazard characterization and risk characterization. Hazard identification is familiar to those already working with the HACCP system. It is contained in the first of the seven principles – 'conduct a hazard analysis of all potential hazards at each process step' – and links back to Task 2 – 'describe the product' – (CAC 2001b). In this context hazard identification is the determination of the microbiological agents that are the potential cause of health hazards in the product under analysis. Identifying these hazards requires expert knowledge of the process, the product and the related microbiology. Accurate identification of the micro-organisms determines the value of the risk

assessment. It yields a list of potential hazards caused by microbiological agents which are then described.

Once the potentially hazardous microbiological agents have been identified as accurately as possible, they are described under exposure assessment and hazard characterization. In exposure assessment the level of microbiological pathogens or their toxins in the food at the time of consumption is determined. It is a measure of the level of contamination by individual micro-organisms in the food when it is eaten. Factors that influence this include the taxonomic characteristics of the micro-organisms, the processes applied to the food and the degree of variability of each stage within a process, and the behaviour of the food under conditions of use and abuse together with dietary information and consumption patterns of the consumers. Thus compiling and analysing information to determine exposure assessments involves consulting a comprehensive range of sources. No matter how efficient the survey, however, the biological nature of the factors under consideration and differences in processing techniques mean that there will be uncertainty and variability in the information collected. In this context variability and uncertainty have precise meanings. Uncertainty is 'an indication of the range of values that are consistent with all of the observations, data and expert judgement, and that with varying degrees of credibility can be attributed to the value, assumption or conclusion'. Variability is 'an indication of the range of individual values that are expressed as a summary value' (Voysey 2000). The credibility of an exposure assessment depends on the accuracy of the sources consulted and how closely they are applicable to the food under analysis.

Having classified the micro-organisms causing the hazards and having determined their potential effects on different groups of consumers, the severity, duration and type of illness which may occur are determined under hazard characterization. Here the factors to be considered include variations in the behaviour of the microbiological agent and the characteristics of the food such as composition, temperature of storage, degree of heat treatment during cooking and conditions of holding immediately before consumption. It is recommended that a dose-response assessment should be made if suitable data is available. A dose-response assessment 'determines the relationship between the exposure of a consumer to a hazard (dose) and the severity and/or frequency of associated adverse health effects (response)' (Voysey 2000). This parameter has been developed for use in the chemical contamination of food but in microbiological hazard characterization considerable variability and uncertainty can be expected in both the dose and the response.

The information from the previous steps is used to determine the risk characterization, that is the likelihood of harm to the consumer from the consumption of the food specified. If all the information used in the

exposure assessment and hazard characterization determinations is quantitative, then the results will be mathematical expressions and the risk characterization may be calculated and expressed mathematically or graphically. In practice it is unlikely that all the information will be quantitative, and qualitative observations are then used as appropriate. Qualitative observations lack the precision of quantitative data but they can be ranked to give a measure of their significance. The inclusion of qualitative information in a risk assessment will mean that it is not possible to apply a mathematical calculation to the final conclusion and that the estimate of the risk is qualitative not quantitative. Preparing the final report on the risk assessment requires statistical expertise to ensure that the uncertainty and variability inherent in the information is correctly evaluated. But it also requires input from an expert in the food product and the method of processing under analysis. As stated in Voysey (2000) Guideline No. 28 'It is essential to ensure that the results of the risk assessment accord with common sense and with experience'.

CAC (2001d) has identified eleven underlying principles on which a microbiological risk assessment should be based. These are given in figure 4.1.

Risk management

Having completed a microbiological risk assessment the next step is to implement a management system that will control the risk throughout all processing operations until the food is consumed. The most widely used system in the food industry is HACCP. The introduction of risk assessment into the HACCP system involves wider investigations during the hazard analysis than have previously been undertaken. It may also be necessary for the enterprise to source additional expertise and will require more extensive documentation than the previous form of HACCP.

Risk communication

The final report of the risk assessment should be detailed, objective and transparent. Thus it is a useful tool for discussions with regulatory bodies and with customers. Information contained in it can also be used for training purposes. It is essential, however, that the risk assessment measures the current situation. To present information from an obsolete report on an assessment carried out prior to changes in the process, or from some years previous, is embarrassing and dangerous. The regular review of the HACCP system should include the risk assessment.

Figure 4.1 General principles of microbiological risk assessment

1. Microbiological risk assessment should be soundly based upon science.
2. There should be a functional separation between risk assessment and risk management.
3. Microbiological risk assessment should be conducted according to a structured approach that includes hazard identification, hazard characterization, exposure assessment and risk characterization.
4. A microbiological risk assessment should clearly state the purpose of the exercise, including the form of risk estimate that will be outputted.
5. A microbiological risk assessment should be carried out objectively and should not be influenced by commercial considerations.
6. Any constraints that impact on the risk assessment such as cost, resources or time, should be identified and their possible consequences described.
7. The risk estimate should contain a description of uncertainty and where the uncertainty arose during the risk assessment process.
8. Data should be such that uncertainty in the risk estimate can be determined; data and data collection systems, should, as far as possible, be of sufficient quality and precision that uncertainty in the risk estimate is minimized.
9. A microbiological risk assessment should explicitly consider the dynamics of microbiological growth, survival and death in foods and the complexity of the interaction (including sequelae) between human and agent following consumption as well as the potential for further spread.
10. Wherever possible, risk estimates should be reassessed over time by comparison with independent human illness data.
11. A microbiological risk assessment may need re-evaluation, as new relevant information becomes available.

(CAC 2001d)

Microbiological criteria

A microbiological criterion for food is defined as 'the acceptability of a product or food lot, based on the absence or presence, or number of micro-organisms including parasites, and/or the quantity of their toxins/metabolites, per unit(s)

of mass, volume, area or lot' (CAC 2001c). Microbiological criteria are used by regulatory bodies to define and determine compliance of foods to microbiological standards. They are also used by the food industry in the design of new products, to establish microbiological norms for the raw materials, the process and the finished food. Microbiological criteria should be determined using reference methods which have been internationally approved. These methods are often not suitable for monitoring a HACCP system because they do not give an instantaneous or rapid result. They can be used, however, to determine the compliance of raw materials, intermediate and end products to the required standard and therefore in the validation of the HACCP system. When establishing microbiological criteria consideration should be given to the points set out in figure 4.2.

Figure 4.2 General considerations concerning principles for establishing and applying microbiological criteria

1. The evidence of actual or potential hazards to health
2. The microbiological status of the raw material(s)
3. The effect of processing on the microbiological status of the food
4. The likelihood and consequences of microbiological contamination and/or growth during the subsequent handling, storage and use
5. The category of consumers concerned
6. The cost/benefit ratio associated with the application of the criterion
7. The intended use of the food

(CAC 2001c)

From the information in figure 4.2 it will be apparent that microbiological criteria are necessary when preparing risk assessments for food products. In the determination of microbiological criteria, microbiological limits are set for the number of micro-organisms which are acceptable in the food product in question. The limits take into account the risk associated with the micro-organism under consideration, conditions of handling and storing the food, the likelihood of uneven distribution of micro-organisms in the food and the variability inherent in the analytical procedure. The sampling plan should define the probability of detecting the micro-organism under test in a specified lot and should include statistical performance characteristics (CAC 2001c).

Chemical risk assessment

Chemical risk assessment is carried out to determine the risk associated with chemicals that may occur in food either as foreign matter or in excess of legally permitted quantities. These include cleaning chemicals, pesticides, fertilizers, herbicides, veterinary residues, growth-promoting substances, allergens and food additives (Mortimore and Wallace, 1998). Many of the chemicals present, apart from additives, enter food during primary production and much attention has been given to eliminating or controlling them to a safe level in the primary product (CAC 1999).

Chemical food additives are controlled by government regulations in most countries and information on permitted quantities is readily available. Benford (2001) gives an excellent introduction to chemical risk analysis. Detailed information is available in CAC 1999 and is presented by Barlow et al (2002) and Renwick et al (2003) reporting on the European Union concerted action programme, *Food safety in Europe (FOSIE): Risk assessment and risk characterization of chemicals in food and diet*.

5. Combining HACCP and ISO 9001:2000

ISO 15161:2001

ISO 15161:2001, *Guidelines on the application of ISO 9001:2000 for the food and drink industry*, has been prepared to assist food handling organizations streamline food safety and food quality control, by managing both together as a single system, based on the requirements of ISO 9001:2000 and HACCP. The combined food safety-food quality system is managed by ISO 9001:2000 but incorporates the elements of HACCP. Retaining the HACCP elements makes it possible to selectively trace food safety control through the combined system. Further, the HACCP requirement for the microbiological investigation of the product and the sequential analysis of the processing operation using microbiological risk assessment are strong techniques for the control of food safety. In countries where the HACCP concept has been incorporated into national food law, even if the acronym is not actually used, it enables the regulatory authorities to audit the combined system for food safety control according to the HACCP concept. It may also be of use when the implementation of a HACCP system is written into a supplying contract. The guidelines and recommendations for HACCP issued by the CAC have been discussed in chapter 3. If the reader is unfamiliar with ISO quality management systems it is recommended that the standard ISO 9001:2000 is read prior to this chapter as clauses 1 to 3 are not discussed here. The notes in ISO 15161:2001 should also be studied, as the application of the guidelines to individual systems in different sectors of the food industry will require specific interpretation. Clauses 4 to 8 of ISO 9001:2000 are mapped against HACCP in figure 5.1. Each of these five sections is then discussed in relation to the incorporation of the HACCP system.

Figure 5.1 Clauses 4 to 8 of ISO 9001:2000 mapped against the elements of HACCP

ISO 9001:2000	HACCP (CAC 2001b)
4. The management system General requirements	H.iii Recommended scope of the system H.iv CCPs H.v There should be a separate HACCP system for each specific operation
Documentation records	H.12 Documentation
5. Management responsibility Customer needs and requirements Legal requirements Policy Objectives Quality planning Quality management system – general requirements Responsibility and authority Management representative Internal communication The quality manual Control of documents Control of quality records Management review	H.ii Management commitment H.vi The system to be reviewed and amended H.vii The system to be flexible and aligned to the nature and size of the operation H.1 Assemble the HACCP team Define the scope of the system H.2 Describe the product H.3 Identify the intended use H.4 Construct flow diagrams H.5 Confirmation of the flow diagrams H.6 Conduct a hazard analysis and set controls for each hazard H.7 Determine the critical control points (CCPs) H.8 Establish the critical limits for each CCP H.12 Documentation
6. Resources Resource management – general Assignment of personnel Competence, training, qualification and awareness Information Infrastructure Work environment	H.i Prerequisites for the application of HACCP – food hygiene H.5 Confirmation of the flow diagrams H.9 Establish a monitoring system at each CCP H.13 Training H.14 Supporting systems
7. Product realization General requirements Customer related processes Customer communication	Customer related processes: H.2, H.3
Design and development – general Design and development inputs Design and development outputs Design and development review Design and development verification Design and development validation Control of changes	Design: H.i, H.2, H.3, H.4, H.5, H.6, H.7, H.8, H.9, H.10, H.11, H.12 H.13, H.14
Purchasing – general Purchasing information Verification of purchased product/services	Purchased product/services: H.i, H.2, H.3, H.4, H.5, H.6, H.7, H.8, H.9, H.10, H.11, H.12, H.13.
Production and service operations – general	Production and service operations: H.4, H.5, H.6, H.7, H.8, H.9, H.10, H.12, H.14

Identification and traceability	Identification and traceability: H.4, H.5, H.6, H.7, H.8, H.9, H.10, H.12, H.14
Customer property	No reference
Handling, packaging, storage, preservation and delivery	Handling, packaging, storage, preservation and delivery: H.i, H.2, H.3, H.4, H.5, H.6, H.7, H.8, H.9, H.10, H.11, H.12, H.13, H.14
Validation of processes Control of measuring and monitoring devices	Validation of processes and control of measuring and monitoring devices H.vi, H.6, H.7, H.8, H.9, H.10, H.11, H.12
8. Improvement Measurement, analysis and improvement – general Measurement and monitoring of system performance Measurement of customer satisfaction Internal audit Measurement and monitoring of processes Measurement of product and/or services Control of nonconformity – general Nonconformity review and disposition Analysis of data for improvement Improvement – general requirements Improvement – corrective action Improvement – preventative action	H.vi The system to be reviewed and amended H.9 Establish a monitoring system H.10 Establish corrective action at each CCP H.11 Establish a verification procedure
Note: The elements of the HACCP system do not correspond precisely to the sub-sections of ISO 9001:2000. In the above table, the elements are generalized for sections 5, 6 and 8. In sections 4 and 7, some degree of specificity has been introduced but it will be noted that the same elements are cited repeatedly. This is because HACCP is written from the aspect of the safety of the product only. The details of managing the system are left to individual organizations, or sectors of the industry, to devise.	

The quality management system (ISO 9001:2000, clause 4)

Product safety issues are automatically incorporated into ISO 9001 when the standard is established in a food organization. The standard of food safety in the end product is of paramount importance to the customer and therefore the control of food safety is a major and essential part of management in the organization. Thus, under 'General requirements' (4.1) the processes needed for the quality management system in general will include those that are concerned with food safety. They should be clearly identified in the documentation. Where the same processes are used to control product safety and quality they should be identified under food safety. The documentation requirements (4.2.1) for a combined system that is using the elements of HACCP for food safety control will include a HACCP plan (see figure 5.2).

Figure 5.2 Documentation to be included in the HACCP plan for a combined HACCP/ISO 9001:2000 system

HACCP plan ref.	HACCP element and working reference		Documents to be referenced or included in the HACCP plan
HP1	H.1	The HACCP team	Reference the structure of the HACCP team and its responsibilities and activities
HP2	H.ii	Management commitment	Reference the hygiene and food safety policy and management responsibilities for food safety
HP3	H.i	Food safety legislation and codes of practice	Reference the statutes, regulations, guidelines and specifications relating to food safety that are used in the system
HP4	H.2, H.3, H.iii	End product Ancillary and intermediate products (if required) Raw material – organic and inorganic Packaging	Reference the description, intended use, microbiological criteria and risk assessments for all materials and products
HP5	H.4, H.5, H.iii, H.v	Verified flow diagrams of each operation after on-site inspection	Include a verified flow diagram for each operation showing the process parameters at each step with reference to the operating procedures and work instructions
HP6 HACCP Control Charts	H.6	Hazard analysis and the controls for each hazard	* Include a HACCP control chart for each operation based on the information from HP1, HP2, HP3 HP4 and HP5
HP7	H.7	Determine the CCPs	* On the HACCP control chart (HP6) reference the CCPs Note Include target levels
HP8	H.8	Determine the critical limits of the controls at each CCP	* Determine the critical limits of the controls at each CCP and enter them onto the HACCP control chart (HP6) Note Include target levels
HP9	H.9	Establish a monitoring system for each CCP	* Enter summary of monitoring, with references to procedures and records, onto the HACCP control chart (HP6)
HP10	H.10	Establish corrective action	* Enter summary of corrective action, with references to procedures and records, into matrix (HP6)
HP11	H.11	Establish verification procedure	Enter summary of verification, with references to procedures and records, into matrix (HP6)

HP12	H.12	Establish documentation and record keeping	Reference any other documentation applicable to food safety from the combined system which is not included under the headings HP1 to HP14
HP13	H.13	Training	Reference food hygiene and HACCP training from the combined system
HP14	H.14	Other components of the combined system which have a bearing on food safety	Reference components such as: laboratory accreditation supplier quality assurance calibration of instruments preventative maintenance visitor control
* The chart on which the summarized information from items HP6 to HP11 is entered, is called a 'worksheet' by the CAC and a 'HACCP control chart' by other authors. When preparing the chart, the organization should adapt it to meet specific requirements of the organization and of the combined food/safety quality system.			

Within the combined system the HACCP approach is extended to include food quality hazards. In such a system the descriptions of the products and their use will include quality parameters, the same flow diagrams will apply and hazard analysis will be carried out for quality control points as well as safety CCPs. The quality control points may be abbreviated to QCPs (Mortimore and Wallace, 1998).

The quality manual (4.2.2.) should describe the reason for including the elements of HACCP in the system and state the identification method used to denote the documentation relating to food safety. The HACCP plan may either be included in the quality manual or referenced in it and held separately. The control of documents (4.2.3) to the standard required for an ISO quality system brings food safety to a level not always achieved when HACCP stands alone. It also alerts the organization to the full range of documents, which should be controlled. Apart from the documentation arising directly from the system, these include specifications for supplied material, customer specifications, packaging designs and externally generated documents. Current food legislation forms a particularly important section that should be efficiently updated and maintained at all times. The legislation will include general and sector specific food law of the country of location and of importing countries, guidelines and codes of practice. When combining two systems into one, as in this case, care should be taken to avoid document duplication. An important aspect of record control in food safety management is the period for which the records are retained. For some products this is governed by legal requirements and for all, the retention period should be at least the length of the maximum shelf life. Customer claims can be made against products after their shelf life has

expired, however, and the possibility of this should be taken into account when determining the retention period of all records relating to food safety.

