

ISO 22000 Food Safety Guidance and Workbook for the Catering Industry



DAVID SMITH, TRACEY JACKSON-SMITH and ROB POLITOWSKI

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and Rob Politowski

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Introduction

This workbook has been produced for those wishing to implement ISO 22000:2005 in their catering operations. Whilst the organizations may range in size from an owner-managed business to part of a large nationwide organization they all have one basic thing in common – the provision of meals for customers in a variety of outlets, e.g. restaurants, cafés, takeaways.

Much of the focus in the use of ISO 22000 since its introduction has been in the manufacturing sector. Because of its more specific focus on food safety issues, building around the Hazard Analysis and Critical Control Point (HACCP)-based approach to food safety, there are clearly opportunities for application throughout the food chain including agriculture, health care, leisure and hospitality catering sectors. It is with this in mind that this workbook has been developed to provide support to catering organizations in the implementation of an ISO 22000:2005 food safety management system. It is intended to be used by those charged with the implementation and running of the system in the catering sector and will be found particularly helpful by members of the food safety team as well as departmental managers. For those requiring a greater depth of knowledge and understanding the workbook should be used in conjunction with ISO 22000 and/or the handbook *Managing Food Safety the 22000 Way*.

The globalization of food and food products, together with the large-scale production and manufacturing processes used in the food industry, has changed the way many people and governments view the question of food safety. Whilst international trade in food products has been going on for centuries it remained a comparative rarity. However, it is a commonplace matter today for a whole range of food products to be traded extensively around the world – a simple glance at the shelves at your local supermarket will confirm this. The global food industry faces not inconsiderable challenges in this ever-growing market, e.g. food safety, purity, traceability, let alone the more esoteric matter of quality. Safe practices are now expected as an integral part of trade as a food safety problem can potentially result in food-borne illnesses and, in some cases, death.

According to Foodlink (a Food and Drink Federation initiative):

‘Each year it is estimated that as many as 5.5 million people in the UK may suffer from food borne illnesses – that’s 1 in 10 people.’

There have been a number of attempts at the creation of an international food standard but with the introduction of the ISO 22000:2005, *Food safety management systems — Requirements for any organization in the food chain*, a document has been created that is a suitable standard for all stakeholders in the food industry. It is possible to apply the standard to all organizations in the food chain, from primary producers to catering and retail outlets, and the importance of the development of this standard was recognized by the involvement of many countries in its drafting, as well as significant international bodies such as the Global Food Safety Initiative. With its open structure and specific focus

upon food safety issues it is a positive addition to the many other standards that are already evident in the food industry.

ISO 22000:2005 is an international management systems standard that has several features in common with other management systems standards. Many organizations have successfully embraced the requirements of ISO 9001:2000, *Quality management systems — Requirements*, ISO 14001:2004, *Environmental management systems — Requirements with guidance for use* and OHSAS 18001:1999, *Occupational health and safety management systems* and found them to be useful in managing the specific discipline and demonstrating conformance. Similar requirements to the other specifications can be found in ISO 22000 and these can be integrated into one overall management system such as outlined in PAS 99:2006, *Specification of common management system requirements as a framework for integration*, a specification developed to assist organizations who have multiple formal management systems and who wish to minimize the duplications of arrangements and procedures.

ISO 22000 specifies the requirements that need to be met for an effective food safety management system (FSMS), which can enable an organization to demonstrate that it is meeting customer and regulatory needs. It is not a guide; it describes what needs to be in place but not necessarily in the best order in which to carry out the task of implementation. The simple steps outlined in this workbook will enable organizations to follow an implementation programme in a series of straightforward steps. This will support the operation of a practical, effective and efficient FSMS.

The requirements of ISO 22000 are not significantly different from what the organization will already have in place to meet its HACCP needs. Both approaches are risk based. For those with ISO 9001 and an HACCP system the majority of the requirements will have already been met. Some individual countries have their own schemes (such as the British Retail Consortium (BRC) in the UK) and again the requirements here will not be in conflict with them and they can be embraced within this FSMS. The links between the *Codex Alimentarius* (a collection of international food standards), ISO 9001 and ISO 22000 are given in Annexes A and B of ISO 22000:2005.

In the industry the issues of quality and food safety may be seen as separate subjects but often they are managed together. It is therefore not difficult to integrate ISO 22000 systems with existing ISO 9001 systems and such integration can bring benefits in a number of ways such as reduction of duplication of management system requirements and records, auditing and reviewing schedules.

This workbook contains a number of prompt lists, case studies and scenarios that will help you to gain a better picture of what is required. These are provided as illustrations and will need to be customized to reflect your circumstances.

In the first section, Chapter 1 gives an outline of the requirements and how to meet them. The first few pages give an overview of the content of the workbook and the flow of the implementation programme.

Chapter 2 outlines what has to be done in more detail and Chapters 3 and 4 describe how this is to be achieved. Finally, Chapter 5 describes how the system operates in practice.

Section 2 contains a self-assessment that enables progress to be measured in implementing the system and its operation. At each stage through the book there are a number of checklists to allow the reader to identify the current position and any shortfalls.

Section 3 contains tables and pro formas, which may be useful for those who have few systems in place. These are provided as indicators and should be adapted to fit the organization's specific needs.

Section 4 contains extracts from the ISO 22000:2005 standard including a glossary of terms and the main clauses, four to eight.

Section 5 lists sources of useful information on legal and regulatory issues and best practice, and contains references.

This workbook is one of a series of publications intended to provide support to organizations in the implementation of ISO 22000:2005 *Food safety management systems — Requirements for any organization in the food chain*.

Section 1

Implementing ISO 22000:2005

1

Requirements and how to meet them

1.1 What have we got to do?

For anyone considering the implementation of an FSMS built around the requirements of the ISO 22000 standard there are some initial steps to take as outlined below.

1.1.1 Understand the business

The organization needs to understand how it fits into the food chain (see Figure 1.1).

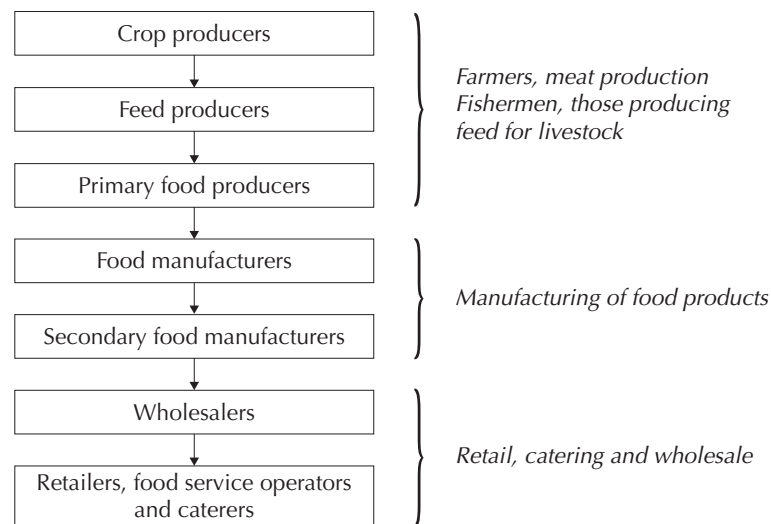


Figure 1.1 – The food chain

A business may operate at several levels within the food chain. For instance a farmer will be a crop producer and may sell to a feed producer, a wholesaler and to the public (as a retailer) at a farmers’

market. It is essential that you identify those who supply you and what is critical about their supplies, i.e. how their product could affect the food safety of your product. Equally you need to know the next step in the chain and how you can have an impact on your customer.

1.1.2 Identify all inputs and outputs

All the inputs to your products need to be systematically identified and the output of each process determined. For those new to this concept it is covered in greater detail in 2.2.

1.1.3 Look at each process and identify the hazards that could arise

Those with an HACCP system in place will know this method well. It is a requirement under the 2006 regulations (The Food Hygiene (England) Regulations 2006 [SI 2006/14] and equivalent) that organizations carry out an HACCP evaluation. This enables the organization to determine any part of the processes that poses a risk to food safety.

1.1.4 Determine what controls are needed

The next step is to install controls to eliminate or significantly reduce the risk of the food product becoming unsafe.

1.2 How do we do it?

The standard identifies a number of key steps that need to be satisfied at the start of the process. (References in parentheses refer to ISO 22000:2005. Some sections of this standard are reproduced in Section 4.)

1.2.1 Appoint a food safety team leader (5.5)

This is a key stage in the implementation of the standard and a specified requirement.

1.2.2 Select the food safety team members (7.3.2)

To support the food safety team leader in the implementation programme there is a requirement to have a food safety team. This will have some permanent members and may have some ad hoc members.

1.2.3 Provide resources (6)

An organization must demonstrate commitment to support the management systems and provide the necessary resources for it to be effective. There are detailed requirements in the standard.

1.2.4 Outline of planning and safe product realization (7)

This is the most important clause for the implementation and operation of the system. It closely follows the *Codex Alimentarius* HACCP system but includes some additional requirements.

2

How we establish the system – the basics

In order to move forward it is necessary to understand the business and what we are setting out to achieve. Implementation of the standard follows in Chapters 3 and 4.

2.1 Understanding the business and operational processes

It is often the case that organizations have procedures and processes in place, although these may well be informal. Some readers will already be familiar with the ISO 9001:2000 standard for quality management systems and will have identified the processes used by the organization. For those for whom this is new the following will assist in getting started.

All organizations have customers and need to satisfy their requirements whether they are in the private, public or charitable sector. In the food sector the basic aim will be to provide a food product to the desired quality, which is safe to the consumer. The overall processes undertaken need to be profitable and meet these needs.