Management responsibility (ISO 9001:2000, clause 5)

The commitment of senior management is essential for the efficient operation of the combined food safety/quality control system (5.1). This is referenced in both ISO 9001:2000 and the elements of HACCP (H.ii). To demonstrate their commitment in a combined food safety-food quality control system, senior management should:

- focus on customer requirements;
- prepare a joint food safety-quality policy;
- ensure that the objectives of food safety and quality are established;
- make the necessary resources available for the implementation of the system;
- promote improvement of the system through management reviews.

The focus on customer requirements (5.2) is fundamental to the modern food industry. Not only should food be aesthetically and gastronomically pleasing, it should also be packaged to maintain safety and quality until it is consumed. The food safety/quality policy (5.3) should specify the sector of the food industry in which the organization operates and also the processes carried out. Many food organizations do not cover the full range of food-handling operations required to bring food from primary production to the final consumer. The limits of the operations undertaken by the organization should be defined and awareness of the extended responsibility for product safety beyond those limits should be stated. Planning for product safety-quality (5.4) is an integral part of a food operation. Most food raw materials are expensive and losses due to inferior consignments or inefficient processing can have serious economic results. But, even worse, if the organization is connected with either fact or rumour relating to food safety it will have great difficulty in surviving the incident. When planning product safety the nature of the hazards considered to be critical for the safety of the products should be identified (5.4.1; H.2 and H.3). When planning the food safety/quality system, the HACCP plan becomes a 'quality plan', particularly the hazard analysis and determination of the CCPs. These two elements establish the food safety inputs into the system as they determine the level of the preventative measures and their control (5.4.2).

In the section dealing with management responsibility, authority and communication (5.5) senior management is required to appoint a representative to take responsibility for the system – the management representative for quality (5.5.2). The HACCP system prescribes the establishment of a team of specialists, either in-house or external, who will formulate the HACCP plan (H.1). It is logical for the same person to be both the management representative for quality and the leader of the HACCP team with the authority and responsibilities of both positions. Establishing a team, drawn from the technical, quality assurance, production, engineering and design and development departments, to lead the food safety/quality system means that senior operatives and middle and junior management are actively involved in its planning, implementation, maintenance and improvement. Among other benefits, this will assist in setting up effective communication within the organization (5.5.3) and will be a source of hands-on information for management reviews (5.6).

Resource management (ISO 9001:2000, clause 6)

Adequate provision of resources to implement, maintain and improve the food safety/quality system, and give improved customer satisfaction, is a function of senior management (6.1). In the HACCP system it is recommended that the HACCP team should advise on resource requirements (H.1). This can be useful as the team will have comprehensive knowledge of the whole operation including information from external sources. The management of human resources for a combined food safety/quality system is given in ISO 9001:2000, 6.2. In a combined system this will cover the training required for the HACCP system (H.13).

The infrastructure and work environment (ISO 9001:2000, 6.3) covers the following sections from the *Recommended International Code of Practice General Principles of Food Hygiene* (CAC 2001a):

- section III primary production;
- section IV establishment: design and facilities;
- section VI establishment: maintenance and sanitation;
- section VII establishment: personal hygiene;
- section X training.

The other relevant sections of the above principles are covered in clause 7 of ISO 9001:2000. They are:

- section V control of operation;
- section VIII transportation;
- section IX product information and consumer awareness.

Product realization (ISO 9001:2000, clause 7)

Sub-clause 7.1 on product realization establishes the process requirements of the operation and the criteria for product acceptance. In the food industry, hazard analysis and critical control point determination – as recorded in the HACCP plan – forms the basis on which to develop the operating procedures, work instructions and records required to control the safety and quality of the products. The use of microbiological criteria and risk assessment, as applicable, in the HACCP plan gives quantified information from which the controls may be determined.

The food industry is familiar with the demand to meet customer specifications including delivery and post delivery requirements (7.2.1 and H.iii). The presence of immuno-compromised, and allergy- and disease-sensitive groups within the end consumer market has resulted in statutory and regulatory requirements for the labelling of many food products. Identification of the use of the product, as specified in the HACCP system, is of use here (H.3). As food products are supplied to specification, which may be originated by the customer or by the organization, the requirement to review this specification against the goods to be supplied before the order is accepted is a good management practice.

Customer communication is well developed in the food industry and is covered in section IX of *Recommended International Code of Practice General Principles of Food Hygiene* (CAC 2001a) (7.2.3). Design and development to ISO 9001:2000 requirements will incorporate food safety controls for the new product and its processes and these will be documented in the HACCP plan (7.3). The control of raw materials and other material purchased by a food handling organization is well established (7.4). Many operate supplier quality assurance (SQA) systems and these can be absorbed into ISO 9001:2000. Information from the HACCP plan regarding the susceptibility of raw materials to adverse health agents is important here (H.2).

The control of food safety by the use of documented process procedures is a requirement of sections V and VIII of the *Recommended International Code of Practice General Principles of Food Hygiene* (CAC 2001a) and will be absorbed into ISO 9001:2000 under 'Control of production and service provision' (7.5.1). 'Validation of processes for production and service provision' (7.5.2) will strengthen HACCP requirements to verify the system

(H.11) by confirming that the operational procedures, parameters and personnel are suitable and functioning to an acceptable standard within the system. Product identification and traceability (7.5.3) is essential at all stages of the food chain and customers and regulatory authorities increasingly make all sectors of the food industry aware of their responsibility for this. The use of customer property (7.5.4) in the form of packaging and gift inserts is common in some sectors of the food industry. Including the control of this in the food safety/quality system strengthens the prevention of adverse health agents from gaining access to food products.

Measurement and test activities are part of product realization; as is accreditation of the on-site laboratory (Mortimer and Wallace, 1998). The control of monitoring and measuring devices (7.6), which includes the calibration, identification and protection of the instruments used for this purpose, formalizes measurement control throughout the processing operation. This is not specified in the HACCP system proposed by the CAC, although various authors recommend it (Mortimore and Wallace, 1998). The need to calibrate instruments varies in different sectors of the food industry. Under this clause, and in sub-clauses 6.2.2 and 8.2.4 of ISO 15161:2001, special mention is made of the use of sensory evaluation by the food industry. It is recommended that staff carrying out this type of analysis receive appropriate training and that tests are carried out according to international standards such as ISO 6658 and ISO 10399.

Measurement, analysis and improvement (ISO 9001:2000, clause 8)

In the HACCP system, the control of nonconforming products is addressed in principle 4 and conformity in the system in principle 6 (H.9 and H.11). This subject is covered in clause 8.3 of ISO 9001:2000. In the food industry the control of nonconforming products is important, not only in relation to quality standards, but to ensure that no potentially adverse health agents are allowed into the public domain. The disposition of nonconforming foods should be documented and controlled and any legal requirements met. Quantifiable information on food products is available from the monitoring practices carried out as part of food handling operations (8.4 and H.9). Analysis of such data is used in ISO 9001:2000 to provide information on levels of customer satisfaction, conformity of products, opportunities for preventative action and supplier performance. Continual improvement of the system is emphasized throughout ISO 9001:2000 and is implied in HACCP principle 6 (8.5 and H.11). If the global standard of food safety is to

advance then the control systems operated by food handling organizations should show progressive improvement at national and international level. A combined food safety/quality system offers a realistic opportunity of achieving this if it uses the HACCP concept managed by ISO 9001:2000, with its strong bias towards continual improvement.

In the combined system, the elements of HACCP are contained within the ISO 9001:2000 system. A method of identifying them, using a HACCP plan, has been described in Figure 5.2. As the documents of the HACCP plan are part of the working system they may be identified in the plan by reference, or in an abbreviated form, only. The HACCP elements of the combined system may be inspected selectively by identifying them in the HACCP plan and auditing according to the reference system (see figure 5.2).

6. Food safety and quality in an IMS

Introduction to the IMS

This chapter considers in more detail how the system for the management of food safety and quality fits into the framework of the IMS. The framework for the IMS, which is shown in appendix 1, is reproduced here with commentary on each of the main elements.

IMS section 0, the basis of the system

Section 0 describes the basics of the management system. The requirement to identify the processes needed for the management system, and the means to ensure that these are effective, are shown at the beginning. This is precisely in line with the requirements previously discussed for the effective implementation of a system for food safety and quality and the FSQ system is included as part of the overall management of the organization. The organization should establish, document, implement and maintain a management system and seek to continually improve its effectiveness.

The organization should:

- identify the processes needed for the management system and their application throughout the organization;
- determine the sequence and interaction of these processes;
- determine criteria and methods needed to ensure that both the operation and control of these processes are effective;
- ensure the availability of resources and information necessary to support the operation and monitoring of these processes;

- monitor, measure and analyse these processes; and
- implement actions necessary to achieve planned results and continual improvement of these processes.

IMS section 1, policy

Section 1 on the subject of policy is similarly of general applicability in any management system. The statement here is based on the wording of ISO 9001:2000, but is reproduced in similar form in other standards and is a common-sense statement of the intentions of the organization. The FSQ policy forms part of the organization's policy.

Senior management should ensure that the policy:

- is appropriate to the organization;
- includes a commitment to comply with all relevant requirements and continually to improve the effectiveness of the management system;
- provides a framework for establishing and reviewing objectives;
- is communicated, where appropriate, and is understood within the organization; and
- is reviewed for continuing suitability.

IMS section 2, planning

Planning is at the heart of the FSQ system. The organization should establish a process for identifying those aspects of its operations which need to be controlled and/or improved in order to satisfy the relevant interested party/parties. This includes research and design. Where appropriate, legal requirements should be identified.

As previously explained in IMS terminology, 'aspects' are those features of a process designed to produce a desired outcome on which the result depends. In terms of food safety, these are the equivalent of hazards in that they are essential to the success of the process. It is necessary to identify all the processes and the risks associated with each of them. The identification of processes, their mapping and a complete understanding of how they interrelate, is an essential step in the installation of any management system. The effect that an aspect has on the outcome is known as an 'impact'.

A significant difference between FSQ and other management systems is in the scope. FSQ is concerned only with the safety and quality of the product. It does not concern itself with other activities of the organization which do

not affect the product. It is not concerned with sales or finance or any other non-food activities which may go on within the organization. In this it contrasts with occupational health and safety, for example, which involves all employees, or with the environment which involves all activities of the organization, and the effects on other stakeholders. It should be noted, however, that in the food industry employees with only slight contact with the process or product are considered to be food handlers. These include engineers, drivers, contractors, visitors and in some cases office staff. Care should be taken to ensure that the work of all these people is examined for food materials contact.

The organization should establish a process for prioritizing its aspects, so that those which make a significant impact are readily identified for control measures where this is appropriate. This will be recognized as the identification of CCPs (as described in chapter 2), in the terminology of food safety, the steps in the operation and where they should be controlled. As well as safety control, attention should be given to quality standards and care should be taken when prioritizing aspects that both types of control are adequately met.

Senior management should ensure that the objectives, including those needed to meet requirements for product and/or service, are established at relevant functions and levels within the organization. The objectives should be measurable and consistent with the policy.

This will be recognized as the establishment of the critical limits of the control for them to be effective in controlling or eliminating the hazard.

The organization should ensure the availability of adequate human, infrastructure and financial resources. It should determine and provide the resources needed:

- to implement and maintain the management system and continually improve its effectiveness; and
- to enhance satisfaction by meeting requirements.

This is clearly a requirement of any management system.

The organization should identify the roles, responsibilities, accountabilities and their interrelationships within the organization as far as necessary to ensure effective and efficient operation. Senior management should ensure the responsibilities and authorities are defined and communicated within the organization. This requirement is of particular significance to HACCP as a specialist team is formed for the installation of the system.

The organization should identify those operations and activities that are associated with the identified significant aspects in line with its policy,

objectives and targets. The organization should plan and develop the process necessary for effective implementation of the operational control measures. This is the essence of what the food safety and quality system is all about.

The organization should establish and maintain a process for identifying and responding to any potential emergency situation. The process should seek to prevent and mitigate the consequences of any such occurrence.

This is clearly of the greatest importance and is critical in the context of food safety and quality. If a failure does occur it may put the health or even the lives of many customers at risk. When a manufacturer of an engineering product discovers a fault and decides to recall the product for repair or replacement, it is possible for the organization to survive and even preserve its reputation if the recall is done well. Every major motor manufacturer has recall notices published on many of its products. Often it has been possible for them to trace affected customers individually without public advertisement, and if the operation is handled efficiently the reputation of the manufacturer will not be badly affected. This is not possible with food products unless it is possible to prevent the faulty consignments reaching the consumer. More often public advertisements will be needed in national newspapers, on television, radio and any other suitable medium. Even if the recall is handled efficiently the reputation of the producer may be badly affected and the organization may not survive. Whilst the entire FSQ system will be devoted to the prevention of such an occurrence, there should be plans in existence in case the worst does happen. If the producer waits until it has occurred before making plans, the chances of survival are slim and the consequences to the customer may be exacerbated.

IMS section 3, implementation and operation

The organization should ensure arrangements are in place at the operational level to ensure that:

- the objectives and requirements for the product/services are being met;
- the necessary processes, documents and resources specific to the product/service are provided;
- the necessary verification, validation, monitoring, inspection and test activities specific to the product/service are instigated;
- the necessary records are produced to provide evidence that the realization processes meet the standards required.

As will be seen, these criteria are fully met if the FSQ system is implemented as suggested. Principles 6 and 7 (H.11 and H.12) cover verification procedures, documentation and record keeping (see tables 3.1 and 3.2).

The organization should ensure that the personnel carrying out activities on its behalf are competent on the basis of appropriate education, training, skills and experience to enable them to undertake all their duties.

The organization should:

- evaluate the effectiveness of the actions taken;
- ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives.

The organization should determine, provide and maintain the infrastructure needed to achieve its objectives. Infrastructure includes, as applicable:

- buildings, workspace and associated utilities;
- process equipment (both hardware and software); and
- supporting services (such as transport or communication).

These are obvious requirements for the functioning of any organization.

Documentation requirements

The management system documentation should include:

- documented statements of the policies and objectives;
- a manual describing the working of the management system (see 3.4.2);
- documented procedures that are required by specific standards;
- documents needed by the organization to ensure the effective planning, operation and control of its processes; and
- records required by any specific standard.

NOTE 1 Where the term 'documented procedure' appears, this means that the procedure is established, documented, implemented, controlled and maintained.

NOTE 2 The extent of the management system documentation can differ from one organization to another due to:

- the size of organization and type of activities;
- the complexity of processes and their interactions; and
- the competence of personnel.

NOTE 3 The documentation can be in any form or type of medium.

The documents required are the same as for any other management system, the minimum needed to demonstrate the operation of the system. In a combined FSQ system it is essential that the food safety elements are identified and may be achieved by compiling a HACCP plan. This document should hold all the HACCP information essential for the product(s) under manufacture and it should reference all records associated with product safety. It should include risk determinations (see chapter 4) and be constructed to give the traceability of all food products handled on the site.

Integrated management system manual

The organization should establish and maintain a manual that includes:

a) the scope of the management system, including details of and justification for any exclusions;
b) the documented procedures established for the management system, or reference to them; and
c) a description of the interaction between the processes of the management system.

Some form of system manual is clearly needed. If the organization has a quality manual meeting the requirements of ISO 9001:2000, and does not wish to incorporate this with other systems within an integrated management system, then the HACCP procedures should be incorporated within the quality manual. A separate manual for HACCP should be avoided.

The preferred solution is a single manual covering all the management systems operating within the organization. A quality manual incorporating the HACCP system can be the basis for such a manual, but this is not an ideal approach as it is limited in scope to those aspects affecting the product only. A better solution, if it is the aim of the organization to end up with an integrated management system, is to start with a manual that will serve the needs of such an integrated system. The requirements of each discipline, such as quality or safety, can then be incorporated as necessary into the overall manual. With each new discipline added the advantages of such an integrated manual will become increasingly apparent. The repetition and

duplication of common elements will be avoided and the overall aim of serving the organization as a whole will be emphasized.

The compilation of such a manual for an integrated system has been described in detail in a separate book in this series, *IMS: Creating a Manual*.

Control of documents

Documents required by the management system should be controlled. Records are a special type of document and should be controlled according to the requirements of those specific standards covered by the IMS.

A documented procedure should be established to define the controls needed in order to:

- approve documents for adequacy prior to issue;
- review and update as necessary and re-approve documents;
- ensure that changes and current revision status of documents are identified;
- ensure that relevant versions of applicable documents are available at points of use;
- ensure that documents remain legible and readily identifiable;
- ensure that documents of external origin are identified and their distribution controlled; and
- prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

Control of records

Records should be established and maintained to provide evidence of compliance with requirements and of the effective operation of the management system. Records should remain legible, readily identifiable and retrievable. A documented procedure should be established to define the controls needed for the identification, storage, protection, retrieval, retention and disposal of records.

The control of documents, including records, is clearly essential to the operation of FSQ as with any other management system. Documents are not necessarily on paper, and increasingly the use of computers makes an information technology (IT) solution preferable as long as the above criteria can be met. In the food industry particular attention should be paid to the records needed to ensure traceability of the product.

The organization should determine and implement effective arrangements for communication:

- between the various levels of the organization as appropriate to their needs;
- for receiving, documenting and responding to relevant communication from external interested parties.

These criteria apply to any management system and there are no special requirements for FSQ.

The organization should formalize its arrangements for those who supply and contract their services, both internal and external, which have an impact on the organization's performance. Relationship with suppliers and contractors is of critical importance in the food industry. The organization should ensure that all necessary controls are in place with their suppliers of goods and services to ensure that safety and quality are preserved throughout the process chain, from primary producer to the supply of the finished product to the consumer. The ideal situation is where every producer is operating to a FSQ system, including HACCP, using common methods as described in this book.

IMS section 4, performance assessment

The organization should establish and measure the characteristics of the product and/or services to verify that requirements have been met. This should be carried out at appropriate stages of the process in accordance with the planned arrangements. This is exactly what the FSQ system as described in this book is designed to do.

The organization should establish and maintain arrangements to monitor and measure, on a regular basis, the key characteristics of its operations and activities that can have a significant impact. This should include the recording of information to track performance, relevant operational controls and conformance with the organization's objectives and targets. The organization should establish and maintain a process for periodically evaluating the performance against the stakeholder requirements. These 'key characteristics' are the hazards described in the FSQ system and the critical control points.

The methods used for analysing performance should demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, corrective action should be taken. Evidence of conformity with the acceptance criteria should be maintained and recorded. A failure to achieve planned results can have more serious consequences in the food industry than in many other industries and the functions of monitoring and

corrective action are accordingly of the greatest significance. The organization should establish and maintain a programme for periodic management system audits to be carried out, in order to determine whether or not the management system:

a) conforms to planned arrangements for the management system;
b) has been properly implemented, maintained and adhered to.

The audit programme, including any schedule, should be based on the results of risk assessment of the organization's activities, and the results of previous audits. The audit arrangements should cover the scope, frequency, methodologies and competencies, as well as the responsibilities and requirements for conducting audits and reporting results.

Wherever possible, audits should be conducted by personnel independent of those having direct responsibility for the activity being examined. Effective auditing of the system is essential to ensure its ongoing effectiveness. Frequent or continuous auditing is preferable to annual or six-monthly exercises. Auditing the integrated system as a whole has many advantages over multiple audits for different disciplines. Auditing should be seen as one of the principal means of improving the system by demonstrating where the difficulties of operating the system have been found.

IMS section 5, improvement

The organization should establish a process for defining responsibility and authority for implementing action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions should be appropriate to the effect of the nonconformities encountered.

A process should be established to define requirements for:

- reviewing nonconformities (including stakeholder comments);
- determining the causes of nonconformities;
- evaluating the need for action to ensure that nonconformities do not recur;
- determining and implementing the action needed;
- recording the results of action taken; and
- reviewing corrective action taken.

The organization should establish a process for defining responsibility and authority for implementing action appropriate to the risk.

The organization should continually improve the effectiveness of the management system through the use of the policy, objectives, audit results, analysis of data from monitoring and measurement, corrective and preventive actions and management review.

Continual improvement in the performance of the system should be one of the main aims of the organization. Improvements will normally be measured in terms of customer service, costs and profits, but should be apparent to all stakeholders. Overall improvement can usually be achieved by the improvement of individual processes.

IMS section 6, management review

Senior management should review the organization's management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness. This review should include assessing opportunities for improvement and the need for changes to the management system, including policy and objectives. Records from management reviews should be maintained.

The input to management review should include information on:

- results of audits;
- stakeholder feedback;
- status of preventive and corrective actions;
- follow-up actions from previous management reviews;
- changes that could affect the management system; and
- recommendations for improvement.

The output from the management review should include any decisions and actions related to:

- improvement of the effectiveness of the management system and its processes;
- improvement related to stakeholder requirements; and
- resource needs.

Review is at the heart of the management system. The audit processes show that the system is being followed; the management review checks that it is the right and sufficient system, serving its purpose in achieving continual improvement throughout the organization. Audit and review are an essential part of the FSQ system.

7. Implementing the system

Introduction

In chapters 5 and 6 we discussed ways in which ISO 9001:2000 and HACCP, with reference to ISO 15161:2001, may be combined into a food safety/quality system that in turn may be incorporated into an IMS. This chapter looks at the practicalities of setting up such a system. Table 5.1 shows clauses 4 to 8 of ISO 9001:2000 mapped against the working references of HACCP from Table 3.1. The actions required to set up the food safety/quality (FSQ) system, including the documentation required for the HACCP plan (table 5.2), are now aligned with the IMS elements shown in appendix 1. The reader should make reference to, *IMS: Implementing and Operating* (Smith, 2002) and appendix 1. If the organization is not operating, or not intending to operate an IMS, the implementation outlined in this chapter will still apply, but the references will be to ISO 9001:2000. To demonstrate the design of an IMS incorporating a FSQ system, a case study is given of a milk pasteurizing and bottling plant. The dairy receives raw milk from a number of suppliers and processes it into full cream, semi-skimmed and skimmed pasteurized liquid milks. The milks are distributed to retail outlets in disposable containers in three sizes 0.5 litre, 1 litre and 2 litre. The containers and caps are purchased and surplus cream is sold on for further processing. UK and European Union legal standards have been applied.

NOTE The case study is included to demonstrate the implementation of a combined food safety and quality system within an IMS. The information presented is not intended to be complete or applicable to all operations of the type described. The objective is to illustrate the main points of a FSQ system by working through suitable documentation. Examples are given within each document. Where outcomes

are described, as in the determination of CCPs, these are illustrations applicable to this example and are not recommendations. It is important that each organization should prepare its own system taking into account the conditions and requirements of its individual operation.

IMS 0 – the management system

The project begins with an initial status review carried out by senior management taking into account the requirements of the integrated management system as given in chapter 6 (IMS 0, see also figure 7.1). If it is agreed to establish a FSQ system as part of the IMS of the organization, the following decisions will be taken (*IMS: Implementing and Operating*, chapter 2):

(a) adopt a food/safety quality system within the IMS of the organization to meet the requirements set out in IMS 0 (a) to (f);
(b) appoint a subcommittee or senior manager to oversee the project;
(c) allocate finance for the provision of resources.

Figure 7.1 Decision to implement a food safety/quality system within the IMS of the organization

IMS 0	FSQ – Example
Ref: FSQ0 – Decision to implement a food safety/quality system within the IMS of the organization	
Prepared by _____ Approved by _____ Date _____ Issue no. _____	
Minutes of the status review with points for action and projected time scale Relevant sections of the minutes from the status review of (insert *date*) Points for action Projected time scale	

The amount of detail entered in FSQ 0 is the decision of senior management. It may reference the minutes of the meeting when the decision was taken or contain excerpts from them. The points for action and the relevant timescales are necessary to ensure that implementation of the system progresses at an acceptable rate and that the actions which concern senior management are addressed promptly.

IMS 1 – Policy and principles

The food safety/quality subcommittee or senior manager assumes responsibility for the project, assisted by the FSQ team (see IMS 2.5). The team for the FSQ system should be appointed at the beginning of the planning stage. The senior manager and the team will prepare together the following in draft form for approval by senior management:

- a draft FSQ policy;
- a description of the products to be included in the system; and
- the principles on which the system will be based.

The FSQ policy will form part of the organization IMS policy. It should include a statement emphasizing management commitment to food safety/quality as applicable to the products of the organization (see chapter 6 (1)). The draft policy will be reviewed and approved by senior management (see *IMS: Implementing and Operating*, chapter 3).

Figure 7.2 An example of a policy statement for a FSQ system

IMS 1. ISO 9001:2000/ISO 15161:2001 – 5.1 and 5.3 HACCP, H.ii, H.vii,	FSQ – Example
Ref: FSQ 1.1 – Policy statement for the FSQ system Prepared by _____ Approved by _____ Date _____ Issue no. _____	
FSQ policy statement: 'It is our policy to provide consumers with products that are safe to eat. All of our products meet the relevant statutory requirements and all specifications set by our customers. We have systems in place that maintain our standards of food safety and quality and enable us to continually improve. All the management and staff of (*insert name*) Dairy are fully committed to this policy.'	

The policy statement should be aligned to the other policy statements in the IMS and it should include reference to the commitment of the organization to maintaining and improving food safety and quality.

Description of products and materials included in the system

This description includes food products for human consumption and animal feed and the disposal of organic waste. Each type of raw material, intermediate and end product should be described. The description should include legal regulations, customer specifications and in-house standards

for safety and quality. It also takes into account the intended use of the products and is therefore based on the relevant microbiological data and criteria. The scope of the system is defined from these descriptions.

Figure 7.3 Examples of products and materials included in the FSQ system

IMS 1. FSQ – Example ISO 9001:2000/ISO 15161:2001 – 5.1 and 5.3 HACCP: H.iii, H.2, H.3
Ref: FSQ 1.2 – Description of products and materials included in the FSQ system
Prepared by _____ Approved by _____ Date _____ Issue no. _____
Descriptions of the following to be included in the system stating legal requirements, contractual specifications, in-house standards and the intended use of the products: 1.2.1. raw milk (bovine); 1.2.2. packaging – disposable bottles, caps and outer wrapping; 1.2.3 labels for the disposable bottles; 1.2.4 cleaning products; 1.2.5 pasteurized liquid milks in bulk; 1.2.6 pasteurized liquid milks in final packaged form; 1.2.7 cream for further processing; 1.2.8 reject milk; 1.2.9 the disposal of organic waste (link to ISO 14001:1996).

When preparing the description of a product and/or material its subsequent use should be kept in mind. The information it contains, together with that presented in the flow diagrams, will form the basis for the hazard analysis and therefore should be accurate and up to date. It may be either transcribed into the document (FSQ 1.2), or used directly from the original texts as intended in the example.

Principles on which the FSQ system is based

The safety and quality of food is managed as a combined system within the IMS, and is therefore based on a joint quality/food safety standard aligned to the integrated management system. At present there is no single standard for an FSQ system as ISO 15161:2001 does not fully address the requirements of HACCP. Thus it is necessary to identify the principles on which the system is based and the sources which are used.

Hopefully the number of documents cited in FSQ 1.3 will be reduced as the system for controlling food safety and quality evolves.

Figure 7.4 The principles on which the FSQ system is based

IMS 1. ISO 9001:2000/ISO 15161:2001 – 5.1 and 5.3 HACCP: H.iv		FSQ – Example
Ref: FSQ 1.3 – The principles on which the FSQ system is based		
Prepared by _____ Approved by _____ Date _____ Issue no._____		
Principle	Reference	
Integrated management	Integrated management systems	*IMS: The Framework* (Smith, 2002) *IMS: Implementing and Operating* (Smith, 2002)
Quality management	Quality management systems – requirements	ISO 9001:2000
	Guidelines in the application of ISO 9001:2000 for the food and drink industry	ISO 15161:2001
HACCP	The Hazard Analysis and Critical Control Point (HACCP) system and guidelines for its application	Joint FAO/WHO Food Standards programme (CAC) Codex Alimentarius vol 1B, General Requirements (Food Hygiene) Second edition, revised 2001
Good hygiene practice (GHP)	CAC 2001a	Joint FAO/WHO Food Standards programme (CAC) Codex Alimentarius vol 1B, General Requirements (Food Hygiene) Second edition, revised 2001
Microbiological criteria for foods	CAC 2001c	Joint FAO/WHO Food Standards programme (CAC) Codex Alimentarius vol 1B, General Requirements (Food Hygiene) Second edition, revised 2001
Microbiological risk assessment	CAC 2001d	Joint FAO/WHO Food Standards programme (CAC) Codex Alimentarius vol 1B, General Requirements (Food Hygiene) Second edition, revised 2001
	Principles and guidelines for incorporating microbiological risk assessment in the development of food safety standards guidelines and related texts	Report of a Joint FAO/WHO Consultation, Kiel Germany 18–22 March 2002
Chemical risk assessment	Food safety in Europe (FOSIE) Risk assessment of chemicals in food and diet	Barlow et al, Food and Chemical Toxicology 40 (2002), pp 145–424
	Risk characterization of chemicals in food and diet	Renwick et al, Food and Chemical Toxicology 41 (2003), pp 1211–1271
	Food additives, food irradiation and food contaminants.	Joint FAO/WHO Food Standards programme (CAC) Codex Alimentarius vol 1A, General Requirements, Second edition revised 1999.

Documents generated externally

In this section it will be noted that reference is made to externally generated documents such as legal requirements, codes of practice, national and international standards, published information from trade associations, scientific organizations and regulatory bodies as well as customer specifications. As this comprises a large number of documents this information should be referenced and a record maintained. The type of document to be included in such a record is given in figure 7.5.

Figure 7.5 An example of a register of documents generated externally

IMS 1 ISO 9001:2000/ISO 15161:2001 – 5.1 and 5.3 HACCP: H.12	FSQ – Example
Ref: FSQ 1.4 – Documents generated externally	
Prepared by _____ Approved by _____ Date _____ Issue no. _____	
Section	Reference: Title: ISBN number
1.4.A The management system	A1 *IMS: Implementing and Operating*. David Smith. ISBN 0 580 33328 0 A2 ISO 9001:2000, *Quality management systems – Requirements*.
1.4.B Food hygiene	B1: Directive on the Hygiene of Foodstuffs 93/43/EEC ISBN 0 11 911 664 2 B2 National legal standards
1.4.C Raw milk	C1 Legal standards
1.4.D Milk/cream	D1 Legal standards
1.4.E Packaging	E1 Legal standards E2 Instructions from equipment manufacturers, suppliers of chemicals and others
1.4F Labelling	F1 Legal standards F2 Instructions from equipment manufacturers, suppliers of chemicals and others F3 Customer specifications
1.4.G Packaging	G1 Legal standards G2 Instructions from equipment manufacturers, suppliers of chemicals and others G3 Customer specifications
1.4.H Labelling	H1 Legal standards H2 Instructions from equipment manufacturers, suppliers of chemicals and others H3 Customer specifications
1.4.I Waste management	I1 Legal standards I2 Instructions from equipment manufacturers, suppliers of chemicals and others

The externally generated documents record will build into a large file; only a few examples are given here.

IMS 2 – Planning

Having defined the scope of the system in IMS 1, the designated FSQ subcommittee, or senior manager, will begin planning the FSQ system assisted by a team of specialists. These are usually drawn from the employees of the organization although external consultants may be included. The subcommittee or senior manager will appoint the FSQ team and its leader and will continue to liaise with both the committee and top management. In small enterprises the senior manager may be the FSQ team leader.

IMS 2.1 – Identification of aspects and risks

In the FSQ system the aspects, that is the critical issues that are to be controlled, are the safety and quality of the products offered for sale, the organic by-products and also the safety of the food waste (see chapter 6). The term risk is used as defined in chapter 4. In HACCP the identification of the aspects and risks is performed by a hazard analysis of the process flow. This method is followed in the present system, however, both safety and quality hazards are identified.

Constructing the flow diagrams

The first step is to construct flow diagrams for each of the operations showing the process parameters that affect the safety and quality of the product. Before the flow diagram is approved it is important that it is verified by on-site inspection to ensure that it accurately reflects the process. The flow diagram FD-1 given in figure 7.6 shows processing raw milk into pasteurized liquid milks with various fat contents.

It should be noted that the flow diagram header carries the signature of the person responsible for verifying the flow diagram. The linear design in figure 7.7 does not show the detail of the various end products and their packaging. To achieve this requires a schematic layout as shown in figure 7.8. This format is also useful if there are a large number of raw materials to be included.