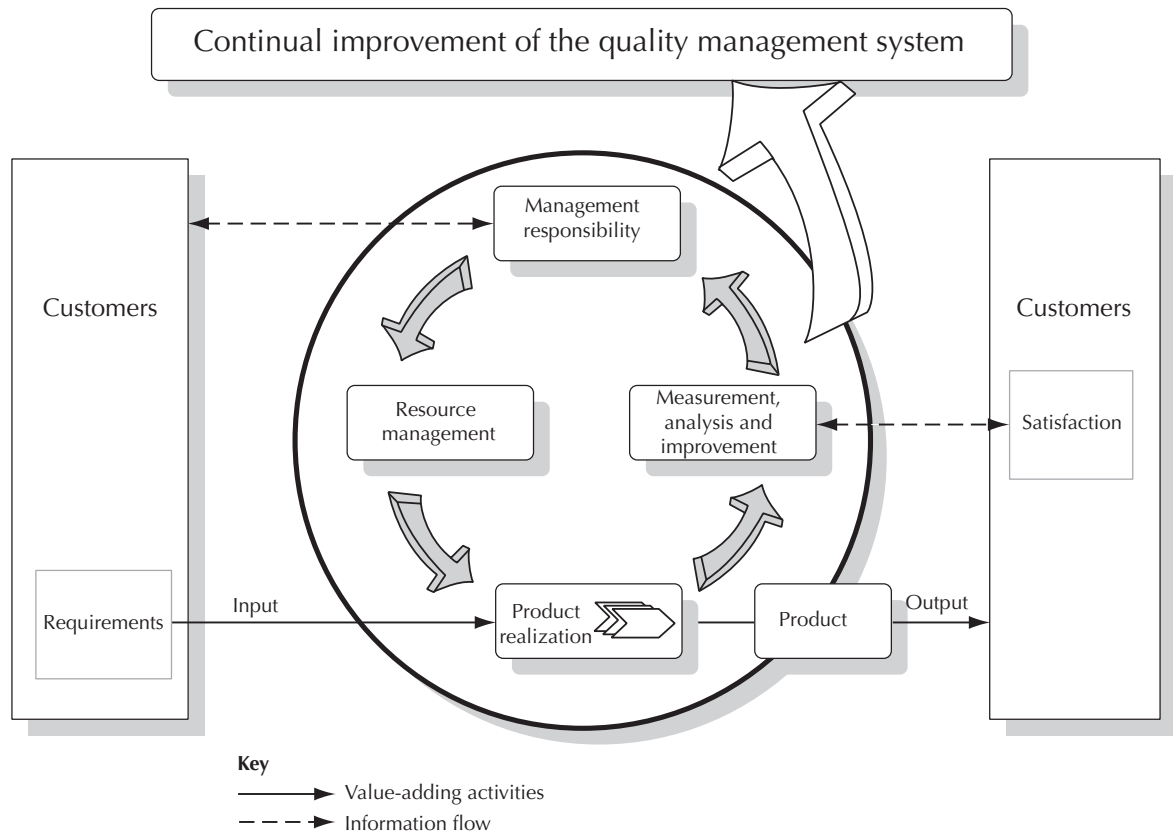
Figure 2.1 shows the relationship between the customer and supplier and how the organization (the supplier) controls this product realization through management responsibility, resource management and measurement, analysis and improvement.

In the food sector the organization may have a number of customers such as a farmer selling at the farmers' market, to supermarkets and as feedstock to another food producing organization. The control of the product realization stage of the various processes will need to be oriented to satisfy the particular customer. The organization therefore needs to identify its customers and their specific needs and where they fit in the food chain. The level of control may well need to be different for every customer.

2.2 Identifying all the inputs and outputs

The first stage is process mapping. It may be you are only aware, in the first instance, of the goods and services you buy in (inputs) and the goods and services you provide to your customers (outputs). In practice this breaks down into a number of processes.

The approach is that the processes are identified and then mapped to show their inputs and outputs.



Source: ISO 9001:2000

Figure 2.1 – Quality management process model

In simple terms the relationship between inputs and outputs can be seen in Figure 2.2.

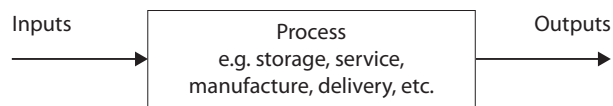


Figure 2.2 – Input/output relationship

The output from one process, such as stored items, may well form the input to another process. There will be many processes and the interrelationship needs to be understood.

It is a requirement of the ISO 22000:2005 standard that the various processes used in the organization for production are mapped. This idea is a simple one and can be applied to a huge range of activities. Figure 2.3 is an easy-to-understand flow chart for the everyday activity of making a sandwich.

This is a very simple case but illustrates the point that even in this case we need to consider such issues as the ingredient INPUTS (bread, butter, ham, mustard/mayonnaise), the preparation PROCESS steps (slicing bread, spreading butter, etc.) and the OUTPUT product (the sandwich!). The law requires that you have a documented system for the traceability of your food on a 'one-step-up and one-step-down' basis. This means that your food ingredient inputs must be recorded, showing details of

the supplier, date, items, quantities and any batch/lot/storage details that enable you to identify their utilization. Where product outputs are supplied to other businesses you will also need to identify their details, along with any control checks made by you at the point of delivery. Supplies, i.e. inputs to your business, may be common to a number of different products (e.g. bread from one supplier used in many different sandwich varieties) and the control checks will only need to be undertaken once per delivery.

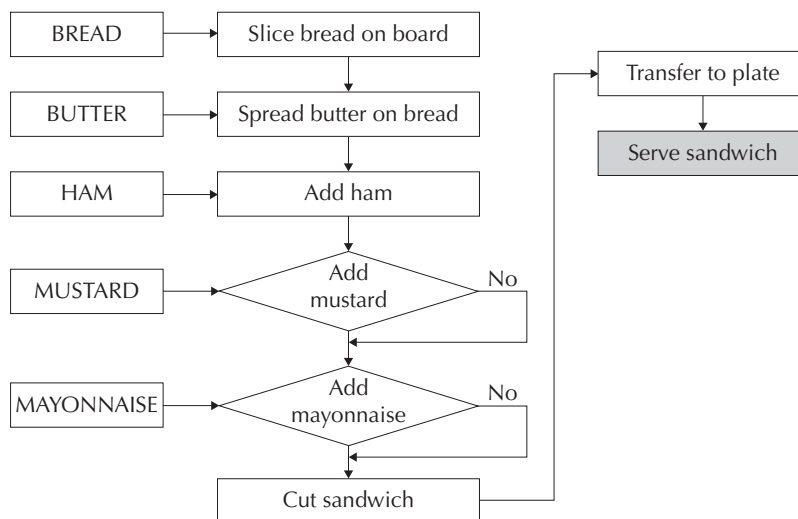


Figure 2.3 – Simple flow chart: ham sandwich

Figure 2.3 uses a familiar process to show the principle. In practice the organization will need to look at a number of things on a broader scale. All of the processes in your business will need to be viewed in this way, and the ‘inputs’ and ‘outputs’ will extend beyond product ingredients and finished products. For ISO 22000 compliance you will need to consider information inputs such as the validity of any scientific data on which you base your risk assessments and controls. Outputs will also cover communication outputs, such as monitoring data used to verify and/or review the system and information for enforcement agencies.

2.3 Looking at each process and identify the hazards that could arise

The UK and EU regulatory requirements are such that organizations have to carry out HACCP-based procedures for all their processes. Those already operating in the food sector will be well aware of this requirement and how they have applied it. However, it should be noted that simplified HACCP-based systems devised for smaller catering operations may not meet all of the requirements of ISO 22000.

In the simple case of making a sandwich above, there are very obvious areas that need control. The integrity of the ingredients supply is vital to ensure that the product is not contaminated before you even start; storage temperatures of the butter, ham and mayonnaise must be kept within legal limits to control the growth of harmful micro-organisms; and the process activities indicate steps at which potential cross-contamination needs to be controlled. The first stage of the hazard analysis is to identify all of these potential hazards that could harm your customer, and your business, and evaluate the risk that they each pose.

Identifying these hazards requires some food safety expertise, particularly in relation to microbiological contamination and growth. Information regarding pathogen risks for specific food types, along with their growth factors such as A_w , pH and temperature range, is necessary for the accurate and complete identification of potential hazards and will inform subsequent decisions as to appropriate controls. Reference to valid, externally published scientific and technical data is vital for a stringent HACCP plan and this can be accessed through a variety of industry sources.

2.4 Determining what prerequisite programmes and controls are needed

Every organization should have a number of generic programmes in place to ensure that the basic operating conditions are present for the production of safe and wholesome food. These include such things as cleaning and housekeeping practices, pest control and even the design and facilities of the premises itself. Operating and managing these programmes generically not only ensures a solid foundation of food safety within the organization, but also makes good management sense – for example, to assess the hazards arising from poor cleaning in respect of each product or recipe dish produced would be repetitive, time-consuming and might miss out areas that do not directly come into contact with the food (e.g. walls, floors, ceilings). As such, these programmes are considered prerequisite programmes (PRPs).

For specific hazards identified for individual food products or recipe dishes, specific controls will need to be determined. These hazards may arise due to particular ingredients or to the cooking, chilling or serving methods for that dish. Examples of these controls are checking the delivery temperature of frozen food ingredients or ensuring that hot food is held at the correct temperature between cooking and serving. Where a control is essential to prevent, eliminate or reduce a hazard to an acceptable level it is referred to as a critical control point (CCP) – this is the last opportunity in the process to stop this hazard from reaching the end consumer.

For each hazard identified, a judgement is made as to whether the hazard is managed by a PRP or whether other control measures are required. A further decision-making procedure surrounds the determination of CCPs within the process. As with the hazard identification, reference to technical data may be required to ensure that control measures are valid and can be justified.

2.5 Identifying what you have got in place

You will almost certainly have some systems in place.

The checklist below is provided to help the reader indicate where requirements have been met (Yes) or need to be addressed (No).

Checklist

	Yes	No
Is management commitment established?	<input type="checkbox"/>	<input type="checkbox"/>
Has a food safety team leader been appointed?	<input type="checkbox"/>	<input type="checkbox"/>
Has a food safety team been appointed?	<input type="checkbox"/>	<input type="checkbox"/>
Have the processes been identified and defined?	<input type="checkbox"/>	<input type="checkbox"/>
Have you produced a food safety policy?	<input type="checkbox"/>	<input type="checkbox"/>

	Yes	No
Have the resource issues been addressed?	<input type="checkbox"/>	<input type="checkbox"/>
Have you produced specifications for each of the products?	<input type="checkbox"/>	<input type="checkbox"/>
Do you have operational PRPs in place?	<input type="checkbox"/>	<input type="checkbox"/>
Have the food hazards been identified?	<input type="checkbox"/>	<input type="checkbox"/>
Do you carry out food safety risk assessments?	<input type="checkbox"/>	<input type="checkbox"/>
Have you identified the legal and other requirements?	<input type="checkbox"/>	<input type="checkbox"/>
Does the organization adopt best practice?	<input type="checkbox"/>	<input type="checkbox"/>
Have objectives been set?	<input type="checkbox"/>	<input type="checkbox"/>
Do employees know their roles and responsibilities?	<input type="checkbox"/>	<input type="checkbox"/>
Have employees been adequately trained?	<input type="checkbox"/>	<input type="checkbox"/>
Are internal communications established?	<input type="checkbox"/>	<input type="checkbox"/>
Are external communications established?	<input type="checkbox"/>	<input type="checkbox"/>
Do you have a documented traceability system?	<input type="checkbox"/>	<input type="checkbox"/>
Do you have the required documentation in place?	<input type="checkbox"/>	<input type="checkbox"/>
Are necessary control measures and CCPs in place?	<input type="checkbox"/>	<input type="checkbox"/>
Are emergency preparedness and response arrangements in place?	<input type="checkbox"/>	<input type="checkbox"/>
Are internal audits undertaken?	<input type="checkbox"/>	<input type="checkbox"/>
Are management reviews carried out?	<input type="checkbox"/>	<input type="checkbox"/>

A self-assessment scoring system can be found in Section 2 for you to monitor your progress.

If you have addressed the above and established arrangements for managing food safety the following elements should be present. As a check indicate the current status in Table 2.1.

Table 2.1 – Food safety management system status

Management system element	Status
General requirements	
Management system policy	
Planning HACCP and identification of control points Identification of legal and other requirements Contingency Objectives Organizational structure, roles, responsibilities and authorities	
Implementation and operation Operational control Management of resources Documentation requirements Communication	
Performance assessment Monitoring and measurement Evaluation of compliance Internal audit Handling of nonconformities	
Improvement General Corrective, preventative and improvement action	
Management review	

3

How do we do it? – In detail

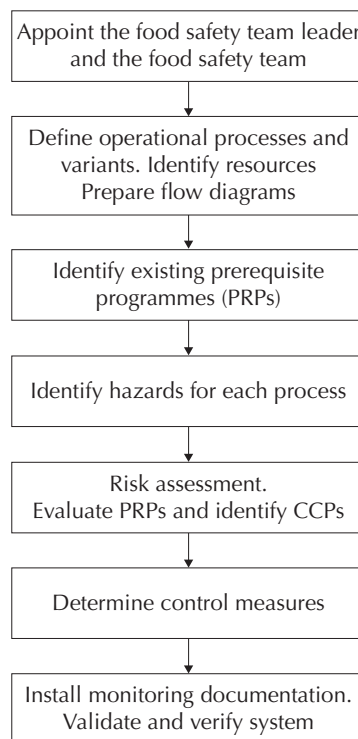


Figure 3.1 – Flow chart for implementing a food safety management system

It is a requirement of the standard to plan how the system is to be implemented and maintained. Each of the boxes in Figure 3.1 is expanded and considered in detail during the course of the workbook.

3.1 Appoint the food safety team leader

The first task in implementing the system is to choose an appropriate team leader for the project. Correct appointment to this role is crucial for the success of the project and is not a task to be taken lightly. The

most appropriate choice for the position is a person who possesses the skills, knowledge, leadership capability and the *time* to carry out his/her duties effectively. In some smaller organizations this may be a member of the senior management team, but this does not have to be the case for all businesses. In fact, it may be more appropriate for a middle manager or departmental manager to take on the responsibility. One of the key factors in terms of the seniority of the position is that the individual has the authority to implement the system effectively, including the ability to influence senior management in making any necessary changes to organizational policy and practice, the ability to influence staff and other managers to operate the system correctly and access to the resources required.

Key responsibilities of the role include:

- team leadership capability;
- exemplifying the goals of the system through own practice;
- initiating and supporting communication;
- organizing administrative support;
- development and production of an achievable project plan;
- liaising with other functions and with senior management;
- effective utilization of resources, including human resources;
- advising and supporting team members;
- delegation, problem solving and decision-making.

As we can see, the team leader role demands a range of management and leadership skills, and it is recommended that he/she also possesses a suitable level of technical skills and/or experience in food safety. Indeed, the law requires that the person responsible for the development and maintenance of the food safety management procedures must have received adequate training. This training does not have to constitute a formal external course or qualification but can be an amalgamation of various development activities including research, involvement with sector/trade organizations and professional experience. However, the team leader does not need to be an 'expert' in all aspects of the food operation, rather to be able to draw on the expertise provided by the rest of the food safety team.

Clearly, the team leader may benefit from some specific training prior to undertaking their role, and suggestions for all the team members are given later in this chapter.

3.2 Appoint the food safety team

Once the team leader role has been allocated, the next step is to draw together a food safety team, which should comprise a small group of food safety-focused individuals, each with their own area of expertise or experience to bring to the project. The permanent members of the food safety team should, ideally, number no more than six people who have ongoing input to the implementation and operation of the system. Additional members may be co-opted onto the team from time to time as required.

When setting up the food safety team, the emphasis should be on their practical skills and their ability collectively to cover the range of operational processes within the business. As such, it would be appropriate at this point to refer to the analysis of business processes and inputs/outputs discussed in the previous chapter in order to determine the appropriate team model for your business. Let us consider a couple of examples.



A large city centre hotel has several different restaurants/bistros on site, each with its own kitchen area and staff team. Ingredients and other catering resources are purchased centrally, whilst food preparation and service are devolved. An effective food safety team would include representatives from each of the restaurants/bistros on site, who should also bring expertise across the range of culinary disciplines to the team. The individual responsible for evaluating the quality and food safety of ingredient supplies upon receipt should also be included in the team. The hotel's quality manager and a representative from the engineering/maintenance team may also be considered, although they may not be required to be permanent team members.



A busy restaurant employs a team of five chefs, including the head chef, in a single kitchen providing both lunchtime and evening service, for which there are separate menus. An appropriate food safety team should comprise representatives from both the lunch and evening service (if staff cover both services on a rota system, then this should not be a problem), and there should be some division of responsibility as to the area of the menu covered, e.g. one person taking responsibility for sweet dishes, another for savoury, etc. The head chef should be a member of the team, although given his/her existing range of responsibilities, it may be appropriate for another member of staff to lead the team.

Overall, the team should be representative of the catering operation as a whole and each should bring specific expertise to the team in terms of their ability to identify potential hazards and determine suitable controls. As with the team leader, these individuals should exemplify a high standard of food safety practice in their work.

There is a requirement for responsibilities within the system to be clearly defined by the senior management and it is recommended that this is established and documented at an early stage. This is particularly important with regard to the development of any policies and procedures, or the commencement of the HACCP study. It would not be appropriate for a member of the team to set up aspects of the system or sign off documents if the authority for this activity is subsequently allocated to someone else. Allocation of all sign-off authority to the team leader (e.g. the head chef) may not be practical. Consideration must be given to the availability of this individual, and how the system will effectively operate at times when this person is not on duty. Key areas of responsibility and authority to consider are:

- authorization of policies and procedures;
- approval of product specifications;
- approval of process flow charts;
- approval of hazard analysis and control charts;
- authority to sign off monitoring documents (for PRP monitoring as well as CCP monitoring);
- reporting structure for nonconformance and corrective actions;
- authority to sign off corrective actions;
- authority to approve revisions to the system.

All of the above should be clearly designated and be thoroughly understood by the individuals concerned. It may be appropriate to draw up a list of responsibilities (role specifications) that can be adopted and accepted through signed confirmation from these key personnel. This will require training.

The responsibility for food safety extends to all personnel within the business, not just the food safety team, and it is important to ensure that this is communicated unequivocally at the start of employment and on an ongoing basis. Conformance to food safety practices and responsibility to report any problems should be conditions of employment, defined contractually and included in induction training. Notices reminding staff of the food safety reporting requirements can be posted in the workplace as a useful reminder.

3.3 Identify resources

Prime responsibility for identifying who is responsible and accountable for the provision of the FSMS lies with top management. This can be implemented in the form of an organogram and job descriptions. The identification of the food safety team leader has been addressed above.

It is important that all those involved in the catering service understand their individual responsibilities and the impact they can have if they do not follow the correct controls and procedures. It is generally found that when the commitment and culture of the organization are poor the likelihood of failure is greater. The issue of creating an effective climate for achieving organizational commitment is dealt with in 5.2.

It is essential that clear reporting lines are established with effective communication between all groups within the organization.

The ISO 22000 standard places considerable emphasis on the provision and continued availability of resources, both material and human. These requirements are not exclusive to the implementation and operation of the ISO 22000 system. Indeed, as previously stated, all food businesses have a legal obligation to operate HACCP-based food safety management procedures and, as such, much of the resource requirements relate to this prevailing need.

It is clearly a requirement that the organization has the necessary building and infrastructure for its operation. The material resources required by the system will vary from one business to another, depending upon such factors as the scale and nature of the business operation, the prerequisite programmes (PRPs) required, the range of hazards identified, their relevant controls and whether certain tasks are outsourced (e.g. pest control). In order to ensure that the requirements are satisfied, the material resource needs should be evaluated and noted at each stage of the implementation process. In addition, the ongoing input to maintain those resources should be planned. For example, there should be programmes in place for the regular service and maintenance of refrigeration equipment, the regular calibration of temperature probes and thermometers, etc.

Key points to consider for material resources are as follows.

- All PRPs – e.g. is there a sufficient and reliable supply of equipment and consumables to support your cleaning/sanitation programme?
- All critical control points (CCPs) – ensure that the resources are in place to both operate the control and, where appropriate, monitor the control.
- Team members and auditors should trace backwards from non-compliances or problems in the system to determine whether there is a link to a material resource issue.

- Contingency planning – is there a plan in place to immediately address failures or shortfalls in material resources? If the resource problem relates to a CCP, failure to immediately address it may result in a breach of food safety law.
- Alternative resources – where contingency plans identify alternatives, these resources must be subject to the same hazard analysis and risk assessment as the usual resource, e.g. if you substitute one of your cleaning chemicals due to a supply problem, then this substitute must be evaluated with regard to the chemical hazard it presents to foodstuffs. This must be documented and added to your records.

There are some further aspects of human resource requirements to consider.

The ISO 22000 standard places emphasis on the competence of the food safety team and other relevant staff. Auditors are required to ensure that personnel associated with any part of the food preparation and service, especially where specific hazards have been identified, are able to demonstrate the necessary abilities required by the FSMS. A key part of meeting this requirement is to ensure that all staff have the requisite skills for both their food handling task and their food safety responsibilities. All staff should have a documented personnel record detailing their prior experience, training and any qualifications achieved. A programme of ongoing training for staff should be planned, implemented and appropriate records kept.

It is recommended that the food safety team undergo a specific programme of training to support their roles within the system, i.e.:

- food hygiene and safety training at a level appropriate to their responsibilities;
- HACCP system training;
- auditor skills training (even those who do not have an auditor role would benefit from the ability to view the system from this perspective).

Fulfilling training requirements need not be onerous, either in respect of the budget allocation or the release of staff. Training can be ‘cascaded’ internally by key members of staff who have undergone more formal programmes, and a carefully planned programme of training can ensure that releasing staff from their normal duties does not adversely affect the business.