Figure 7.6 An example of a flow diagram for a HACCP system (linear)

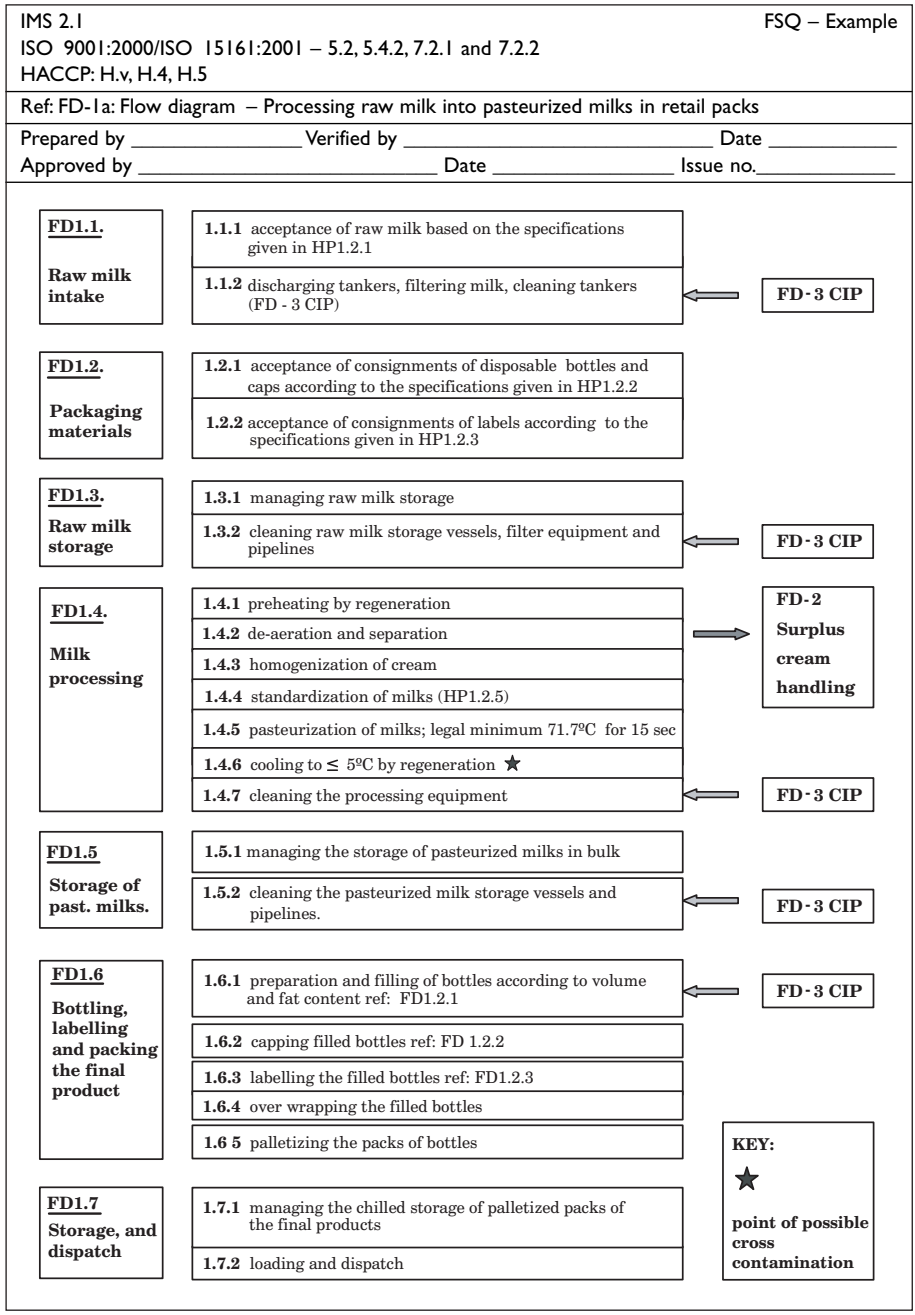
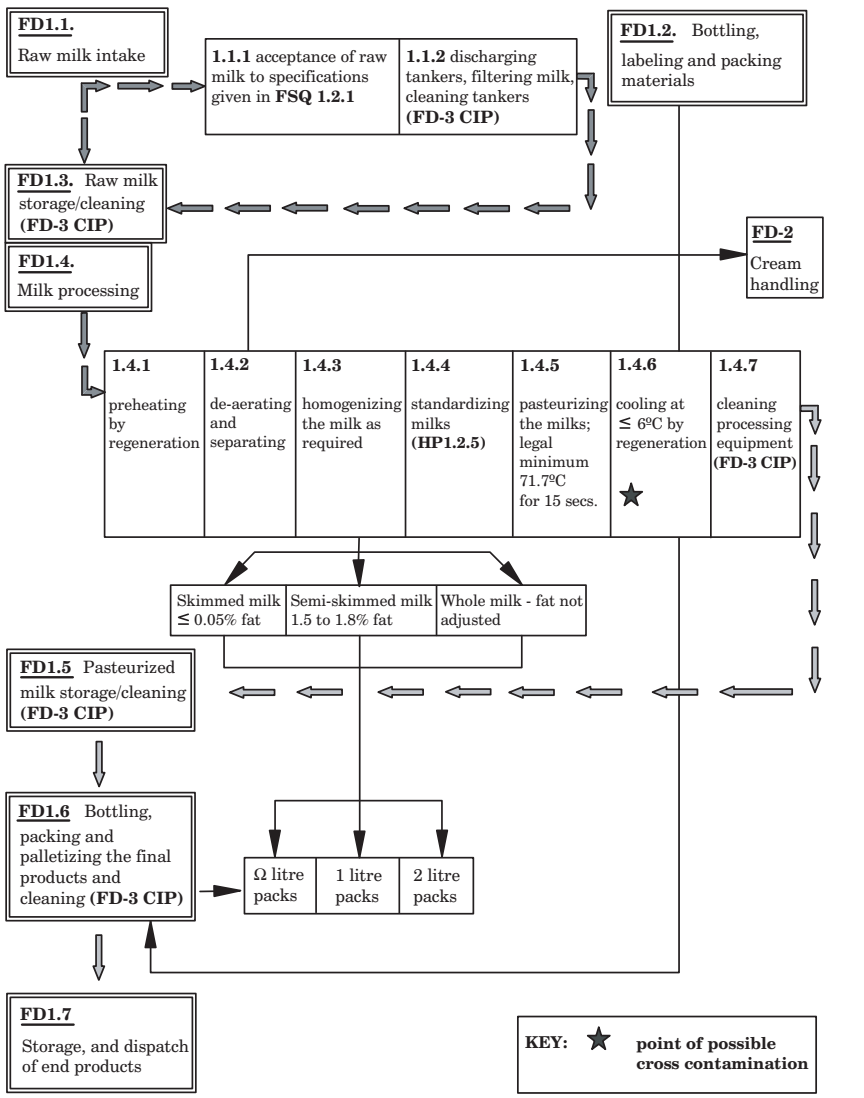


Figure 7.7 An example of a flow diagram for a HACCP system (schematic)

IMS 2.1 FSQ – Example
ISO 9001:2000/ISO 15161:2001 – 5.2, 5.4.2, 7.2.1 and 7.2.2
HACCP: H.4, H.5

Ref: FD-1b: Flow diagram – Processing raw milk into pasteurized milks in retail packs

Prepared by _____ Verified by _____ Date _____
Approved by _____ Date _____ Issue No_____



Hazard identification

This is a systematic diagnosis of the potential hazards associated with the food materials at each step of the flow diagram. The hazards are identified from the safety and quality factors of the raw materials, intermediate products, end products, by-products and food waste, as applicable, from document FSQ 1.2 (figure 7.2). Carrying out a hazard identification of this type requires detailed knowledge of the process and the product. If such knowledge is not available in-house, advice should be sought externally. A record of potential hazards is compiled from the information collected as shown in figure 7.8.

The hazards are divided into safety/quality hazards (SQs), denoting that the safety and quality of the food is affected and quality hazards (Qs) where quality only is involved. The two groups are then subdivided into microbiological, chemical and physical safety/quality hazards, denoted MSQ, CSQ and PSQ respectively, and similarly into MQ, CQ and PQ quality hazards.

Care should be taken, however, to ensure that identical hazards occurring at different stages in the process, or in different processes, but requiring different control measures are listed individually.

Once the hazard has been described in the index it is subsequently entered by its reference number only. Where the hazard may affect food safety and food quality it is denoted by using a safety/quality reference (MSQ, CSQ or PSQ) across the two relevant columns but is listed under safety. Most microbiological hazards may be described as safety/quality (MSQ) because if pathogens are able to grow or survive in non-sterile foods, so too are spoilage micro-organisms. In fermented foods there will be a group of microbiological quality only (MQ) hazards arising from defects associated with the cultures used in their production.

Figure 7.8 A hazard identification record

IMS 2.1 FSQ – Example
ISO 9001:2000/BS ISO 15161:2001 – 5.2, 5.4.2, 7.2.1, 7.2.2
HACCP: H6.1

Ref: HI1 – Hazard Identification for processing raw milk into pasteurised milks in retail packs

Prepared by _____ Verified by _____ Date _____
Approved by _____ Date _____ Issue No_____

Process step	Microbiological hazards		Chemical hazards		Physical hazards	
	safety	quality	safety	quality	safety	quality
1.1 Acceptance of raw milk to specifications given in **FSQ1.2.1**	**MSQ1** Presence and growth of pathogens and development of their toxins	Presence and growth of spoilage micro-organisms	**CS1** Chemicals from primary production including antibiotics **CSQ2** Presence of cleaning chemicals	**CQ1** Compositional defects **CQ2** Extraneous water Presence of cleaning chemicals		**PQ1** Visible extraneous matter **PQ2** Organoleptic defects
1.2 Discharging tankers, filtering milk, cleaning tankers **(FD - 3 CIP)**	**MSQ1**		**CSQ2**			Inadequate removal of visible extraneous matter

Key: **MSQ:** – microbiological safety and quality **CQ:** – chemical quality
CSQ: – chemical safety and quality **PQ:** – physical quality

Note: Although they do not occur in above example. It is possible to have the categories
PSQ – physical safety and quality
MS – microbiological safety

IMS 2.2 – Selection of significant aspects to be addressed – Hazard analysis

The purpose of the significant aspects to be addressed is to determine the risks which they present in the end product, in order that appropriate controls may be put in place. In HACCP this is termed hazard analysis. The most efficient way of carrying out a hazard analysis is to perform a fully quantitative risk assessment. However, the data required for this is currently not fully available to the food industry and qualitative information is used instead. Risk assessment in a FSQ system is usually limited to microbiological and chemical safety aspects. Food quality hazards and safety/quality physical hazards are usually specific to the operation and the site should be effectively controlled by the correct implementation of a quality management system such as ISO 9001:2000. Chemical risk assessment is well established particularly for primary food products and quantitative data is available (CAC 1999). Microbiological risk assessment is being developed as a tool for the improvement of food safety but as yet its use in FSQ systems in the food industry is limited. Many food companies do not have the resources to prepare the quantitative data required for full microbiological risk assessment and look to the regulatory bodies to provide information and to prepare guidelines and standards for their use. Within many food companies, however, there is a bank of information that should be used in hazard analysis to provide local knowledge. For commodity foods, where there is extensive historical evidence, it is not anticipated that food companies will undertake a full risk assessment unless there is a specific reason to do so, such as the emergence of a pathogen not previously associated with the product. For compound foods, however, in which high-risk ingredients are used in unusual combinations, a microbiological risk assessment of key materials and the end product(s) should be carried out during the design stage. Thus risk assessment is at present beyond the reach of many food companies, but risk profiling provides a useful means of giving a systematic and scientific approach to hazard analysis (see chapter 4).

To assess risk accurately, risk profiles need to be carried out for each hazard (Voysey 2000). The FSQ team may undertake the risk profiling or advice may be sought from external consultants. This depends on the level of scientific expertise within the organization but, in any case, there should be input from in-house experience and records.

Risk profiles provide evidence for the requirement of a full risk assessment. The outline of a risk profile for pathogens in pasteurized milk with examples of the questions to be asked are shown in figure 7.9. The information is based on the worked examples given in Voysey (2000) which

it is recommended that the reader should consult for further information before carrying out a risk profile.

Figure 7.9 An example of the information included in a risk profile based on worked examples given in Voysey (2000)

IMS 2.2 ISO 9001:2000/ISO 15161:2001 – 5.2, 5.4.2, 7.2.1 and 7.2.2 HACCP: H.6.1		FSQ – Example	
Ref RP-1: Risk profile for assessing the health risk posed by food borne pathogens and/or their toxins in pasteurized milk			
Prepared by _____ Approved by _____ Date _____ Issue no. _____			
			score
Hazard identification	(1) What is the product?	Pasteurized milk	
	(1) What pathogens are associated with this product?		
	(2) Which pathogen is profiled here?		
	(3) Is it toxigenic?		
Hazard characterization	(1) Who are the consumers of concern?		
	(2) Which are the vulnerable groups?		
	(3) What is the severity of the hazard?		
	(4) What is the hazard level of the pathogen in this risk assessment?		
	(5) What is the uncertainty of this estimate?		
Exposure assessment	(1) What is the range of this pathogen in raw milk?		
	(2) What is the uncertainty of this estimate?		
	(3) How efficient is the pasteurization process in destroying the pathogen and its toxins?		
	(4) What is the uncertainty of this estimate?		
	(5) What is the frequency and level of contamination of the product by the pathogen due to post-pasteurization handling and packaging?		
	(6) What is the uncertainty of this estimate?		
	(7) What is the effect of refrigerated and non-refrigerated storage of the product, up to the end of its shelf life, on the level of the hazard?		
	(8) What is the uncertainty of this estimate?		
Risk characterization – interpretation of the risk profile.	When the questions on hazard characterization and exposure assessment have been answered they are each allotted a value between 1 and 5, with the higher the value the greater the risk. Therefore a high total value indicates a high level of risk From the scores for the questions relating to the uncertainty of the information – shaded in the table – it is possible to obtain an 'information quality profile'. A low score indicates that the information is more reliable than when the score is high		

2.3 – Objectives and targets

The objectives and targets of the FSQ system are to ensure the safety and quality of the end products of the process. The objectives are to control the hazards that have been identified and selected during the hazard analysis, while the targets are the legal standards and customer specifications for the end products. Meeting these targets is of particular importance in relation to food safety. Apart from the legal and ethical issues involved, consumers demand a high standard of safety in the products they purchase and immediately withdraw their loyalty from brand names and associated products if these become linked to a food safety scare. Also, because food is an essential purchase, consumers are critically aware of perceived quality and will discriminate against products thought to fall short of the standard they expect. Therefore, it is essential that food safety and quality objectives are controlled and that targets are met for the success of the organization.

CCPs and CQPs

The CCPs are the steps in the process at which the food safety and safety/quality hazards occur. It has been argued that hazards from raw materials or from processes at early stages in the operation, usually before heat treatment, do not constitute CCPs, because they are controlled later. When working with high-risk raw materials, however, there is a health and safety risk to the operatives and the potential for post heat-treatment recontamination. Therefore, the control of food safety is necessary at all stages of such a process. The use of risk profiles and, if necessary, risk assessment to determine CCPs takes the guesswork out of the exercise.

Low risk raw materials do not have the same microbiological potential for causing adverse health effects and, unless there is a risk of toxic chemical contamination the FSQ Team may decide not to include them as CCPs. Nevertheless they should be designated CQPs and monitored to ensure that the specifications for their acceptance are met.

Figure 7.10 An example of a CCP register

IMS 2.3 ISO 9001:2000/ISO 15161:2001 – 5.4.1 HACCP: H.iii, H.v, H.4, H.5, H.6			FSQ – Example
Ref: CCP-1: CCP register for processing raw milk into pasteurized milks in retail packs			
Prepared by _____ Approved by _____ Date _____ Issue no. _____			
Microbiological		Chemical	
Hazard	Controls or preventative measures (all documentation should be referenced)	Hazard	Controls or preventative measures (all documentation should be referenced)
MSQ 1 Growth of pathogens and spoilage micro-organisms	MSQ 1.1 Primary production control on the farm to the specifications given in FSQ 1.2 (figure 7.3) MSQ 1.2 Temperature control of milk (Standard operating procedures) MSQ 1.3 Testing for bacterial numbers and activity (Laboratory standard operating procedures)	CSQ 1 Chemicals from primary production including antibiotics	CSQ 1.1 Primary production control on the farm to the specifications given in FSQ 1.2 (figure 7.3) CSQ 1.2 Testing for antibiotics (Laboratory standard operating procedures)
		CSQ 2 Presence of cleaning chemicals	CSQ 2.1 Operation of CIP system according to documented procedures (Standard operating procedures) CSQ 2.2. Maintenance of CIP records (Monitoring) CSQ 2.3. Training of CIP operators (Technical training) CSQ 2.4 Awareness of the standard of hygiene required (Food hygiene training)
Key: MSQ – microbiological safety and quality CSQ – chemical safety and quality Note Although they do not occur in above example, the following categories are allowed: PS – physical safety; PSQ – physical safety and quality; MS – microbiological safety; CS – chemical safety.			