A final point on human resources relates to the documentation and records requirements, particularly in the development and implementation phase. The compilation of the system manual, as well as the design of appropriate recording documents is a key task when setting up the system, and the administrative resource needed to fulfil this function should be considered at an early stage. In larger organizations, it may be possible to co-opt some administrative support to the team for the development phase and any later revisions. In smaller organizations, this function may be delegated to one or more permanent team members. In either case, there is an ongoing responsibility for administration of system documents, including the production of meeting minutes and the storage of records.

4

Clause 7 of ISO 22000:2005 – Planning and realization of safe products

Clause 7 of the ISO 22000 standard concerns the planning, development, implementation and maintenance of the FSMS. It is framed around the existing requirement for the business to operate a HACCP-based FSMS and therefore an established food business with a HACCP system in place would use this section to benchmark its existing system against the requirements and make any appropriate revisions. For new businesses, this section serves to outline the basic steps to putting such a system in place.

The HACCP system is required to take account of the seven principles defined in the *Codex Alimentarius*. In addition, the *Codex Alimentarius* has defined a 12-step sequence for the application of a HACCP system. The distinction between the seven principles and 12 steps can sometimes prove confusing to those unfamiliar with HACCP; Figure 4.1 illustrates the relationship between the two.

The latest edition of the *Codex Alimentarius* can be a useful reference document for the food safety team leader or indeed the team as a whole: details of the publication are given in Chapter 18.

4.1 General (Clause 7.1)

This clause sets up the need for an organization to implement process planning and development for food safety in its preparation and service activities. This means that the business must consider food safety as an intrinsic part of any overall operational planning as well as with specific development areas, e.g. recipe development, method planning, etc. Thus, the business operates an 'intelligent' food safety system with hazards identified at the planning and development stage and controls introduced in an efficient and effective manner. For example, an ingredient may be substituted to eliminate a hazard, or a method adapted to reduce a level of risk or enable it to be controlled by an existing CCP. This proactive approach to food safety is more cost-effective and successful in managing risk than a reactive approach.

Logic sequence for application of HACCP (12 steps)

Seven principles of the HACCP system

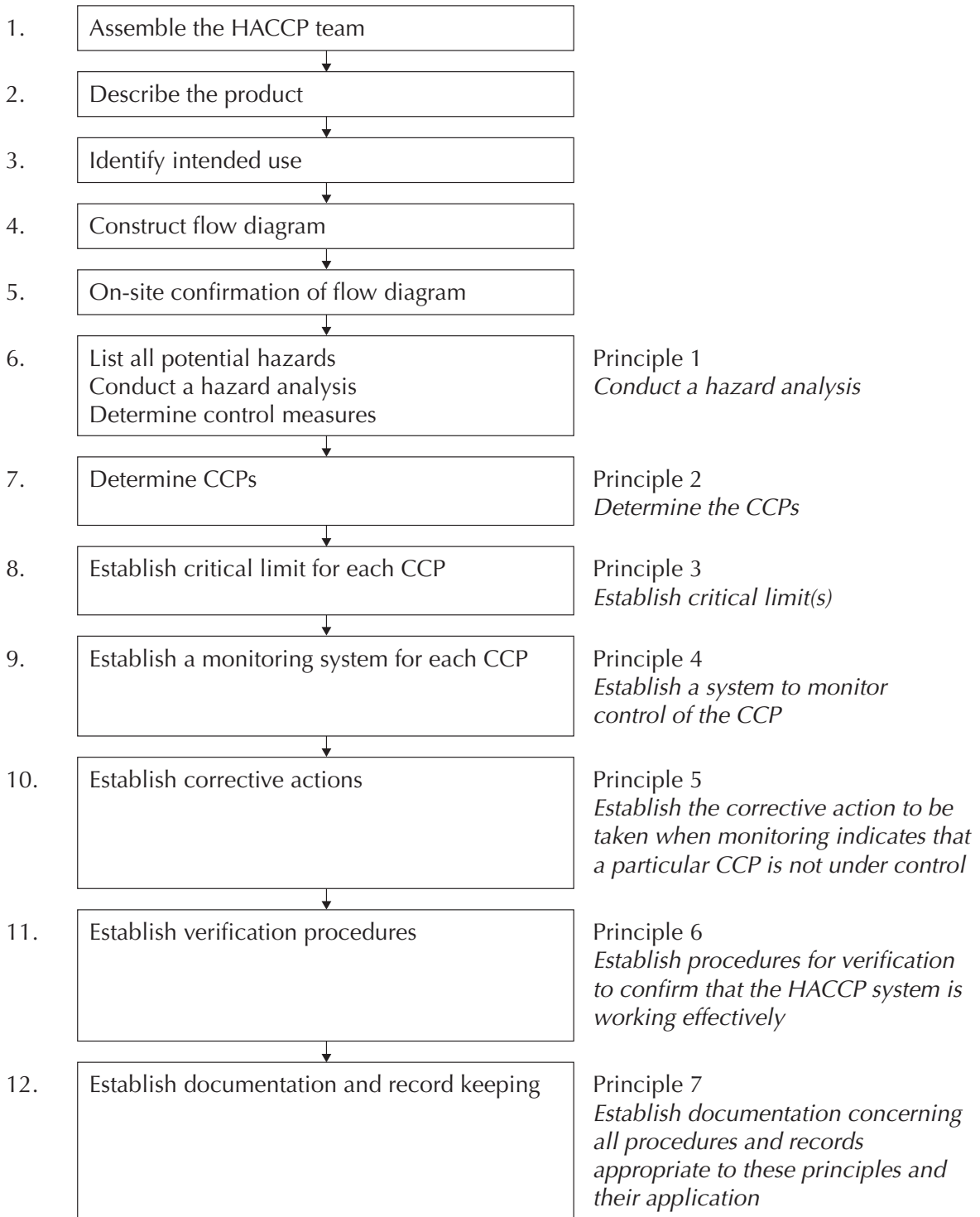
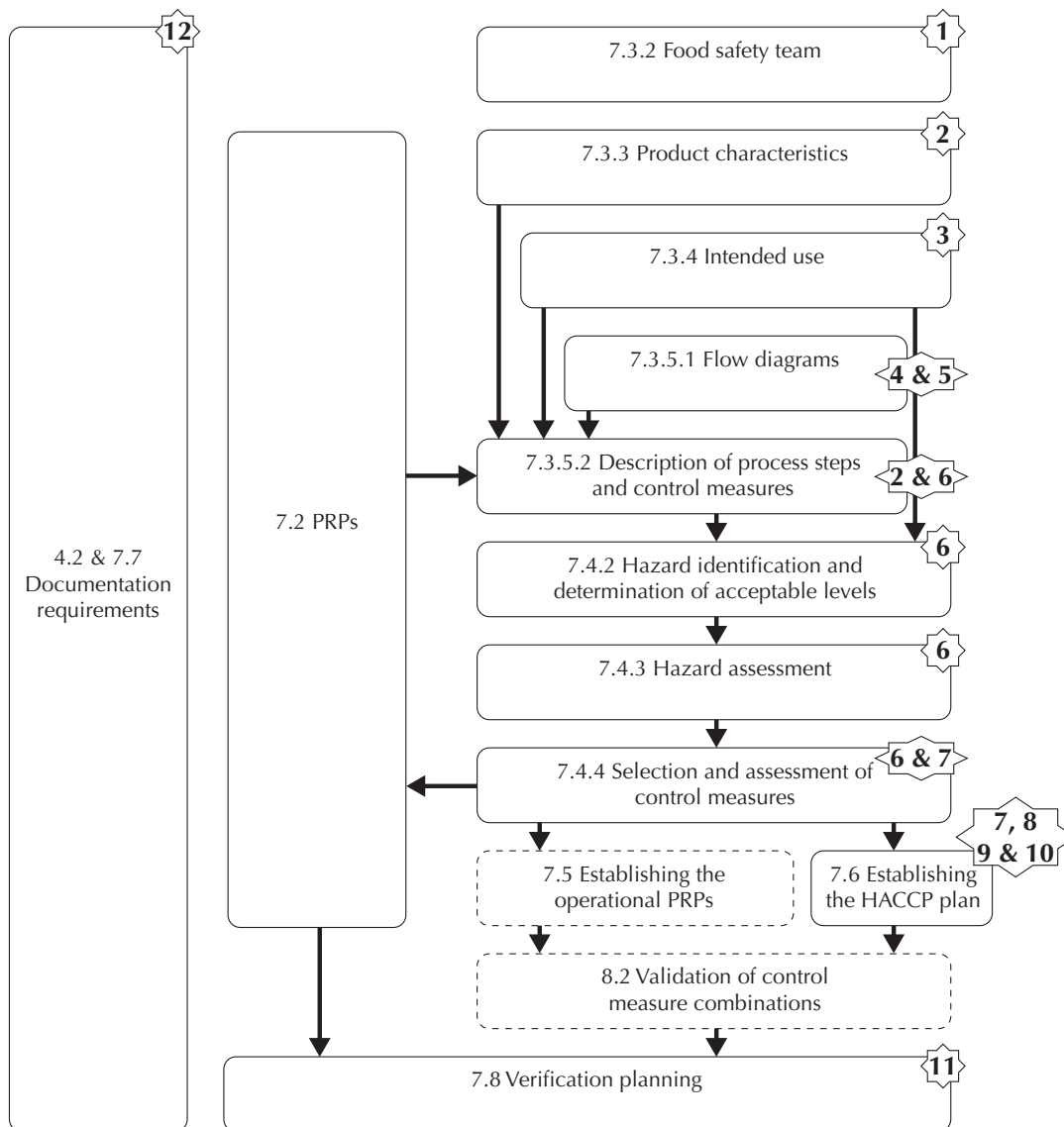


Figure 4.1 – The relationship between the 7 principles and 12 steps of HACCP in Codex Alimentarius



Source: ISO/TS 22004:2005

Figure 4.2 – Planning of safe foods

Figure 4.2 illustrates the components of an effective FSMS and shows the relationship between ISO 22000:2005 and the *Codex Alimentarius* ‘Hazard analysis and critical control point (HACCP) system and guidelines for its application’.

The checklist below is provided to help the reader indicate where requirements have been met (Yes) or need to be addressed (No).

CHECKLIST

	Yes	No
Do you have a project plan in place for developing and implementing the system?	<input type="checkbox"/>	<input type="checkbox"/>
Do you have a procedure for completing HACCP requirements for new recipe dishes?	<input type="checkbox"/>	<input type="checkbox"/>
Do you have clear sign-off responsibility for new dishes prior to their introduction?	<input type="checkbox"/>	<input type="checkbox"/>

4.2 Prerequisite programmes (Clause 7.2)

One of the key elements for any HACCP system is to have a set of prerequisite programmes (PRPs) in place. These are systems that are normally present before the HACCP plan is developed to ensure that the business is:

- operating to relevant food safety legislation and codes of practice;
- operating good hygiene practices;
- managing its 'low risk' and/or generic hazards through a series of wide-ranging preventative measures;
- operating certain non-food safety-related systems that will support the HACCP system.