Figure 7.11 An example of a QCP register

IMS 2.3 ISO 9001:2000/ISO 15161:2001 – 5.4.1 HACCP: H.iii, H.v, H.4, H.5			FSQ – Example
Ref: QCP1: QCP register for processing raw milk into pasteurized milks in retail packs			
Prepared by _____ Approved by _____ Date_____ Issue no. _____			
Chemical		Physical	
Hazard	Controls or preventative measures (all documentation should be referenced)	Hazard	Controls or preventative measures (all documentation should be referenced)
CQ 1 Compositional defects	CQ 1.1 Testing for milk constituents (Laboratory standard operating procedures)	PQ 1 Visible extraneous matter	PQ 1.1 In-line filter or clarifier PQ 1.2 Testing for visible extraneous matter (Laboratory standard operating procedures)
CQ 3 Extraneous water	CQ 3.1 Testing for extraneous water (Laboratory standard operating procedures)	PQ 2 Organoleptic defects	PQ 2.1 Inspection and testing for appearance, taste and smell (Laboratory standard operating procedures)
Key CQ – chemical quality PQ – physical quality Note Although it does not occur in above example the following category is allowed: MQ – microbiological quality			

2.4 – Identification of resources

The resources required for the efficient functioning of the FSQ system comprise:

- the specific support systems and mechanisms necessary for the operation and monitoring of the preventative measures/controls; and
- the maintenance of a safe food handling environment or GHP (good hygiene practice).

In HACCP both of these are presented as adjuncts to the main system, but they are included in the general terms of ISO 9001:2000/ISO 15161:2001. In this system they are included under the elements of the IMS standard thus ensuring the same level of competence, but the maintenance of a safe food handling environment is based on the requirements for food hygiene specified by the CAC (2001a).

Determination of the resources is by gap analysis, the findings from which should be documented and presented to senior management for approval and action. An example of the specific resources required for the operation and monitoring of the controls is shown in figure 7.12. It will be noted that the dairy will require both microbiological and chemical laboratory facilities (MSQ 1.1, MSQ 1.3, CSQ 1.2, CQ 2.1, CQ 3.1, PQ 1.2 and PQ 2.1). Further, the standard of the laboratory analysis will require consideration and the organization should decide whether it is preferable to have an on-site laboratory, accredited or not accredited, or whether to send samples off-site for analysis. Temperature control of the incoming raw milk (MSQ 1.2) introduces the requirement for a calibrated thermometer. Calibration of laboratory equipment is also essential and the calibration system for the dairy will need to include these instruments. The example also illustrates a need for training (see IMS element 3.2).

Figure 7.12 An example of gap analysis used to identify services and systems required to support and monitor controls

IMS 2.4 ISO 9001:2000/ISO 15161:2001 – 5.4.2 HACCP: H.i, H.14			FSQ – Example	
Ref: GAP1a – Gap analysis to show services and systems required to support and monitor the controls for processing raw milk into pasteurized milks in retail packs				
Prepared by _____ Approved by _____ Date _____ Issue no._____				
Gap or deficiency	Required for	Action proposed	Time scale	Decision of senior management
1. On-site laboratory not accredited	MSQ 1.1 MSQ 1.3 CSQ 1.2 CQ 1.1 CQ 2.1 PQ 1.2 PQ 2.1	Upgrade the laboratory to accredited status	1.5 to 2 years to achieve accreditation status. Prepare a Gantt chart to show projected action	
2. Thermometer used for checking the temperature of the incoming milk and laboratory measuring equipment not calibrated	MSQ 1.2 and laboratory measuring equipment	Extend existing calibration contract to cover all laboratory measuring equipment as required	One month	
3. Staff not fully trained in all areas of technical skill and food safety and quality and hygiene	All controls	Carry out a training needs analysis See element 3.2	Two months	

The gap analysis used to identify the resources for the maintenance of a safe food handling environment lists the support services required, analyses their current status and proposes improvements to ensure that they operate at the required standard for the system. The list of support services given in figure 7.13 may not be exhaustive nor is it implied that improvements are always necessary in each of the areas cited.

Figure 7.13 An example of gap analysis used to create a safe food-handling environment

IMS 2.4 ISO 9001:2000/ISO 15161:2001 – 5.4.2 HACCP: H.i, H.14				FSQ – Example
Ref: GAP1b – Gap analysis to show hygiene services and systems required to create a safe handling environment for processing raw milk into pasteurized milks in retail packs				
Prepared by _____ Approved by _____ Date _____ Issue no._____				
Service/system required	Required for	Action proposed	Timescale	Decision of senior management
Contractors – rules for	Site	Rules in place –. document reference	_____	_____
Drivers non-employees – rules for	Site			
Incoming materials handling	All types			
Laundry	Site			
Maintenance	Site			
Maintenance	Buildings			
Maintenance	Plant and equipment			
Personal hygiene awareness and food hygiene training	All staff	Carry out a training needs analysis See IMS element 3.2	Two months	
Pest control	Site			
Staff facilities	Site			
Vehicles and transport	On and off site			
Visitors – rules for	Site			
Waste control	Site			
Water supply	Site			

2.5 – Identification of organizational structures, roles, responsibilities and authorities

The standards ISO 9001:2000/ISO 15161:2001 specify that a member of management shall be appointed to take responsibility for quality matters throughout the organization – the management representative for quality. The HACCP concept, however, requires the appointment of a team, drawn from the various departments of the organization, to take responsibility for the food safety system under a team leader. The latter approach is used in this system but the responsibility of the team is extended to cover food quality as well as food safety. The team is referred to as the FSQ team and reports to a subcommittee or specified person from senior management as discussed in IMS 1. It is likely, but not essential, that the team leader will combine the role with that of management representative for quality. Whoever is appointed the most important criterion is that they are fully conversant with the requirements for planning, implementing and maintaining food safety/quality systems. It is recommended that, as the key person responsible for the FSQ system, the team leader receives training in this field before undertaking the role. The other members of the team are required to support the team leader and will have expertise, relating to the products of the organization, in one or more of the following areas: raw materials, production, engineering, plant hygiene, packaging, distribution, quality assurance, quality control, buying and marketing. This does not mean that the team will necessarily consist of nine members. An example of a FSQ team for a dairy is given in figure 7.14.

Figure 7.14 An example of the composition of a FSQ team

IMS 2.5 ISO 9001:2000/ISO 15161:2001 – 5.4.2 HACCP: H.1			FSQ – Example	
Ref: FSQ 2.5 – Composition of the FSQ team				
Prepared by _____ Approved by _____ Date _____ Issue no. _____				
Position in team	Position in organization manager or departmental representative	Name	Expertise	Date appointed to FSQ team
Leader	Quality systems manager or director		HACCP and quality management systems	
Member	Quality assurance manager		Microbiological, chemical and physical hazards of the products including on-line quality control checks.	
Member	Representing the engineering department		The operation of the plant, and ancillary equipment	

Member	Representing the production, packaging and plant cleaning departments		Production and packaging processes, CIP and plant cleaning	
Member	Representing distribution and marketing		Primary production and raw milk safety and quality	
Other members representing, for example, purchasing, primary production and raw milk intake to be co-opted as required				

In order to understand their function within the FSQ system, the team members should be given clear terms of reference and trained in the structure and purpose of the system, the expected outcomes and value of the system to their individual departments and the organization as a whole. The terms of reference are based on HACCP and ISO 9001:2000/ISO 15161:2001 requirements and an example of them is given in figure 7.15.

Figure 7.15 Suggested terms of reference for a FSQ team

IMS 2.5 FSQ – Example
ISO 9001:2000/ISO 15161:2001 – 5.4.2
HACCP: H.1

Ref: FSQ 2.5.2 – Terms of reference for the FSQ team

Prepared by _____ Approved by _____ Date _____ Issue no. _____

Terms of reference for the FSQ team include:

- preparing a quality manual for the FSQ system. In an IMS this will be a section in the quality manual for the integrated system;
- describing the products and raw materials including the parameters which affect food safety and quality;
- documenting, implementing, monitoring and recording good hygiene practices;
- compiling a flow diagram of the process showing food safety and quality parameters and indicating areas or sites where cross contamination could occur;
- carrying out a hazard analysis of the product(s) from a verified flow diagram by identifying the process steps at which the hazards occur and classifying the safety/quality hazards and the quality hazards and designating the former as CCPs and the latter as CQPs;
- putting preventative measures in place to control both safety/quality and quality hazards to the standard of efficiency required;
- setting critical limits and target levels for each control;
- preparing documented operating procedures for the process identified in the flow diagram, including the critical limits and target levels of the controls;
- preparing, documenting and implementing support systems for the process identified in the flow diagram;
- designating monitoring procedures for each control to include documented methodology, frequency of monitoring and record keeping;
- reviewing the monitoring procedures for effectiveness;
- designing and implementing corrective action procedures including the preparation of contingency plans to deal with breakdowns, including automated control system failures;

- establishing reporting procedures so that corrective action may be taken efficiently and speedily;
- reviewing records and corrective procedures for effectiveness and for continual improvement;
- specifying training needs for technical and food hygiene instruction to include FSQ system awareness;
- designing the audit programme;
- validating and verifying the system;
- preparing safety/quality and quality plans to show the control of food safety and quality in the FSQ system;
- preparing systems to meet potential emergency situations;
- presenting an annual review of the FSQ system to senior management.

2.6 – Planning operational control

The operational control for the system is planned by the FSQ team in accordance with the terms of reference shown in figure 7.15. As the members of the team are drawn from the various departments of the organization they bring in-house experience to the task ensuring the plans for the operation of the system are realistic and workable. If outside consultants are employed it is essential that they work with the in-house members of the team. Without such interaction the FSQ system will not reflect the specific requirements of the processes it is designed to control and its full potential will not be realized.

When the planning process for the FSQ system is completed the plan for the operational control of the system is summarized as a matrix based on the HACCP control chart format but separating safety/quality from quality as shown in figures 7.16 and 7.17.

2.7 – Contingency preparedness for foreseeable events

Contingency preparedness in the food industry is required in the following four main areas:

- defects in raw materials;
- plant breakdowns;
- employees suffering from communicable food related illnesses;
- defects in end products whether on-site or dispatched from the factory.

Figure 7.16 An example of a safety/quality control chart for an FSQ system

IMS 2.6 ISO 9001:2000/ISO 15161:2001 – 5.5.2, 5.5.3 HACCP: H.12								FSQ – Example	
Ref: SQC 1 – Safety/quality control chart for the FSQ system									
Prepared by _____ Approved by _____ Date _____ Issue no. _____									
Ref for the CCP in the process flow	Hazard ref.	Preventative measures (controls)			Monitoring			Corrective action	Personnel responsible
		Procedure	Target level	Critical limits	Procedure	Frequency	Records		
1.1.1	MSQ 1	Temperature control – milk cooled if necessary Milk intake work instruction reference Ref: IN-1	≤ 6 °C	> 6 °C	Calibrated Thermometer Milk intake work instruction reference Ref: IN-1	Every tanker	Milk intake sheet reference Ref: IN-R1	Hold milk in tanker and report to the QA or production manager Complete corrective action report reference Ref: CARa	Production manager QA manager
1.1.2	CS 1	Test for antibiotics reference Ref: Lab-1	Negative	Nil	Laboratory standard operating procedure reference	Every tanker	Laboratory day sheet reference Ref: Lab-R1	Hold milk in tanker and report to the QA or production manager Complete corrective action report reference	Production manager QA manager

Figure 7.17 An example of a quality control chart for an FSQ system

IMS 2.6 ISO 9001:2000/ISO 15161:2001 – 5.5.2, 5.5.3 HACCP: H.12								FSQ – Example	
Ref: QC 1 – Quality control chart for the FSQ system									
Prepared by _____ Approved by _____ Date _____ Issue no. _____									
Ref for the QCP in the process flow	Hazard ref.	Preventative measures (controls)			Monitoring			Corrective action	Personnel responsible
		Procedure	Target level	Critical limits	Procedure	Frequency	Records		
1.1.1	CQ1 Compo-sitional defects	Reference Milk intake work instructions IN-1	Compo-sition as specified	As determined	Laboratory standard operating procedures reference	Every load	Maintained and referenced IN-R1	Hold milk in tanker and report to the QA or production manager Complete corrective action report reference	Production manager QA manager
1.1.2	CQ2 extraneous water	Reference Milk intake work instructions IN-1	No indication of extraneous water	As determined	Laboratory standard operating procedures reference	Every load	Maintained and referenced IN-R1	Hold milk in tanker and report to the QA or production manager Complete corrective action report reference	Production manager QA manager

Defects in raw materials

High-risk, perishable raw materials that are rejected at intake should be dealt with efficiently and quickly because, although rejected for one type of product, they may be suitable for another. For example, milk rejected because of its temperature at intake for the liquid market may be acceptable for use in making butter. To achieve efficient handling, there should be an operating procedure in place detailing the action to be taken and who is responsible for making the decision to reject. It is essential that the reporting mechanism is clearly understood by all involved so that the reject material may be quarantined and removed from the factory site as speedily as possible. In the case of the rejection of raw milk at the dairy in the case study, the analysis of the milk will be recorded on the laboratory day sheet, and the action taken, on the milk intake record. A rejection report, containing the information shown in figure 7.18, should also be completed.

Figure 7.18 An example of a record for use when documenting the rejection of raw materials or incoming goods

IMS 2.7 ISO 9001:2000/ISO 15161:2001 – 7.1, 8.3 HACCP: H.1O		FSQ – Example
Ref: RR 1 – Rejection of raw materials and incoming goods		
Prepared by _____ Approved by _____ Date _____ Issue no. _____		
Date:	Details of consignment	
Cause of rejection:		
Analysis/inspection carried out:	Procedure:	Recorded
Results of analysis/inspection		
Analyst/inspector signature(s)		
Reported to		
Report of manager responsible		
Signature of manager responsible		Date

Plant breakdowns

The detrimental effect of plant breakdowns can be minimized by operating a preventative maintenance programme and having reserve units for all essential equipment. The planning, implementation and maintenance of this system is the responsibility of the engineering department. It should include a documented reporting procedure so that production and engineering staff are aware that when a breakdown occurs the quality assurance (QA) department should be informed. The responsibility of the QA department during such incidents is to ensure the safety and quality of the product. This

may include attention to temperature control, heat treatment, composition and the possibility of microbiological, chemical and physical contamination during the repair operation. A corrective action report should be prepared covering the incident, which the FSQ team will analyse during performance assessment to provide evidence of the effectiveness of the programme.

Employees suffering from communicable food-related diseases

Organizations require a procedure for dealing with employees suffering from communicable food related diseases. The details of such a procedure will be determined by the level of risk in the raw materials and the end products in use. New employees should be instructed in the reporting procedure for ill health during induction and care should be taken to ensure that the process is understood and remembered. All incidents should be recorded.

Product recall

This has been discussed in chapter 6, element 2.7. It requires a recall procedure in place that will enable rapid action to be taken in order to minimize damage to the organization. Documentation for such an incident is shown in figure 7.19.

Figure 7.19 An example of a record for use when documenting the recall of end-products

IMS 2.7 ISO 9001:2000/ISO 15161:2001 – 7.1, 8.3 HACCP – H-12			FSQ – Example
Ref: RC 1 – Recall of end product(s)			
Prepared by _____ Approved by _____ Date _____ Issue no. _____			
Date:	Details of consignment		
Cause of the recall			
Analysis/inspection carried out Procedure:	Ref:	Recorded ref:	
Results of analysis/inspection			
Analyst/inspector signature(s)			
Reported to			
Report of manager responsible			
Signature of manager responsible			Date

IMS 3 – Implementation and operation

3.1 – Operation control

Control of the FSQ system is applied and maintained through standard procedures which are documented to give uniformity of operation, irrespective of changes of operator. To achieve this it is essential that the procedures accurately reflect the processes and that the operators, including relief operatives, are trained in the tasks that they are required to perform. It is recommended that, when preparing the standard procedures, the operatives working on a given process are included in the discussions relating to it. The procedure should ensure that the task is carried out according to best practice and that the process parameters are recorded at the appropriate time. Supervision is needed to maintain record keeping at a high standard. All records should be checked and countersigned by a supervisor or manager to a timescale which will avoid irretrievable loss of information. The success of operation control is demonstrated by throughput and the standard of the end products. If the FSQ system is functioning efficiently and is meeting the requirement for continuous improvement, then there will be a progressive decrease in the number of safety and quality defects. This is, of course, important in any industry but particularly so in the food industry where any FSQ defect may result in prosecution with accompanying media coverage. The standard operating procedures are referenced on the safety/quality and quality control charts (figures 7.16 and 7.17).