4.2.1 Food safety PRPs

The aim of food safety PRPs is to underpin the control mechanisms specified in the HACCP system with a range of programmes designed to tackle the generic food safety hazards as opposed to the specific hazards, which are controlled by the CCPs. The aim is to streamline the HACCP system and, in particular, its documentation. The food safety PRPs that you have or require for your food business may be different to others and, indeed, you may organize or manage these programmes in a manner specific to your business. However, the range of issues that these programmes are designed to cover relate to most businesses, and the following list, whilst not necessarily exhaustive, should provide a guide for consideration.

- Premises and facilities – a programme is required to ensure that the layout, construction and facilities within your premises meet legal requirements and take account of good practice guidelines. This programme should not only evaluate the premises at the start, but should manage any changes and any ongoing maintenance.
- Personal hygiene – the personal hygiene of staff is of major importance to food safety, and there should be a programme that communicates the requirements and monitors compliance in respect of personal cleanliness, hand washing, personal habits (e.g. smoking), health/fitness for work and the wearing of protective clothing.
- Pest control – food businesses must have adequate procedures to prevent access to the premises by pests and domestic pets, and control infestations. This may be carried out by a pest control contractor, but it is the responsibility of the business to manage and monitor this contract and ensure that the contractor is diligent in their monitoring and corrective actions, and that they are acting in accordance with the law (particularly in relation to baits and chemicals). A failure on the part of a contractor will still be a non-compliance with regard to the business.

- Sanitation and cleaning – all aspects of the premises must be appropriately cleaned and disinfected on a regular basis. This includes food contact surfaces, equipment and utensils, as well as the internal fabric of the food area itself. A well-organized cleaning programme covering all areas at appropriate frequencies is required, along with the careful storage, handling and use of cleaning chemicals to control risk of chemical contamination.
- Waste management – this programme is often incorporated with the sanitation and cleaning programme but, if so, care must be taken to ensure that the handling and disposal of waste during food preparation and service is included rather than just waste disposal during cleaning.
- Raw materials and ingredients – this programme must control and monitor the supply of raw materials to your business to ensure that you do not accept anything that might contaminate or pose a food safety risk to your food products. In addition, this programme must control the storage, handling, stock rotation and reuse of ingredients or components with particular regard to the introduction of contaminants and any temperature control requirements.
- Maintenance and servicing – this programme should be in place to manage the maintenance and any required calibration of equipment within the food preparation and service operation, including equipment that is not directly used for preparation but the malfunction of which could have food safety implications, e.g. ventilation systems, temperature probes.
- Foreign object control – this programme should evaluate, monitor and control any potential foreign object risks that are not covered by other PRPs such as regular checks on any glass/hard plastic items, and rules governing the use of hazardous items such as paper clips or pens with separate caps.
- Packing and transport – if you deliver your products to your customer, a programme to evaluate, control and monitor food safety hazards arising from the wrapping, transport containers and vehicles must be in place.

4.2.2 Non-food safety PRPs

In addition to the food safety-specific PRPs, there are further elements that support the HACCP system, which it may be useful to consider as PRPs in their own right, particularly if you have a separate quality system already in place within your organization. Whilst it is not essential to have these set up as PRPs, they are issues that must be addressed within your HACCP system.

- Document control – a set of procedures governing the update, replacement and tracking of manual and electronic documents within your HACCP system should be considered. Where documents are produced and kept electronically, care must be taken not to simply revise or overwrite the existing file as past documents will be required for evidence of due diligence where legal compliance is questioned.
- Traceability – a system that tracks the source and destination of all materials and ingredients used in your food is a legal requirement. A system that records the batch/lot details of all ingredients/raw materials and monitors/records their use should be maintained.

The ISO 22000 standard requires that a risk-based approach is taken to the planning, determination and evaluation of the PRPs, and it is not sufficient for the food safety team to acknowledge that the PRP is in place and therefore assume that the associated hazards are under control. Auditors are required to seek

evidence that this process was undertaken thoroughly, objectively and at the appropriate stages in the implementation process (PRPs should be revisited as part of the hazard analysis step). PRPs should also be included in verification planning.

The checklist below is provided to help the reader indicate where requirements have been met (Yes) or need to be addressed (No).

CHECKLIST

Have you addressed the following:	Yes	No
Premises and facilities?	<input type="checkbox"/>	<input type="checkbox"/>
Personal hygiene?	<input type="checkbox"/>	<input type="checkbox"/>
Pest control?	<input type="checkbox"/>	<input type="checkbox"/>
Sanitation and cleaning?	<input type="checkbox"/>	<input type="checkbox"/>
Waste management?	<input type="checkbox"/>	<input type="checkbox"/>
Raw materials and ingredients?	<input type="checkbox"/>	<input type="checkbox"/>
Maintenance and servicing?	<input type="checkbox"/>	<input type="checkbox"/>
Foreign object control?	<input type="checkbox"/>	<input type="checkbox"/>
Packing and transport?	<input type="checkbox"/>	<input type="checkbox"/>
Document control?	<input type="checkbox"/>	<input type="checkbox"/>
Traceability?	<input type="checkbox"/>	<input type="checkbox"/>
Records in place to monitor all of these points?	<input type="checkbox"/>	<input type="checkbox"/>

4.3 Preliminary steps to enable hazard analysis – General (Clause 7.3.1)

All information contributing to the hazard analysis must be properly managed and recorded. Information sources used must be reliable, robust and comparable with normal industry practice. To meet this requirement the business must be able to demonstrate the source of any external or internal information used to identify a hazard, conduct a risk assessment or determine appropriate critical limits and control measures. Where copies of legislation, codes of practice or other industry guidance is utilized, it should be relevant and up to date.

The checklist below is provided to help the reader indicate where requirements have been met (Yes) or need to be addressed (No).

CHECKLIST

	Yes	No
Have you created a list of all your information sources?	<input type="checkbox"/>	<input type="checkbox"/>
Have you checked that your information sources are current?	<input type="checkbox"/>	<input type="checkbox"/>
Have your information sources been checked for validity?	<input type="checkbox"/>	<input type="checkbox"/>

4.4 Food safety team (Clause 7.3.2)

The requirements of this clause are addressed in detail in Chapter 3.

4.5 Product characteristics (Clause 7.3.3)

This clause requires the compilation of specification information on all materials, including finished food products, contributing to the hazard analysis. The specification should include a full description of the product considering, for example, composition, physical structure, pH, treatments (e.g. cooking processes, brining, smoking, etc.), serving temperature, storage, etc. Due regard should be given to labelling regulations where food is wrapped or packaged.

4.6 Intended use (Clause 7.3.4)

Whilst the food that you are preparing is clearly intended to be *eaten* by the consumer, the term 'intended use' in this context refers to the circumstances in which it takes place and who the end consumer may be. If, for example, you are serving food to be consumed on your premises then you have greater control of the holding and serving temperature of that food item than if you are operating a takeaway outlet. Food that is designed to be swallowed in whole mouthfuls rather than being cut up on a plate and/or chewed carries a far greater risk of a consumer ingesting a contaminant. Consideration of the end consumer themselves also has an impact on any hazard analysis, particularly anyone considered vulnerable, such as the elderly or small children.

Product characteristics/intended use – Baked chicken Kiev

The product is a prepared meal containing chicken breast stuffed with garlic butter and coated with beaten raw egg and breadcrumbs prior to being cooked at an oven temperature of 200 °C. The cooked, stuffed chicken portions are removed from the oven and kept at a minimum holding temperature of 63 °C for a maximum of 2 hours. The product is served hot to the customer from this facility.

Ingredients

Raw chicken, garlic puree, butter, chopped raw parsley, raw egg, breadcrumbs (wheat flour, water, salt, yeast, sugar, vegetable fat), lemon juice, pepper.

Intended use

The product is a hot prepared meal likely to be consumed by adults. It is suitable for all groups, except those who may be sensitive to food allergens (see below).

Note: this product may not be suitable for customers with allergies to wheat flour or eggs.

Figure 4.3 – Example of product characteristic and intended use specification for baked chicken Kiev

The checklist below is provided to help the reader indicate where requirements have been met (Yes) or need to be addressed (No).

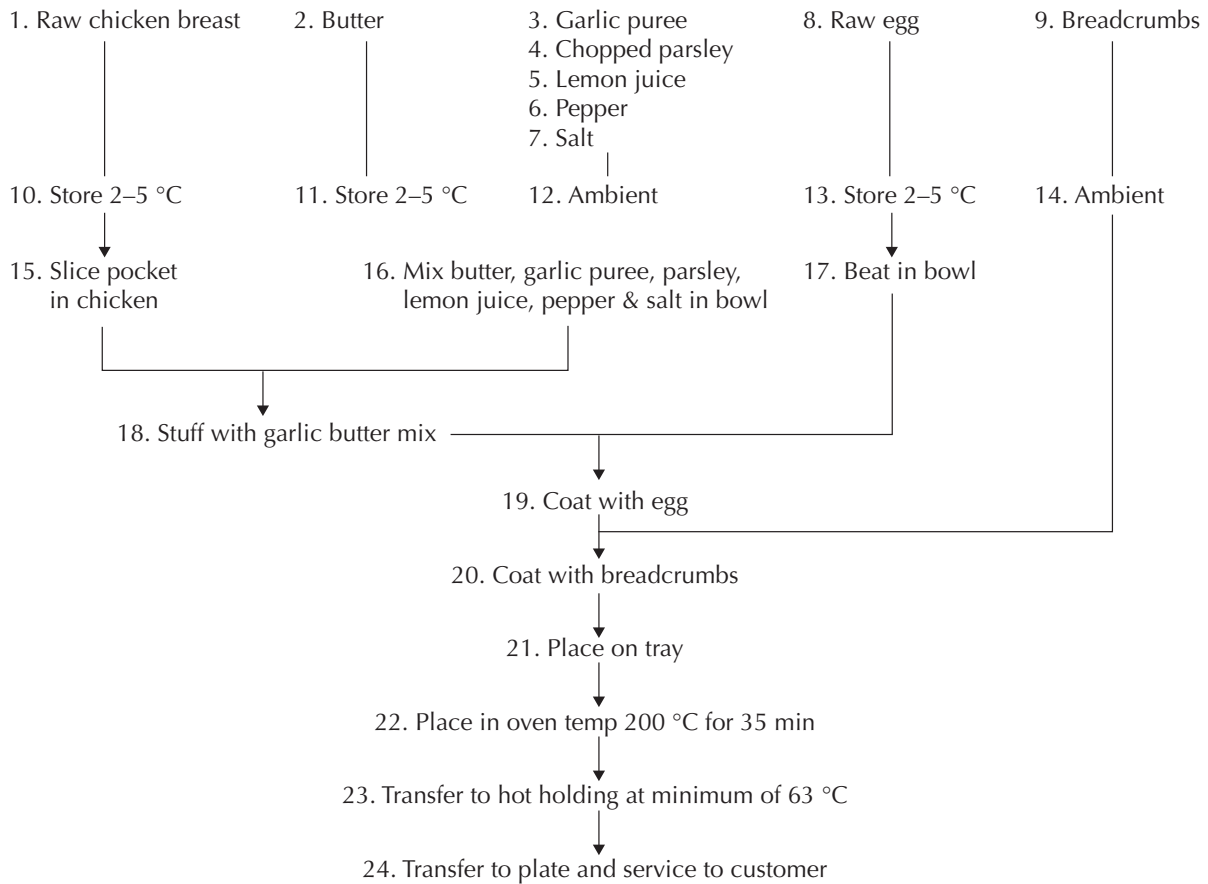
CHECKLIST

	Yes	No
Have you developed specifications for all recipe dishes?	<input type="checkbox"/>	<input type="checkbox"/>
Have you considered issues relating to specific, vulnerable groups of people (e.g. allergy sufferers, pregnant women)?	<input type="checkbox"/>	<input type="checkbox"/>
Have you prepared advice and/or action guidelines for vulnerable consumers?	<input type="checkbox"/>	<input type="checkbox"/>
Have you trained staff in procedures for vulnerable consumers?	<input type="checkbox"/>	<input type="checkbox"/>

4.7 Flow diagrams, process steps and control measures (Clause 7.3.5)

The mandatory use of flow diagrams to describe the inputs, preparation/cooking process steps and outputs for all of the food products/recipe dishes produced by the business is intrinsic to the ISO 22000 standard and HACCP. Separate flow charts are required for each product, although products which vary by only one ingredient (e.g. the addition of cheese or dried fruit to scones) may have a combined flow chart providing it includes all of the variants. Clear identification of all of the processes applied to the food at each stage helps to identify any existing control measures which are intrinsic to the preparation and cooking process (e.g. sieving a dry ingredient or cooking at high temperatures). Flow diagrams must be checked for accuracy by the food safety team, preferably by practical comparison with an observation of the process, before being utilized. Evidence of this validation activity must be apparent to an auditor – signatures and dates on the flow chart, for example.

Summary process flow chart: baked chicken Kiev



Issue: (date) (issue no.)

Signed:

Figure 4.4 – Example of a schematic flow diagram for baked chicken Kiev

The checklist below is provided to help the reader indicate where requirements have been met (Yes) or need to be addressed (No).

CHECKLIST

	Yes	No
Have you prepared flow diagrams covering each product and their variants?	<input type="checkbox"/>	<input type="checkbox"/>
Are the diagram steps sufficiently detailed to enable a thorough hazard analysis?	<input type="checkbox"/>	<input type="checkbox"/>
Has each flow chart been validated by the team?	<input type="checkbox"/>	<input type="checkbox"/>

4.8 Hazard analysis (Clause 7.4)

The food safety team should identify all of the hazards that may be reasonably expected to occur at each step for each process flow chart, right through to the point of consumption. The team should then conduct a hazard analysis to identify for the HACCP plan which hazards are of a nature that their elimination or reduction to acceptable levels is essential for the production of a safe food. *Codex Alimentarius* suggests that, wherever possible, the following should be included in the hazard analysis:

- the likely occurrence of hazards and severity of their ill effects;
- the qualitative and/or quantitative evaluation of the presence of hazards;
- survival or multiplication of micro-organisms of concern;
- production or persistence in foods of toxins, chemical or physical agents;
- conditions leading to the above.

There are a number of models to assist with this process, for example the likely occurrence and severity of hazards is often evaluated through the use of a risk assessment matrix (see Figure 4.5).

Frequency						Severity
Unlikely (1)	Seldom (2)	Occasional (3)	Likely (4)	Frequent (5)		
1	2	3	4	5	Negligible (1)	
2	4	6	8	10	Moderate (2)	
3	6	9	12	15	Critical (3)	
4	8	12	16	20	Catastrophic (4)	

Key: Low Risk Medium Risk High Risk Extremely High Risk

Severity

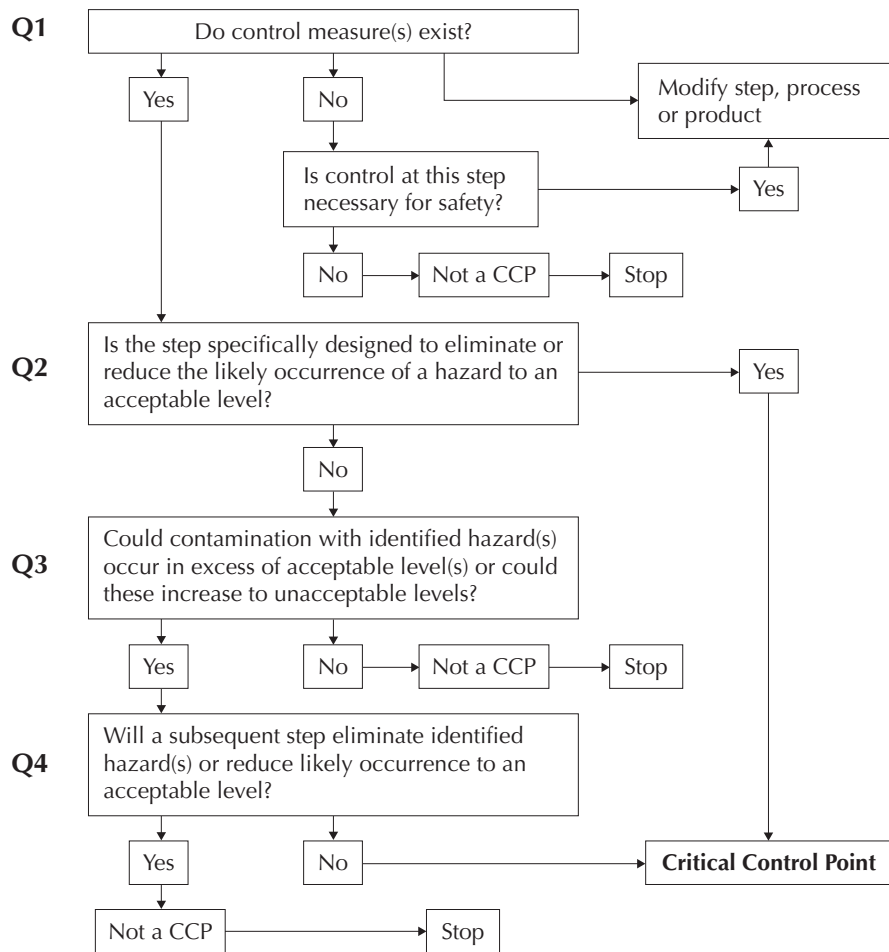
- *Catastrophic* – Complete business failure due to food product contamination resulting in deaths.
- *Critical* – Major business impact due to food product contamination resulting in severe illnesses.
- *Moderate* – Minor business impact due to food product contamination resulting in minor illnesses.
- *Negligible* – Virtually no business impact nor illnesses.

Probability

- *Frequent* – Occurs often to individual and customer is continually exposed.
- *Likely* – Occurs several times and customers are exposed regularly.
- *Occasional* – Will occur and occurs sporadically in population.
- *Seldom* – May occur and occurs seldom in a customer.
- *Unlikely* – So unlikely you can assume it will not occur and occurs very rarely in population.

Figure 4.5 – Example of a food safety risk assessment matrix

The determination of a CCP can be facilitated by the use of a decision tree (see Figure 4.6).



Source: *Codex Alimentarius: Recommended International Code of Practice – General Principles of Food Hygiene*, published by the Codex Alimentarius Commission

Figure 4.6 – Example of a decision tree to identify CCPs

Evaluating hazards and determining appropriate control measures may require a level of technical expertise that is beyond that of the individuals within the team. This is often true with microbial hazards and organic toxins. Consultation with external experts or resources may be required to support this (see 4.3 regarding sources of information).

4.9 Establishing the operational prerequisite programmes (Clause 7.5)

Understandably, part of this activity is to revisit the PRPs already identified and establish the control measures and monitoring activities that will be required for the PRP to operate effectively. The decision to determine that a hazard is sufficiently controlled by a PRP should be reasoned, logical and withstand scrutiny.

The resulting output of this activity should be a hazard analysis record for each product/process flow chart (see Figure 4.7).

Process step	Hazard	Control measure	CCP (Yes/no)	Reason (Decision tree/risk assessment?)
I. Intake of raw chicken breast	Presence of pathogenic bacteria in raw ingredient supply (e.g. <i>Campylobacter spp.</i> , <i>Salmonella spp.</i>) Growth of bacteria due to incorrect temperature during transport and handling	Raw Material Intake prerequisite programme Temperature check at intake	Yes	Risk assessment score ≥ 15 Decision tree Q1 & Q2

Note: there are two hazards at the process step. The first hazard has no CCP specified as it is controlled by a PRP.

Issue: (Date) (Issue No.)

Record ref:

Figure 4.7 – Example extract from a hazard analysis record for baked chicken Kiev

The checklist below is provided to help the reader indicate where requirements have been met (Yes) or need to be addressed (No).

CHECKLIST

	Yes	No
Have all potential hazards been identified?	<input type="checkbox"/>	<input type="checkbox"/>
Has your risk assessment been based upon reliable data sources (e.g. critical limits for bacteria drawn from recognized scientific sources)?	<input type="checkbox"/>	<input type="checkbox"/>
Did the hazard analysis consider the potential for survival/persistence of the hazard?	<input type="checkbox"/>	<input type="checkbox"/>
Did the hazard analysis consider potential hazards that could occur outside normal operating conditions?	<input type="checkbox"/>	<input type="checkbox"/>
Are your risk assessments complete and fully documented?	<input type="checkbox"/>	<input type="checkbox"/>
Are your CCP decisions robust and justifiable?	<input type="checkbox"/>	<input type="checkbox"/>
Has the hazard analysis been fully documented?	<input type="checkbox"/>	<input type="checkbox"/>
Is the link to PRPs established where relevant?	<input type="checkbox"/>	<input type="checkbox"/>
Are the control measures appropriate?	<input type="checkbox"/>	<input type="checkbox"/>
Do the control measures have specified critical limits and monitoring procedures?	<input type="checkbox"/>	<input type="checkbox"/>
Has responsibility for controls and monitoring been specified appropriately?	<input type="checkbox"/>	<input type="checkbox"/>

4.10 Establishing the HACCP plan (Clause 7.6)

The HACCP plan is the business's blueprint for the control of the highest risks to food safety as identified by the hazard analysis. The HACCP plan should contain all of the components explained thus far in this section, i.e.:

- list of food safety team members;
- product descriptions, specifications and intended use;
- process flow charts;
- completed decision trees and/or risk assessments;
- hazard analysis records;
- PRP determination.