3.2 – Management of human resources

The management of human resources follows the sequence – define, appoint, train, appraise (DATA). The first step, define, is to decide the jobs to be undertaken and the number of operators required to do them. This information is obtained from the operating procedures, the throughput of product and the employment structure of the organization. Having determined the number and type of operators needed, a job specification is prepared for each. The next steps are to appoint the operators and to train them. Finally, their performance is appraised as part of the assessment of the efficiency of the operation. This can be done by monitoring the output of the operation and by holding staff appraisal interviews. Food safety and quality issues should be included in the staff appraisal. These may include good personal hygiene, efficiency in reporting controls that are veering from

the target level and/or moving beyond the critical limits and attention to food safety and quality matters when on the job and in the factory.

Training is necessary to obtain efficiency and uniformity in the performance of a task (job skills) and to make the workforce aware of the objectives and targets of the organization with regard to food safety and quality. To establish the training requirements a training needs analysis is carried out. This can be used to determine the scope of training required and also the individual training needs of each employee. The scope of training should cover the technical skills required by the workforce, food hygiene, including personal hygiene, and an awareness of the systems implemented by the organization to achieve food safety and quality. A training needs analysis to determine the scope of the training required is shown in figure 7.20. It is carried out by the FSQ team in conjunction with the training or personnel officer who will then review the individual training required by each employee.

Figure 7.20 An example of a training needs analysis for a FSQ system

IMS 3.3 ISO 9001:2000/ISO 15161:2001 – 6.2.2 HACCP: H.13				FSQ – Example	
Ref: TRA 1 – Training needs analysis to determine the scope, source and timescale of training required relating to the FSQ system					
Prepared by _____ Approved by _____ Date _____ Issue no. _____					
Training	Source of training	Length of the training	Number of staff who require this training	Number of staff to be trained	Number of staff already trained.
FSQ system awareness training	In-house	2 hours	All staff:	All staff	None
Food hygiene foundation level	External training provider	6 hours	All staff		
Food hygiene intermediate level;	External training provider	18 hours	Supervisors		
Food hygiene advanced level;	External training provider	30 hours	Managers as required		
Technical skills Milk intake: to operating procedures: IN-1 and IN-2	Equipment supplier Laboratory on the job under supervision	1 day 0.5 day 1 week	Milk intake staff		

The technical training is done to the relevant operating procedure with an input from the equipment supplier and other specialists as required.

As the FSQ system is operated on HACCP principles the team leader and the members of the FSQ team will require special consideration with regard to training and time to attend meetings and to prepare documents for the system. This has been discussed in section 2.5.

3.3 – Management of other resources

The FSQ system relies on a range of support services some of which are listed in figure 7.13. Others include the buildings, workspaces and utilities of the factory which in many countries should meet legal standards for food safety. With the increase in computerization and automation of plant and equipment, there is a requirement in place for the management and maintenance of these services as a failure in these systems can result in product loss (see section 2.7, plant breakdowns).

3.4 – Documentation and its control

This has been discussed in chapter 6 sections 3.4.1 to 3.4.4. In an IMS the quality manual for the whole system will include FSQ (see chapter 6 section 3.4.2). Taking examples from the case study, it will be seen that the documents required for the FSQ system may be grouped and indexed as shown in figure 7.21.

Figure 7.21 An example of a documentation index for a FSQ system

IMS 3.4 ISO 9001:2000/ISO 15161:2001 – 4.2 HACCP: H.12	FSQ – Example
Ref: FSQ – Documentation index	
Prepared by _____ Approved by _____ Date _____ Issue no. _____	
Index to documents applicable to the whole system:	
FSQ 0	Decision to implement a FSQ system within the IMS of the organization
FSQ 1.1	Policy statement for the FSQ system
FSQ 1.2	Description of products and materials included in the FSQ system
FSQ 1.3	The principles on which the FSQ system is based
FSQ 1.4	Externally generated documents
FSQ 2.5.1	Composition of the FSQ team
FSQ 2.5.2	Terms of reference for the FSQ team
FSQ 2.5.3	Agenda and minutes of FSQ team meetings

FSQ 3.4	Management structure
FSQ 4.3	Internal audit plan
FSQ 6	Agenda for management review and minutes of meetings
RR 1	Rejection of raw materials and incoming goods
RC 1	Recall of end product(s)
TRA 1	Training needs analysis

Index to documents for an individual process: No. 1. Processing raw milk into pasteurized milks in retail packs	
Food safety/quality documents	Food quality documents
FD-1a – Flow diagram, linear FD-1b – Flow diagram – schematic HI-1 – Hazard identification RP-1 – Risk profile of pathogens and their toxins in pasteurized milk CCP-1 – CCP critical control point register GAP1a – Gap analysis SQC 1 – Safety/quality control chart	FD-1a – Flow diagram, linear FD-1b – Flow diagram – schematic HI-1 – Hazard Identification QCP 1 – QCP quality control point register GAP1b – Gap analysis QC 1 – Quality control chart

Index of operating procedures for an individual process: No. 1. Processing raw milk into pasteurized milks in retail packs	
If the procedure involves food safety or food safety/quality issues it is an FSQ procedure. Only procedures that do not include food safety are FQ procedures.	
Food safety/quality (FSQ) procedures	Food quality (FQ) procedures
IN-1: Milk intake procedure – acceptance of raw milk	
IN-2: Milk intake procedure – discharging tankers, filtering milk and cleaning equipment	

Index of records for an individual process: No. 1. Processing raw milk into pasteurized milks in retail packs	
If the record is to be used with procedures that cover food safety or food safety/quality issues it is an FSQ record. Only records that do not include food safety are FQ records.	
Food safety/quality (FSQ) records	Food quality (FQ) records
IN-R1: Milk intake record	

Index of corrective action and preventative action reports for an individual process: No. 1. Processing raw milk into pasteurized milks in retail packs	
If the report covers food safety or food safety/quality issues it is an FSQ report. Only reports that do not include food safety are FQ reports.	
Food safety/quality (FSQ) corrective and preventative action reports	Food safety/quality (FQ) corrective and preventative action reports
CAR 1a – Corrective action report PAR 1a – Preventative action report	CAR 1b – Corrective action report PAR 1b – Preventative action report

In the FSQ system documents relating to food safety only and food safety plus food quality are put into a single category and are clearly distinguished from the food quality documents. This identifies all the food safety issues in the system and allows them to be inspected separately from those concerned with food quality. The organizational plan for the food safety plus food safety/quality documentation equates to a HACCP plan, while that for the quality documents is a quality plan. All documents relating to food safety and food safety/quality issues should be marked in such a way that they are distinguishable from the quality documents. There are various methods of doing this; for example where paper copies are used, colour coding is clear and simple. Otherwise the documents may be marked FSQ and FQ as appropriate or by some suitable individual method. If the system is stored and implemented electronically, separation of folders and files is a simple operation.

Referencing the documents, particularly the records, in the FSQ system is essential for their control and because they are required to establish traceability of the product. This important feature of food safety should be given prominent exposure during training and auditing. The reference system adopted is the choice of the organization but should be as simple as possible. Each document should carry an issue number and there should be a control system to ensure that only the latest issue documents are in use.

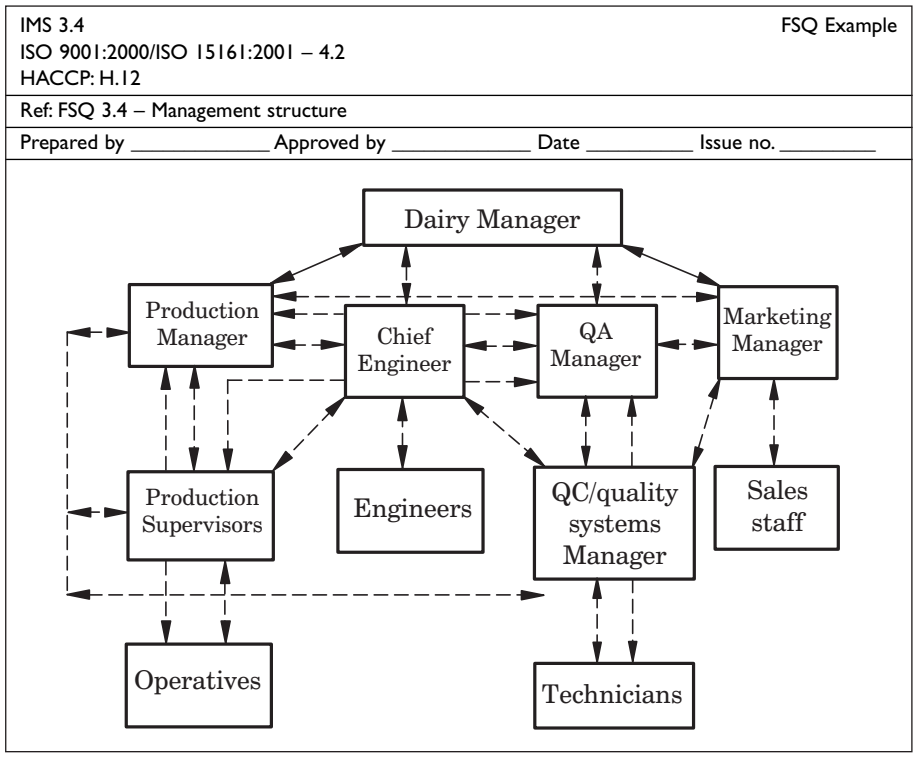
NOTE When preparing records, the control references should appear on the master record only. On the pro forma record sheets the control information should be reduced to an icon identifying the record and the issue number.

3.5 – Communication

A food factory work area is not the ideal place for talking nor is it desirable that lengthy conversations should be indulged, but effective communication is essential, particularly the rapid and efficient reporting of out of line events and the issuing and receiving of instructions. Within the factory, official communication is usually between different types of employees. Therefore it is important that protective clothing does not create anonymity but distinguishes employees' positions. In an organization with a large work force the appropriate employee may be difficult to identify and names embroidered on overalls help as do photographs posted on notice boards of supervisors and management. During training in technical skills and personal hygiene, associated reporting procedures should be included. The trainees should be made aware of the management structure and to whom they are required to report. This should include relief managers and

supervisors. Figure 7.22 shows a possible management structure for the dairy used in the case study. There is communication between all departments at managerial level but the production operatives, engineers sales staff and QC technicians are limited to official communication within their own department. That is, they report to their departmental manager and it is then the responsibility of the manager to communicate with other departments and to ensure that communication continues when he/she is absent. Communication with stakeholders, regulatory bodies and other external organizations such as the media should be through designated spokespersons who are trained in the presentation of information.

Figure 7.22 An example of a schematic representation of the management structure in a food organization



3.6 – Relationship with suppliers and contractors

The main contracts of a food organization are with the suppliers of the raw food materials. As the quality, and in some cases the safety, of the end products

will depend on the safety and quality of the raw materials it is necessary that these are purchased to specification and that the specifications are adhered to at all times. Inspection of consignments of raw materials arriving at the factory, and rejection if specifications are not met, is essential to maintaining the safety and quality of the end products. Because of the effect that raw materials can have on the final products, many food processors carry out supplier auditing to check that the primary production is carried out under hygienic and safe conditions.

NOTE Safety and quality control for the intake of raw milk has been discussed in the case study.

IMS 4 – Performance assessment

4.1 – Monitoring and measurement

Monitoring the preventive measures put in place to control hazards is an important aspect of HACCP as well as ISO 9001:2000/ISO 15161:2001. The success of monitoring a food manufacturing process depends on three factors: methodology (including instrumentation), frequency, and record keeping and reporting. The method, with its corresponding instrumentation, selected to monitor a parameter should be capable of providing measurement at a suitable level of sensitivity and accuracy. To obtain the former is a matter of making the correct selection, while the latter can be determined by calibration. Once the method has been selected an operating procedure is prepared and technicians are trained in its use. Many monitoring processes are operator-dependent, and provision should be made through proficiency testing to ensure that technicians have the necessary expertise. The second factor that affects the efficiency of monitoring is the frequency of checking. This can only be decided on an individual basis for each monitoring activity. When determining the frequency of monitoring it should be remembered that, in the case of a failure, the entire production from the time of the previous check to the point of failure should be quarantined as nonconforming product. The third factor, record keeping and reporting is the outcome of the previous two. Without it monitoring is reduced to an exercise of no lasting value. Information from the records is used to ensure that the controls are operating at the target level or to indicate when they are approaching the critical limits. The records also supply the evidence for reporting out of line results and provide the data for assessing the performance of the process. An example of a monitoring procedure in a dairy is shown in figure 7.16.

4.2 – Analysing and handling nonconformities

Analysing the performance of an FSQ system in the food industry is usually achieved by the examination of monitoring records, microbiological and chemical test results, corrective action reports and customer complaints. The purpose is to determine if the system is operating efficiently and if it is meeting the objectives and targets set by the organization for food safety and quality. The evaluation should be quantitative and statistical analysis enables comparisons to be made and presented in graphical form. These have significant impact and can be used to inform the workforce and stakeholders.

4.3 – Management system audit

The purpose of auditing a FSQ system is to ensure that, as it is being implemented, it is competent to control the safety and quality of the end products and to identify any areas that could be improved. Auditing in the food industry has received considerable attention in recent years and various techniques have been used but, without discussing audit methodology in detail, there are certain factors that should be considered (Weallens, 2000).

The auditors will usually be employees of the organization and will require training in audit techniques and in the FSQ system in use. They should also have knowledge of the processing carried out in the factory. It is important that they are independent of the operation they are auditing. Having selected the auditors and initiated their training, it is necessary to plan the audit. This can be done in a matrix showing the sections to be audited and giving a timed programme for carrying out the audits. An example is shown in figure 7.23.

Figure 7.23 An example of an internal audit plan for a FSQ system

IMS 4.3 ISO 9001:2000/ISO 15161:2001 – 8.2.2 HACCP: H.11						FSQ – Example
Ref: FSQ 4.3 – Internal audit plan						
Prepared by _____ Approved by _____ Date _____ Issue no. _____						
Audit Date	Jan	Feb	Mar	Apr	May	June
Milk intake	■					
Processing and packaging					■	
Laboratory and QC dept.		■				
Engineering department				■		

The shaded squares in figure 7.23 mark the month in which the audit is to be completed. The square is then signed to indicate completion. The matrix shows a period of six months but the cycle of audits does not necessarily

conform to this, nor do all audits have to be carried out after the same interval of time. It is important, however, that audit reports are completed, as these are required for verification and review purposes. For further information on auditing the reader is advised to consult one of the many books on the subject or to attend a course specifically on this subject.

IMS 5 – Improvement

5.1 – Corrective action

A feature of ISO 9001:2000 and ISO 15161:2001 is a pro-active approach to correcting defects in the production process served by the quality system and in its own structure and performance. Defects requiring corrective action may occur and be recognized during the operation of the process system or in the safety/quality control system or detected during an audit. The corrective action process requires the cause of the defect to be examined and a proposal made to correct it. The corrective action should be taken within a specified period, documented in a corrective action report (CAR), and its execution approved. An example of a pro forma CAR is given in figure 7.24.

Figure 7.24 An example of a corrective action report

IMS 5.1 FSQ – Example ISO 9001:2000/ISO 15161:2001 – 8.5.2 HACCP: H.11
Ref: CAR 1 – Corrective action report
Prepared by _____ Approved by _____ Date _____ Issue no. _____
Corrective action report
CAR. Number_____ Raised by _____ Date _____
Identification of defect: Area/department FSQ reference: Other documentation:
Details of the defect: Signed by person raising the CAR_____ Signed by manager of the department or person responsible _____
Corrective action proposal: Completion date: Signed by manager of the department or person responsible
Date action completed_____ Comments:
Action reviewed by FSQ team leader or an appointed representative Date_____ Approved (signature) _____ If not approved new CAR no.: ____
CAR closed: Date _____ Signature_____

5.2 – Preventative action

Corrective action has now been extended to include the prevention of faults either in the process or in the system. Preventative action requires the examination of a situation, often from the monitoring records, a proposal to prevent it from occurring and the implementation of the proposal within a time limit followed by approval of its execution. The action taken is recorded in a preventative action report (PAR). A PAR has a similar format to a CAR. The words 'potential defect' are used and 'preventative' replaces 'corrective'. The continual improvement of the system is assessed at FSQ team meetings and the comments and recommendations are taken forward to the management review meeting.

5.3 – Continual improvement

The practice of correcting and preventing individual defects to bring about an improvement in the system has been extended to include a requirement to work towards continual improvement. This has been adopted by HACCP (H.vi and H.vii), although not expressed as forcibly as in the ISO standards, ISO 9001:2000 and ISO 15161:2001.

IMS 6 – Management review

The FSQ team should meet regularly, at least once a month, as their discussions provide a mechanism by which problems can be identified and discussed on a regular basis rather than waiting for a full management review which may only take place annually. This changes the management review a little. The agenda remains the same, but the review meeting is presented with data and information which has been processed and discussed and which is accompanied by comments and recommendations. As the FSQ team comprises experienced staff from the factory floor their input is from a different perspective from that of senior management and gives a balanced approach to the review. The agenda for a management review is given in figure 7.25. It may be noted that the agenda for the management review is similar to that for FSQ team meetings.

Figure 7.25 An example of an agenda for a management review

IMS 5.1 ISO 9001:2000/ISO 15161:2001 – 8.5.2 HACCP: H.11	FSQ – Example
Ref: FSQ 6 – Agenda for a management review	
Prepared by _____ Approved by _____ Date _____ Issue no. _____	
Agenda: Minutes of previous meeting and matters arising Follow up of actions from previous reviews Summary of Corrective actions Preventative actions Raw material defects Intermediate product defects End product defects Customer complaints Reports on audit findings Comments and recommendations from the FSQ team on the above Forthcoming changes to the processing system Decisions on changes to the FSQ system to achieve continuing improvement	

8. A note on ISO/CD 22000

At the time of writing a new ISO standard is being prepared which will be published as ISO 22000.

The standard will be based on the HACCP system and the management system that is required for its effective operation. It recognizes that in addition to the requirements of HACCP there is also a need for supplementary provisions such as good manufacturing practices appropriate to the activity involved. The standard refers to these as supportive safety measures (SSMs) and describes the systems needed to operate them.

It seems likely that in due course ISO 22000 will supersede ISO 15161:2001. The latter approaches the control of food safety as an adjunct to the application of ISO 9001:2000, whilst the new standard is a self-sufficient stand-alone document, based on the Codex Alimentarius guidelines.

9. Continual improvement

It should be the aim of any organization to achieve continual improvement in its operations. To most people, improvement means an increase in profitability – certainly a good standard yardstick. Profits, however, cannot be achieved directly. In most organizations they are the relatively small difference between two very large numbers – the money that is achieved through sales and the money that is spent on costs. Increasing profit depends on increasing this difference, whether by increasing one or reducing the other or both. These in turn depend on increasing the satisfaction offered, not only to the customer, but also to all the other stakeholders – stakeholders being those who have an interest in the operations of the organization. They will include employees, suppliers, insurers, neighbours and so on. All these are affected by the way the organization behaves and by the success it achieves.

The fundamental model for any management system is illustrated in figure 9.1, which is reproduced from book 2 in this series. This in turn is based on a diagram shown in ISO 9001:2000, modified to demonstrate control measures needed to meet the needs of the organization itself as well as those of interested parties (equivalent to 'stakeholders' for our present purposes). Risk control and the management responsibility for risk management are shown as essential elements in the achievement of continual improvement.

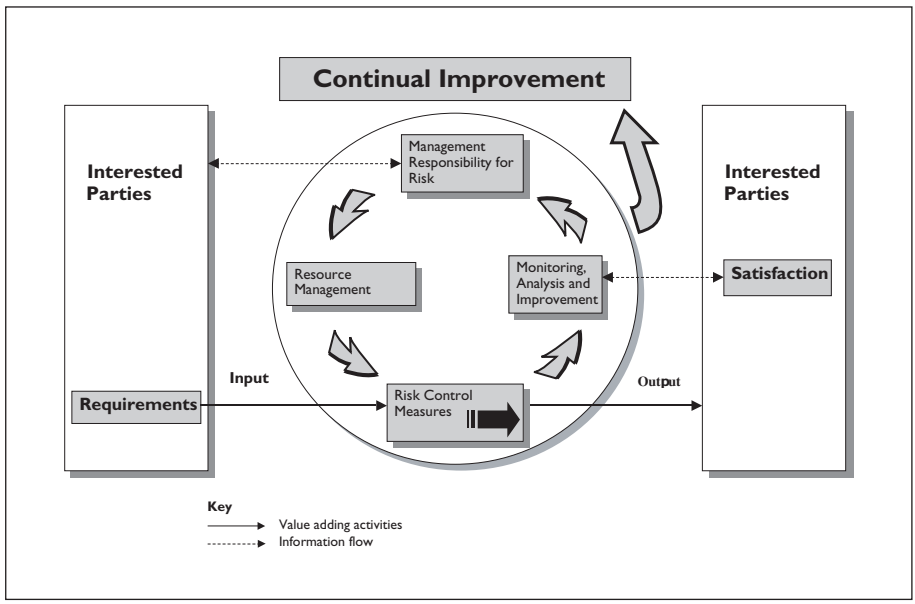
To achieve improvement any organization needs to:

plan what it is going to do;
do what it has planned;
check that things have been done correctly;
act to improve the system.

These can be further expanded as shown in figure 9.2. Each of the P-D-C-A elements is analysed to identify the activities that are needed for implementation. Two extra elements are added: a statement of policy and principles

to start with to say what the organization is setting out to do. The management review appears at the end to assess how successful the system is and how it can be improved, starting another circuit of P-D-C-A.

Figure 9.1 Model for a process-based quality management system



It is these elements that form the IMS framework shown in appendix 1. The elements are in the logical plan-do-check-act order and reflect those steps which are needed in the implementation and operation of any management system, whether embodied in a formal standard or not. In some cases the correspondence is obvious. Often the words are similar to those of ISO 9001:2000 which is the most commonly adopted management system standard. However, it applies to all management system activities – sales, personnel, accounting as well as food safety and quality, occupational health and safety and the more commonly adopted management systems. Other books in this series show how it is equally applicable in such diverse subjects as customer satisfaction and information security.

This illustrates one of the essential benefits of an integrated system – there is no repetition of the basic machinery of any system (documentation, auditing, etc.) – thus additions can be restricted to those specific to the system being added.

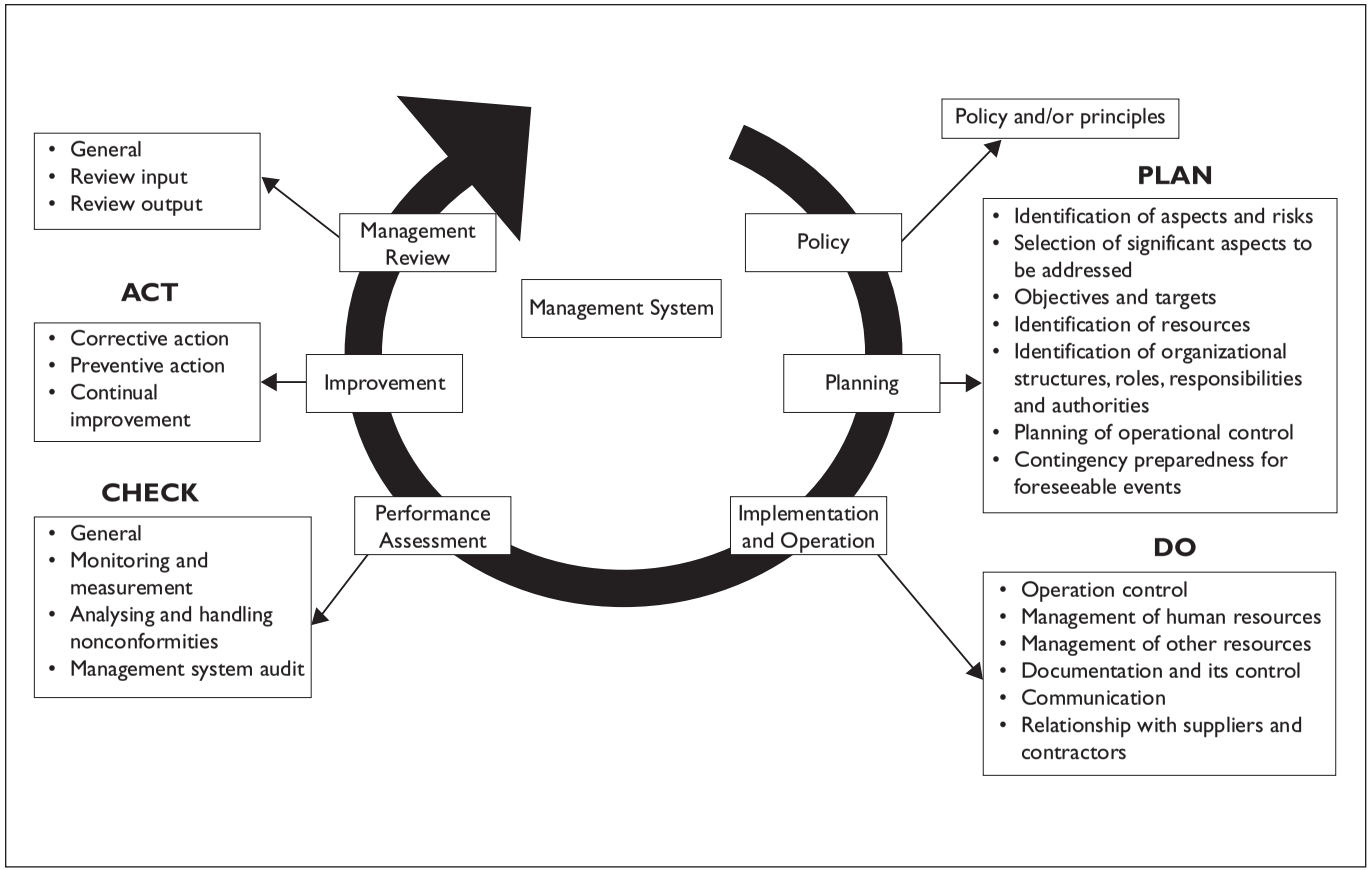
The greatest benefit from an integrated system, however, comes from the recognition it brings that all systems have a common purpose, namely the continual improvement of the organization's performance. Specific systems are no longer seen as the 'property' of a particular department or function but are part of everybody's business in the operation of the organization.

In practical terms most improvement in the organization will be achieved through the improvement of individual processes. The greatest improvement is if the process can be eliminated without adversely affecting the added value – not often achievable, but far from impossible. A process may continue long after the need for it has ceased to exist unless there is a regular critical examination. Techniques such as value engineering can be helpful. More frequently combining one process with another can lead to savings. The process map can often indicate where this might be achieved.

Whilst the emphasis usually has to be on saving cost (as this is more easily measured than added value) opportunities should also be sought in achieving greater added value at relatively little added cost. Again the process map may indicate opportunities.

All improvements should be measured, as far as it is practicable to do so, and subsequently recorded. If accurate measurement is not practicable, or would be stupidly expensive, an estimate can be made as long as it is recorded as such. These records should be regularly reviewed by the responsible manager who can then ensure that the improvement is 'continual'. There is a tendency once a significant improvement in a process has been made to ease off in the search for even better ways of doing things.

Figure 9.2 Model for the IMS framework



Appendix 1. IMS framework

	Elements
0 Management system	0 The organization should establish, document, implement and maintain a management system and seek to continually improve its effectiveness. The organization should: a) identify the processes needed for the management system and their application throughout the organization b) determine the sequence and interaction of these processes c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes e) monitor, measure and analyse these processes, and f) implement actions necessary to achieve planned results and continual improvement of these processes.

	Elements
1 Policy	
1 Policy and principles	1 Top management should ensure that the overall policy: a) is appropriate to the organization b) includes a commitment to comply with all relevant requirements and continually to improve the effectiveness of the management system c) provides a framework for establishing and reviewing objectives d) is communicated, where appropriate, and is understood within the organization, and e) is reviewed for continuing suitability.

Appendix 1 IMS framework

	Elements
2 Planning	
2.1 Identification of aspects and risks	2.1 The organization should establish a process for identifying those aspects of its operations which need to be controlled and/or improved in order to satisfy the relevant interested party(ies). This includes research and design. Where appropriate, legal requirements should be identified.
2.2 Selection of significant aspects to be addressed	2.2 The organization should establish a process for prioritizing its aspects, so that those that would have a significant impact are readily identified for control measures where this is appropriate.
2.3 Objectives and targets	2.3 Top management should ensure that the objectives, including those needed to meet requirements for product and/or service, are established at relevant functions and levels within the organization. The objectives should be measurable and consistent with the policy.
2.4 Identification of resources	2.4 The organization should ensure the availability of adequate human, infrastructure and financial resources. It should determine and provide the resources needed: a) to implement and maintain the management system and continually improve its effectiveness, and b) to enhance satisfaction by meeting requirements.
2.5 Identification of organizational structures, roles, responsibilities and authorities	2.5 The organization should identify the roles, responsibilities, accountabilities and their interrelationships within the organization as far as needed to ensure effective and efficient operation. Top management should ensure the responsibilities and authorities are defined and communicated within the organization.
2.6 Planning of operational control	2.6 The organization should identify those operations and activities that are associated with the identified significant aspects in line with its policy, objectives and targets. The organization should plan and develop the process necessary for effective implementation of the operational control measures.
2.7 Contingency preparedness for foreseeable events	2.7 The organization should establish and maintain a process for identifying and responding to any potential emergency situation. The process should seek to prevent and mitigate the consequences of any such occurrence.

	Elements
3 Implementation and operation	
3.1 Operational control	3.1 The organization should ensure arrangements are in place at the operational level that ensure that: a) the objectives and requirements for the product/services are being met b) the necessary processes, documents, and resources specific to the product/service are provided c) the necessary verification, validation, monitoring, inspection and test activities specific to the product/service are instigated d) the records needed to provide evidence of the realization processes meeting requirements are produced.
3.2 Management of human resources	3.2 The organization should ensure that the personnel carrying out activities on its behalf should be competent on the basis of appropriate education, training, skills and experience to enable them to undertake all their duties. The organization should: a) evaluate the effectiveness of the actions taken b) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives.
3.3 Management of other resources	3.3 The organization should determine, provide and maintain the infrastructure needed to achieve its objectives. Infrastructure includes, as applicable: a) buildings, workspace and associated utilities b) process equipment (both hardware and software), and c) supporting services (such as transport or communication).
3.4 Documentation and its control	3.4.1 Documentation requirements The management system documentation should include: a) documented statements of the policies and objectives b) a manual describing the working of the management system (see 3.4.2 below) c) documented procedures that are required by specific standards d) documents needed by the organization to ensure the effective planning, operation and control of its processes, and e) records required by any specific standard. Note 1: Where the term 'documented procedure' appears, this means that the procedure is established, documented, implemented, controlled and maintained. Note 2: The extent of the management system documentation can differ from one organization to another due to: a) the size of organization and type of activities b) the complexity of processes and their interactions, and c) the competence of personnel.

	Note 3: The documentation can be in any form or type of medium. 3.4.2 Integrated management system manual The organization should establish and maintain a manual that includes: a) the scope of the management system, including details of and justification for any exclusions b) the documented procedures established for the management system, or reference to them, and c) a description of the interaction between the processes of the management system. 3.4.3 Control of documents Documents required by the management system should be controlled. Records are a special type of document and should be controlled according to the requirements of those specific standards covered by the IMS. A documented procedure should be established to define the controls needed: a) to approve documents for adequacy prior to issue b) to review and update as necessary and re-approve documents c) to ensure that changes and current revision status of documents are identified d) to ensure that relevant versions of applicable documents are available at points of use e) to ensure that documents remain legible and readily identifiable f) to ensure that documents of external origin are identified and their distribution controlled, and g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose. 3.4.4 Control of records Records should be established and maintained to provide evidence of conformity to requirements and of the effective operation of the management system. Records should remain legible, readily identifiable and retrievable. A documented procedure should be established to define the controls needed for the identification, storage, protection, retrieval, retention and disposal of records.
3.5 Communication	3.5 The organization should determine and implement effective arrangements for communication: a) between the various levels of the organization as appropriate to their needs b) for receiving, documenting and responding to relevant communication from external interested parties.
3.6 Relationship with suppliers and contractors	3.6 The organization should formalize its arrangements for those who supply and contract their services, both internal and external, which have an impact on the organization's performance.