CCPs identified should be listed on a series of control charts (see Figure 4.8), which clearly identify the control parameters. Critical limits must be specified for each CCP – the value that separates the acceptable product from the unacceptable product. The critical limits must be measurable and the rationale for choosing them documented.

Critical limits need to be as exact as is reasonably possible and be able to be monitored. A fixed numerical limit may not be required in every case. However, flexibility in this respect must not compromise food safety. For example, it is often appropriate to set an acceptable range rather than a single fixed limit. This can have the advantage of indicating when a hazard may be 'creeping towards' unacceptable levels rather than waiting for the CCP to be out of control before action is taken. In some instances, critical limits may need to specify both a maximum and minimum limit, e.g. to ensure effective control of two different hazards concurrently.

Process step	Hazard	Controls	Critical limits	Monitor/check	Corrective action	Responsibility
I. Intake of raw chicken breast	<p>Presence of pathogenic bacteria in raw ingredient supply (e.g. <i>Campylobacter spp.</i>, <i>Salmonella spp.</i>)</p> <p>Growth of bacteria due to incorrect temperature during transport and handling</p>	<p>Raw Material Intake prerequisite programme</p> <p>Temperature check at intake</p>	<p>Continued approved supplier status</p> <p>At intake: Limit = 8 °C Target ≤4 °C</p>	Temperature probe each pack. Record.	<p>>8 °C – reject</p> <p>>4 °C but <8 °C – check load/vehicle temperature record shows kept <8 °C</p>	Sous Chef

Note: there are two hazards at the process step. The first hazard has no CCP as it is controlled by a PRP.

Issue: (Date) (Issue No.)

Chart ref:

Figure 4.8 – Example extract from a control chart for baked chicken Kiev

The rationale for the identification of critical limits must be justifiable and realistically achievable on a consistent basis under normal operating conditions. They should also reflect the relevant factors for determining whether a hazard is under control (e.g. for heat treatment time/temperature parameters and critical limits should reflect published D values for the relevant bacterial hazards identified). Care should be taken in the use and interpretation of source data, both internal and external, and the information sources used to establish controls and their critical limits should be clearly documented within the HACCP plan.

The monitoring of the CCP against its critical limits, along with the frequency and/or amount of monitoring should also be determined. Monitoring regimes should reflect the ability to gather and respond to timely information. For this reason, microbiological limits should normally be avoided. An exception to this would be where rapid testing methods can be utilized to deliver immediate results.

The checklist below is provided to help the reader indicate where requirements have been met (Yes) or need to be addressed (No).

CHECKLIST

Does your HACCP plan contain:		Yes	No
A list of food safety team members?		<input type="checkbox"/>	<input type="checkbox"/>
Product descriptions, specifications and intended use?		<input type="checkbox"/>	<input type="checkbox"/>
Process flow charts?		<input type="checkbox"/>	<input type="checkbox"/>
Completed decision trees and/or risk assessments?		<input type="checkbox"/>	<input type="checkbox"/>
Hazard analysis records?		<input type="checkbox"/>	<input type="checkbox"/>
PRP determination?		<input type="checkbox"/>	<input type="checkbox"/>
Control charts?		<input type="checkbox"/>	<input type="checkbox"/>
Monitoring document examples?		<input type="checkbox"/>	<input type="checkbox"/>

4.11 Updating of preliminary information (Clause 7.7)

This clause sets up the validation cycle for the information specified in Clause 7.3, namely the source information documents, product descriptions/specifications, process flow charts, etc. This is intended to assure the currency of information on which the food safety controls are determined and operated. The document control system already discussed is a key requirement of compliance with this clause.

The checklist below is provided to help the reader indicate where requirements have been met (Yes) or need to be addressed (No).

CHECKLIST

	Yes	No
Has your revalidation frequency been specified (e.g. annually, quarterly)?	<input type="checkbox"/>	<input type="checkbox"/>
Have you allocated team responsibilities for revalidation tasks?	<input type="checkbox"/>	<input type="checkbox"/>
Is there a procedure in place for updating and revalidating following any changes (e.g. suppliers, recipes, processes)?	<input type="checkbox"/>	<input type="checkbox"/>
Do you have a documented revalidation plan?	<input type="checkbox"/>	<input type="checkbox"/>

4.12 Verification planning (Clause 7.8)

Verification is the set of monitoring and audit review activities that are designed to provide assurance that the FSMS is performing effectively on a day-to-day basis. Verification activities can include:

- a review of the HACCP system and its audit records;
- a review of CCP monitoring records;
- a review of corrective action records and product dispositions;
- confirmation that CCPs are kept under control.

A verification plan is vital to ensure that all aspects of the FSMS are considered during these activities and that they take place at a suitable frequency to ensure that system failures can be promptly addressed.

The checklist below is provided to help the reader indicate where requirements have been met (Yes) or need to be addressed (No).

CHECKLIST

Does your verification plan include:		Yes	No
A review of the HACCP system and its audit records?		<input type="checkbox"/>	<input type="checkbox"/>
A review of CCP monitoring records?		<input type="checkbox"/>	<input type="checkbox"/>
A review of corrective action records and product dispositions?		<input type="checkbox"/>	<input type="checkbox"/>
Confirmation that CCPs are kept under control?		<input type="checkbox"/>	<input type="checkbox"/>
A link to your management review?		<input type="checkbox"/>	<input type="checkbox"/>

4.13 Traceability system (Clause 7.9)

We have already made reference to a traceability system previously as a suggestion that this programme be operated as a PRP, and there are some specific requirements within the ISO 22000 standard for the operation of this system.

The scope of your traceability system will depend upon the nature of your business, specifically your customers. All catering businesses are required by law to be able to identify the immediate suppliers of all food and food ingredients, and to be able to make this information available on demand to the competent authorities (e.g. your local enforcement authority). If you supply your finished food products to individual end consumers (e.g. a restaurant serving plated meals to diners) then there is no requirement to identify this end product distribution within your traceability records. However, if you supply foods to other businesses (e.g. institutional catering services delivering to outlying kitchens, pre-prepared meal supplies, corporate event catering) then you must also keep records of the businesses to which those supplies are made, together with details of the type and quantity of products supplied, and the supply dates.

The operation of internal traceability is not prescribed in law, however, an effective FSMS should provide that a food safety incident should not adversely affect the entire system. To this end, it is essential that a simple alert should not be allowed to become a crisis as a result of inadequate or disproportionate product withdrawal because of the lack of internal traceability. The setting up of sufficient internal traceability is therefore recommended with a view to a prompt, efficient withdrawal and notification in the event of a food incident.

In practice, traceability requirements should not prove onerous. A clear link exists to any raw materials delivery prerequisite programme, stock control system, and records that are routinely kept as part of the operation of your business (e.g. delivery notes, invoices, supplier/customer contact details).

On receipt of deliveries it is important that you check that all the products you receive are clearly labelled and identify batch/lot numbers. You should identify any raw materials likely to contain major allergens. When unpacking and preparing keep supplier information and data on the batches of the raw materials you use to prepare your meals. Attention should be given to the complexity and the number of menus and preparations – you should be able to confirm whether or not a batch of ingredients was utilized for a particular meal or over a specific period.

For foods supplied to other businesses, you should retain the following data and be in a position to forward it to the relevant authorities within the shortest possible time:

- batch identification;
- data on volumes or quantities;
- description of the products;
- name and address of the client;
- transaction/delivery date.

In order to achieve this, you may either draw up a register, or maintain, in an orderly and easily accessible manner, documents evidencing product flows (delivery documents, etc.).

Traceability records must be retained for a period clearly defined within the FSMS and should reflect any regulatory requirements and industry guidelines – at least six months for short shelf life products, at least five years for long shelf life products.

4.14 Control of nonconformity (Clause 7.10)

Specific corrective actions must be developed for each CCP in order to deal with deviations and ensure that control is restored. Planned corrective actions should also detail procedures for dealing with potentially affected product, particularly that which may have already been released to the consumer. Responsibility for initiating and/or executing withdrawal must be clearly defined at a senior level within the organization. The control of nonconformity within the system as a whole should also incorporate trend analysis, undertaken as part of the verification activities to identify causes and prevent recurrence.

The checklist below is provided to help the reader indicate where requirements have been met (Yes) or need to be addressed (No).

CHECKLIST

	Yes	No
Do you have a corrective action specified for each potential nonconformity?	<input type="checkbox"/>	<input type="checkbox"/>
Do you have a hold/release procedure in place?	<input type="checkbox"/>	<input type="checkbox"/>
Do you have a critical incident procedure?	<input type="checkbox"/>	<input type="checkbox"/>
Do your procedures establish a clear line of responsibility for nonconformities and food safety incidents that could affect the consumer?	<input type="checkbox"/>	<input type="checkbox"/>
Do you have a system for analysing trends in nonconformities and feeding this data into the verification/management review?	<input type="checkbox"/>	<input type="checkbox"/>

5

Operating the system

Following completion of the initial phases of the system including all the preliminary steps such as identification of PRPs, development of HACCP plans, etc. it is necessary to ensure that the system can be operated for the benefit of the organization as a whole and be improved to take into account changing circumstances.

5.1 Defining a food safety policy

The policy is a statement of commitment by the organization to food safety management.

ISO 22000 contains requirements in two clauses – management commitment (5.1) and food safety policy (5.2). Additionally there is a requirement that senior management must ensure that responsibilities and authorities for operating the system are clearly defined and communicated to all staff. In practice, this means that such matters should be documented, and signatures obtained when such authority is exercised. The communication of responsibility and authority should be explicitly covered within staff training, both on a generic basis and in more detail with key individuals (5.4).

The organization needs to ensure it has a policy that is relevant to the organization's activities, recognizing its position in the marketplace and the food chain. It has to commit resources and establish and review its policy to ensure its ongoing relevance.

Unless the policy is embraced within the business objectives of the organization it is unlikely to be effectively delivered as the necessary commitment is probably absent. The elements covering management review, availability of resources and communication are contained within separate clauses in the standard.

The policy will need to be signed and dated to demonstrate commitment by top management. An example policy can be seen in Figure 5.1.

If you have a policy, evaluate it against the following checklist. An auditor will assess your policy against the requirements below and look for evidence to support it.

Indicate where requirements have been met (Yes) or need to be addressed (No).