	Elements
4 Performance assessment	
4 General	4 The organization should establish and measure the characteristics of the product and/or services to verify that requirements have been met. This should be carried out at appropriate stages of the process in accordance with the planned arrangements.
4.1 Monitoring and measurement	4.1 The organization should establish and maintain arrangements to monitor and measure, on a regular basis, the key characteristics of its operations and activities that can have a significant impact. This should include the recording of information to track performance, relevant operational controls and conformance with the organization's objectives and targets. The organization should establish and maintain a process for periodically evaluating the performance against stakeholder requirements.
4.2 Analysing and handling nonconformities	4.2 The methods used for analysing performance should demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, corrective action should be taken. Evidence of conformity with the acceptance criteria should be maintained and recorded.
4.3 Management system audit	4.3 The organization should establish and maintain a programme for periodic management system audits to be carried out, in order to determine whether or not the management system: a) conforms to planned arrangements for the management system b) has been properly implemented and maintained, and is being adhered to. The audit programme, including any schedule, should be based on the results of risk assessment of the organization's activities, and the results of previous audits. The audit arrangements should cover the scope, frequency, methodologies and competencies, as well as the responsibilities and requirements for conducting audits and reporting results. Wherever possible, audits should be conducted by personnel independent of those having direct responsibility for the activity being examined.

Appendix 1 IMS framework

	Elements
5 Improvement	
5.1 Corrective action	5.1 The organization should establish a process for defining responsibility and authority for implementing action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions should be appropriate to the effect of the nonconformities encountered. A process should be established to define requirements for: a) reviewing nonconformities (including stakeholder comments) b) determining the causes of nonconformities c) evaluating the need for action to ensure that nonconformities do not recur d) determining and implementing the action needed e) recording the results of action taken, and f) reviewing corrective action taken.
5.2 Preventive action	5.2 The organization should establish a process for defining responsibility and authority for implementing action appropriate to the risk.
5.3 Continual improvement	5.3 The organization should continually improve the effectiveness of the management system through the use of the policy, objectives, audit results, analysis of data from monitoring and measurement, corrective and preventive actions and management review.

	Elements
6 Management review	
6.1 General	6.1 Top management should review the organization's management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness. This review should include assessing opportunities for improvement and the need for changes to the management system, including policy and objectives. Records from management reviews should be maintained.
6.2 Review input	6.2 The input to management review should include information on: a) results of audits b) stakeholder feedback c) status of preventive and corrective actions d) follow-up actions from previous management reviews e) changes that could affect the management system, and f) recommendations for improvement.
6.3 Review output	6.3 The output from the management review should include any decisions and actions related to: a) improvement of the effectiveness of the management system and its processes b) improvement related to stakeholder requirements, and c) resource needs.

Appendix 2. Process mapping

In common with most modern management systems the food safety and quality systems described in this book are constructed around processes rather than procedures.

A process is often defined as the mechanism whereby an input is converted into an output. More specifically, in the food industry as in any other business, the objective is to add value to its inputs to meet the needs of its customers. A process is any activity that forms part of that sequence of adding value. A procedure on the other hand describes how an activity is to be carried out. It is concerned with means and methods rather than inputs and outputs. Procedures or operating instructions may still be needed to describe how a process is carried out, but they do not define the process.

There are various ways in which processes can be identified and recorded, but process mapping is most frequently used employing activity sequence flow charts. A simple example – of making a cup of tea – was included in *IMS: Implementing and Operating*, and is reproduced in figure A.2.1.

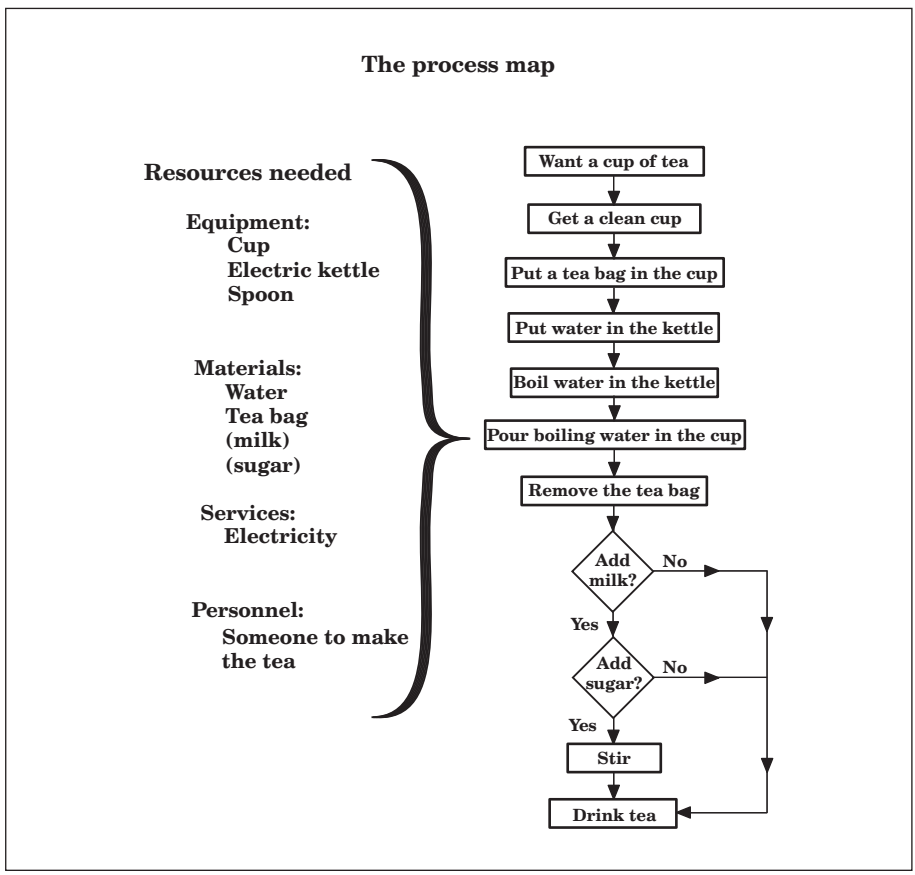
Whilst this may be regarded as a trivial example, it serves to illustrate some important points. Process maps should be kept as simple as possible. Normally only three or four different symbols will be needed to show the activities and their relationship. The symbols commonly used are shown in figure A.2.2. In constructing process maps the following symbols will be sufficient for most purposes.

The example also serves to demonstrate the difference between a flow chart and a critical path diagram. Clearly if you were going to make a cup of tea you would put the kettle on to boil before you put the tea bag in the cup. However, if critical path diagrams are in existence they can be helpful in creating the process map – as indeed can procedures and work instructions as long as the distinctions between them are kept clearly in mind.

In this example the process is complete in itself. In a business organization there will be few stand-alone processes – most will receive output from a previous process and after the process has been carried pass the output on

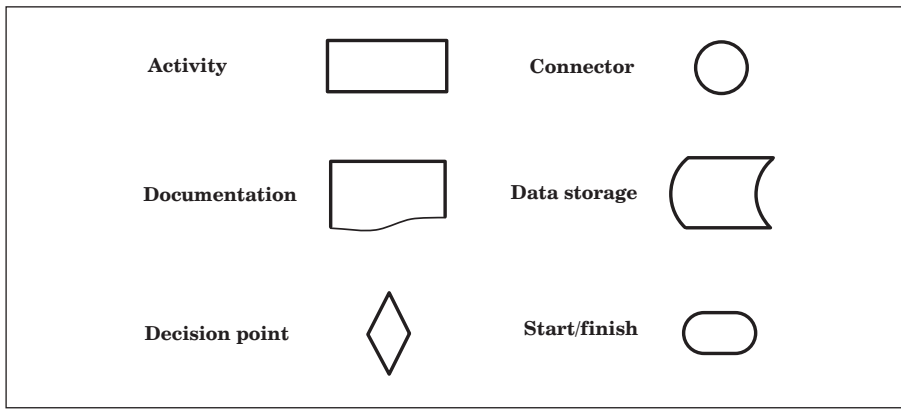
to another. There will need to be link symbols to show where one process connects with another until, at least conceptually; the whole organization will have been mapped. For organizations where the number of processes is not great (and this depends on the complexity of the organization, not its size) a simple manual system of process mapping may be sufficient. If this proves difficult, a computer-based system may be needed – there are a number of packages available. It is important, however, that the processes should be identified and mapped by the people actually carrying them out. Not only do they know what really happens, but also they will appreciate their place in the activities of the organization, and a team attitude is encouraged. All the operatives concerned will need some training in how to identify and map processes, but this is not usually a source of difficulty. It will take longer if computer systems are used.

Figure A.2.1 A simple example – Making a cup of tea



Appendix 2 Process mapping

Figure A.2.2 Symbols used in process mapping



The identification of processes and the construction of a flow diagram is an essential initial step in the application of HACCP. Each process step in the production of the finished goods should be examined and the potential hazards identified – the first of the seven principles of HACCP. For the purposes of food safety and food quality only those processes that are involved in the production sequence need to be examined. (In a fully integrated management system all activities of the organization will be mapped, not only those concerned directly with the product.)

Appendix 3. Glossary of food safety/ quality terms

Definitions of terms are essential in some contexts, but frequently a bare definition fails to convey the full meaning of a term. This is particularly true in the area of food safety where on occasion the same term has come to mean slightly different things in different contexts. Words that have their everyday meaning in the text are not included in this glossary.

The following list is by no means exhaustive. The basic definitions are mainly contained in ISO 9000:2000 in respect of the quality standards ISO 9001:2000 and ISO 15161:2001. In the more specialized subjects the definitions come mainly from the CAC publications (2001 a, b, c, d). The author also wishes to acknowledge Voysey (2000), Gaze (2003), Weallens (2000) and Mortimore and Wallace (1998).

control measure: Any factor, action or activity that can be used to prevent or eliminate a (food safety) hazard or reduce it to an acceptable level. May also be called a preventive measure.

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

NOTE A corrective action eliminates the cause of a detected nonconformity; preventive action is to eliminate the cause of a potential nonconformity that has not yet occurred.

critical control point (CCP): Process (step) at which control can be applied and is essential to prevent or eliminate a food safety hazard (nonconformity) or reduce it to an acceptable level.

critical limit: Criterion which separates acceptability from unacceptability.

deviation: Failure to meet a critical limit (i.e. a nonconformity).

dose-response assessment: Determines the relationship between the exposure of a consumer to a hazard (dose) and the severity and/or frequency of associated adverse health effects (response).

exposure assessment: Assessment of the likely intake of hazards with a food, ideally this should be quantitative but can be qualitative

food: All solid materials that are eaten as part of the human diet, including drinking water and all beverages and water that are used in the preparation of food.

food quality: Characteristics which affect the acceptability of the food to the customer.

NOTE 1 The CAC definition adds 'excluding food safety factors' as food safety and food quality have been seen as different considerations throughout the food industry.

NOTE 2 The definition of quality in ISO 9004:2000 as 'the degree to which a set of inherent characteristics fulfils requirements' clearly implies that the product is safe to use.

food safety: Assurance that the food will not cause harm to the health of the consumer when it is prepared and/or eaten according to its intended use.

food safety control system: System designed to ensure the safety of food to the consumer such as HACCP (hazard analysis and critical control point).

food safety and quality management systems (FSQMS): Systems designed to coordinate and manage all the activities which ensure the safety and quality of food to give customer satisfaction and consumer safety.

food suitability: Assurance that food is acceptable for human consumption according to its intended use.

GMP: good manufacturing practice.

GHP: good hygiene practice.

HACCP system: System which identifies, evaluates and controls hazards which are significant for food safety.

hazard: Biological, chemical or physical agent in, or condition of, food which has the potential to cause an adverse health effect.

hazard analysis: Process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and there should be addressed in the HACCP system (see hazard identification).

hazard characterization: Evaluation of the agent causing the adverse health effects associated with each hazard – the characterization will include quantitative and qualitative information.

hazard identification: Process of identifying and describing the hazards that are likely to be present in a food or group of foods

microbiological criterion: Acceptability of a product or food lot, based on the absence or presence, or number of micro-organisms including parasites, and/or the quantity of their toxins/metabolites, per unit(s) of mass, volume, area or lot.

monitor: Conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.

operation: All the activities required to perform a piece of work in total, or at a specific step in a process (see process).

organization: Business, company or enterprise supplying products or services to the public.

process: All the activities required to perform a piece of work in total or at a specific step in an operation (see operation).

preventative measure: Factor, action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level (also called a control or a control measure).

quality management systems (QMS): Systems designed to coordinate all the activities which achieve customer satisfaction such as ISO 9001:2000.

risk: Likelihood of harm to the consumer from the consumption of the food specified.

risk analysis: Process consisting of three components: risk assessment, risk management and risk communication.

risk assessment: Scientifically-based process consisting of the following steps: hazard identification, hazard characterization, exposure assessment and risk characterization.

risk characterization: Likelihood of harm to the consumer from the consumption of the food specified.

risk communication: Interactive exchange of information and opinions concerning risk and risk management among risk assessors, risk managers, consumers and other interested parties.

risk management: Process of weighing alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate controls.

risk profile: Preliminary analysis of the level of risk of a hazard, by which the feasibility and requirement to carry out a full risk assessment is determined.

step: Point, procedure operation or stage in a food handling operation anywhere in the food chain, from primary production to final consumption.

target level: Optimum level for the operation of a preventative measure (control).

NOTE It may be used as an early warning that the preventative measure is not controlling the hazard effectively.

uncertainty: Indication of the range of values that are consistent with all the observations, data and expert judgement, and that with varying degrees of credibility can be attributed to the value, assumption or conclusion.

validation of the HACCP system: Obtaining evidence that the elements of the HACCP system as presented in the HACCP plan are effective.

variability: Indication of the range of individual values that are expressed as a summary value.

verification of the HACCP system: Application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine compliance with the HACCP plan.

Appendix 4. A note on risk

For any organization, the subject of risk management is a wide one and is dealt with in a separate book in this series (*IMS: Risk Management for Good Governance*).

In this book the term 'risk' is used to denote the chance or possibility that something of an adverse nature will occur. In particular, microbiological risk is the chance or possibility that a hazard, if present in the product, will have an adverse effect on the health of the consumer. This is the risk that is the most important in the field of food production. The CAC defines risk as 'A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food'.

Food safety is concerned with risks to the safety of the product. Any failure can put at risk not only the health and even lives of customers but will damage the reputation of the organization to the point that it may well not survive. Even an efficiently managed product recall may well destroy the trust of the public in any other product of the organization.

In the wider context of the whole organization there are many other risks to be considered and managed. ISO Guide 73 defines risk as the combination of the probability of an event and its consequences. This includes the CAC definition given above but with important differences.

Food safety is concerned with the safety of the product. The organization has to consider many more aspects. In operational terms, the management has to consider not only the things that could give rise to a food hazard, but all the other aspects on which production depends –environment, plant and equipment, power supplies, telephone and computer systems, people and skills needed, and so on.

At a managerial level achieving sales, the availability of capital, of labour etc. all have to be considered. The environmental risks of flood, fire, pollution or even terrorism or other public disorder all have to be considered. Changes in legislation, in fashion, and attitudes to social responsibility all have to be taken into account.

Another important difference between risk in the food safety context and in the organization as a whole is that risks in food production are by definition downsides – hence aspects are described as hazards. In the overall context, risk management has to consider any of the factors which we normally take for granted and assess what would happen if they should change. These can be positive as well as negative. If the price of an essential material increases sharply the effect on the organization may be adverse; but a significant price reduction, or the opening of a new market, may present new opportunities. Managers who fail to identify possible changes that could present a major opportunity are failing their organizations in the same way as if they fail to consider the possibility of an adverse occurrence. Risk analysis is just as much about identifying positive opportunities as it is about avoiding losses.

Many of the risks to be considered for the whole organization will need discussion and resolution at board level or at senior management, for two main reasons. One is that significant capital expenditure may be involved – for example, if it is decided that the risk of a power failure is so great that standby generators should be installed (as in a hospital perhaps) or the consequences of a computer failure would be so dire that a parallel system should be purchased (as with an airline).

Other matters for senior management to consider are major legislative, environmental or social matters eg tobacco, slaughterhouses, food additives, fishing. These may require an organization to change direction significantly and possibly abandon some areas totally. The object of risk management is not to eliminate risk but to ensure that the risks are known and accepted. There should be no surprises.

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IMS: Managing Food Safety

IMS: Managing Food Safety examines product control in the food industry and the characteristics that make its management different from that of other industries. Particular attention is given to the role of the HACCP (Hazard Analysis and Critical Control Point) system, the benefits of operating within the context of an Integrated Management System and the use and application of relevant standards.

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The overall series editor is David Smith of IMS Risk Solutions Ltd, who has been involved in writing management system standards since the early 1990s and is the author of a number of BSI books on the subject.

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