CHECKLIST

Is your policy:	Yes	No
Designed to minimize risks with respect to food safety?	<input type="checkbox"/>	<input type="checkbox"/>
Appropriate to the role of the organization in the food chain?	<input type="checkbox"/>	<input type="checkbox"/>

	Yes	No
Designed to recognize and implement food safety as an integral part of your business performance?	<input type="checkbox"/>	<input type="checkbox"/>
Conforming with both statutory and regulatory requirements and with mutually agreed food safety requirements of customers?	<input type="checkbox"/>	<input type="checkbox"/>
Communicated, implemented and maintained at all levels of the organization?	<input type="checkbox"/>	<input type="checkbox"/>
Reviewed periodically for continued suitability?	<input type="checkbox"/>	<input type="checkbox"/>
Adequately addressing communication?	<input type="checkbox"/>	<input type="checkbox"/>
Supported by measurable objectives?	<input type="checkbox"/>	<input type="checkbox"/>
Including a commitment, at a high level, of continual improvement in your performance?	<input type="checkbox"/>	<input type="checkbox"/>
Designed to make management of food safety a prime responsibility of your senior management team?	<input type="checkbox"/>	<input type="checkbox"/>
Does the policy acknowledge that people are a key resource?	<input type="checkbox"/>	<input type="checkbox"/>

The following is provided for additional guidance on what is required. (Each point relates to a clause within ISO 22000 – 5.2.)

1 Is appropriate to the role of the organization in the food chain.

The policy should be appropriate to the nature and scale of the organization's risks, recognizing the impact it could have within the food chain. The impacts should not be overstated or trivialized but indicate that the organization has taken account of its role and its commitment to meet expectations.

2 Conforms with both statutory and regulatory requirements and with mutually agreed food safety requirements of customers.

The policy should include a commitment to at least comply with currently applicable food safety legislation. It needs to comply with any specific customer requirements about sourcing of materials, packaging, etc. If it subscribes to any voluntary programmes, codes of practice, corporate or group policies, internal standards and specifications these need to be embraced as well.

3 Is communicated, implemented and maintained at all levels of the organization.

The policy should be communicated to all employees in order to make them aware of their individual obligations. The involvement and participation of employees and their representatives is vital in order to gain commitment and to ensure the success of an FSMS. Involving employees is often neglected. In most, if not all, industries employees wish to contribute positively and it follows that a partnership with them can be very beneficial. Equally, management at all levels should understand their responsibilities and be competent to undertake the tasks they are required to perform including managing food safety.

4 Is reviewed for continued suitability.

The policy should be reviewed periodically to ensure that it remains relevant and appropriate to the organization.

Change is inevitable and, as a driver of continual improvement, top management should ensure the food safety management policy and management system is reviewed regularly in order to meet changing circumstances (such as new business demands, legislation and technology), as well as, most importantly, the lessons learnt from incidents, audit findings and good practice.

5 Adequately addresses communication.

Employees at all levels should receive appropriate communication and training to ensure that they are competent to carry out their duties and responsibilities. Training must be appropriate to the needs of each employee and to the positive benefit of the organization.

The method of communication should meet the needs of the workforce and reflect their literacy and language skills.

6 Is supported by measurable objectives.

There is a need to ensure that the policy enables the identification of objectives that are measurable and which lend themselves to be audited within the organization. A policy that does not define its commitment in this manner has little meaning as it is difficult to demonstrate that the organization is striving to achieve any improvements.

In addition to those items listed above there is a need to include those issues it commits to as identified in Clause 5.1 and so a statement on commitment to continual improvement should be included. There should be recognition that food safety is a core part of the business and the policy should be communicated to demonstrate this commitment to interested parties.

An example policy is provided below.



The Wilson Café for Ramblers ***Food safety policy***

The Wilson Café for Ramblers (WCR) aims to be a haven for ramblers visiting the many local footpaths and sites of interest. Its intention is to make all visitors welcome so that they return many times and recognize the café as their first choice for refreshment.

The café thrives on the goodwill achieved through many years of slavishly adhering to good standards and has greatly expanded to meet the needs of its many guests.

The management of WCR recognizes that it is essential that they provide quality food and drinks, which are safe, and as a result visitors will recommend them as a place to visit. This commitment and the essential controls relating to food safety are integrated within the overall operational control of the business.

WCR recognizes that it uses sources of food product from many suppliers and that these need to be carefully selected and evaluated with respect to how they impact on the food served at their café. It ensures it meets all statutory and regulatory requirements and that the necessary equipment is provided and its maintenance meets all the required standards.

The management recognizes that the employees are key to delivering the standards they wish to maintain and that training of employees and regularly reinforcing this training is an essential element of WCR's business needs. Employees are encouraged to communicate with management on better ways of working and any shortfalls they identify with current practices. It recognizes that it is important to continually improve through identifying good practices that are publicized within its sector and aims to be proactive in this respect. In order to achieve this improvement it sets objectives for performance every year.

This policy and the management system to support it will be reviewed annually to ensure it is appropriate to the current circumstances.

Signed

Fred Wilson

Date

5.2 Effective food safety management culture

Some organizations appear on paper to have effective systems that are fully comprehensive, yet in reality there is little commitment to deliver and the performance is poor. The management system manual and procedures are opened only when the organization is audited. There may be a number of reasons for this but if organizational commitment is poor then the results are usually inferior to those found in a well run organization. The culture of the organization is very much influenced by leadership.

The culture in any one discipline is usually inseparable from an organization's overall culture and can rarely be managed in isolation. To achieve a positive culture sustaining a robust system that continually improves requires ongoing effort by the management/supervisory team. Take time to build up the trust of the workforce. Ensure that supervisors/managers model the good practices they advocate, not just when it is convenient. The systems must be robust enough to operate even when they have to meet challenging production targets.

Food businesses face some particular challenges such as high turnover of employees; many workers may not have English as their first language and have a different cultural background. This needs to be taken into account when communicating food safety matters. Team work is vital to ensure all parties work together to deliver the policy and objectives.

A simple checklist to assist you in the assessment of your organizational culture is provided below. Indicate where requirements have been met (Yes) or need to be addressed (No).

CHECKLIST

	Yes	No
Are staff committed to food safety and the aims of the policy?	<input type="checkbox"/>	<input type="checkbox"/>
Is food safety a normal topic of day-to-day discussion in the workplace and is there active feedback on performance?	<input type="checkbox"/>	<input type="checkbox"/>
Is food safety managed with the same determination as other key business objectives?	<input type="checkbox"/>	<input type="checkbox"/>
Do senior staff and supervisors spend time discussing and promoting food safety in the work environment?	<input type="checkbox"/>	<input type="checkbox"/>
Do management and supervisors demonstrate visible food safety commitment and leadership by example?	<input type="checkbox"/>	<input type="checkbox"/>
Do they respond to bad news as well as good news and take action on the information they receive?	<input type="checkbox"/>	<input type="checkbox"/>

If the responses are yes then this is a good sign that a positive culture exists.

There is no quick way to overcome lack of commitment and poor culture. The necessary commitment can be gained only by promoting good practices and the personal involvement of everyone in the organization. It is essential that day-to-day practice reflects policy.

There are many factors that can impair the culture, and some of the indicators are given in the checklist below. Indicate where requirements have still to be met (Yes) or have been addressed (No).

CHECKLIST

	Yes	No
Are there inconsistencies in rules and procedures?	<input type="checkbox"/>	<input type="checkbox"/>
Do supervisors and managers not act upon non-compliances with food safety rules?	<input type="checkbox"/>	<input type="checkbox"/>
Are controls and procedures developed without due consideration for their practicability?	<input type="checkbox"/>	<input type="checkbox"/>
Are impractical controls and safeguards imposed by external agencies and consultants?	<input type="checkbox"/>	<input type="checkbox"/>
Are there failures in communicating shortcomings in food safety arrangements?	<input type="checkbox"/>	<input type="checkbox"/>
Are suggestions for improvements or changes from employees not welcome?	<input type="checkbox"/>	<input type="checkbox"/>
Are employees not involved in developing operating procedures?	<input type="checkbox"/>	<input type="checkbox"/>
Is there an acceptance that problems are inevitable?	<input type="checkbox"/>	<input type="checkbox"/>

	Yes	No
Does a culture of blame exist?	<input type="checkbox"/>	<input type="checkbox"/>
Is there a lack of resources to support food safety practices?	<input type="checkbox"/>	<input type="checkbox"/>

If the response to any of the above is yes then steps should be taken to improve communication, training, etc.

5.3 Documentation requirements

There is a requirement for some documentation but this should be proportionate to the needs of the organization. The documentation should be present to support the system and not be a tome that is kept in binders on a shelf and is never looked at. Certain things are required to be documented:

- food safety policy, which is available and signed by a senior manager;
- all documented procedures and records as specified by ISO 22000;
- all documents needed for keeping the FSMS operationally effective (see list below).

Examples of forms are provided in Section 3.

The documents need to be controlled as they are updated, old documents removed and appropriate records kept.

It is quite acceptable for the system to be an electronic one provided the controls specified are met.

The controls need to ensure that all proposed changes are reviewed prior to implementation to determine their effects on food safety and their impact on the FSMS.

Documented procedures need to be established to define the controls required.

The checklist below is provided to help the reader indicate where requirements have been met (Yes) or need to be addressed (No).

CHECKLIST

Have you set up a system to:	Yes	No
Approve documents for adequacy prior to issue?	<input type="checkbox"/>	<input type="checkbox"/>
Review and update documents as necessary, and reapprove documents?	<input type="checkbox"/>	<input type="checkbox"/>
Ensure that changes and the current revision status of documents are identified?	<input type="checkbox"/>	<input type="checkbox"/>
Ensure that relevant versions of applicable documents are available at points of use?	<input type="checkbox"/>	<input type="checkbox"/>
Ensure that documents remain legible and readily identifiable?	<input type="checkbox"/>	<input type="checkbox"/>
Ensure that relevant documents of external origin are identified and their distribution controlled?	<input type="checkbox"/>	<input type="checkbox"/>
Prevent the unintended use of obsolete documents?	<input type="checkbox"/>	<input type="checkbox"/>
Ensure that they are suitably identified if they are to be retained?	<input type="checkbox"/>	<input type="checkbox"/>

It is essential for traceability reasons and evidence of conformity that records are kept. It is a legal requirement that these records are easily identifiable, retrievable and can be provided on demand to a regulator. They obviously need to be legible.

A documented procedure is required to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

The checklist below will assist in identifying whether all the requirements for documentation specified within ISO 22000:2005 have been completed. The specific clause numbers are inserted for ease of reference.

The following are requirements of ISO 22000, which should have been met.

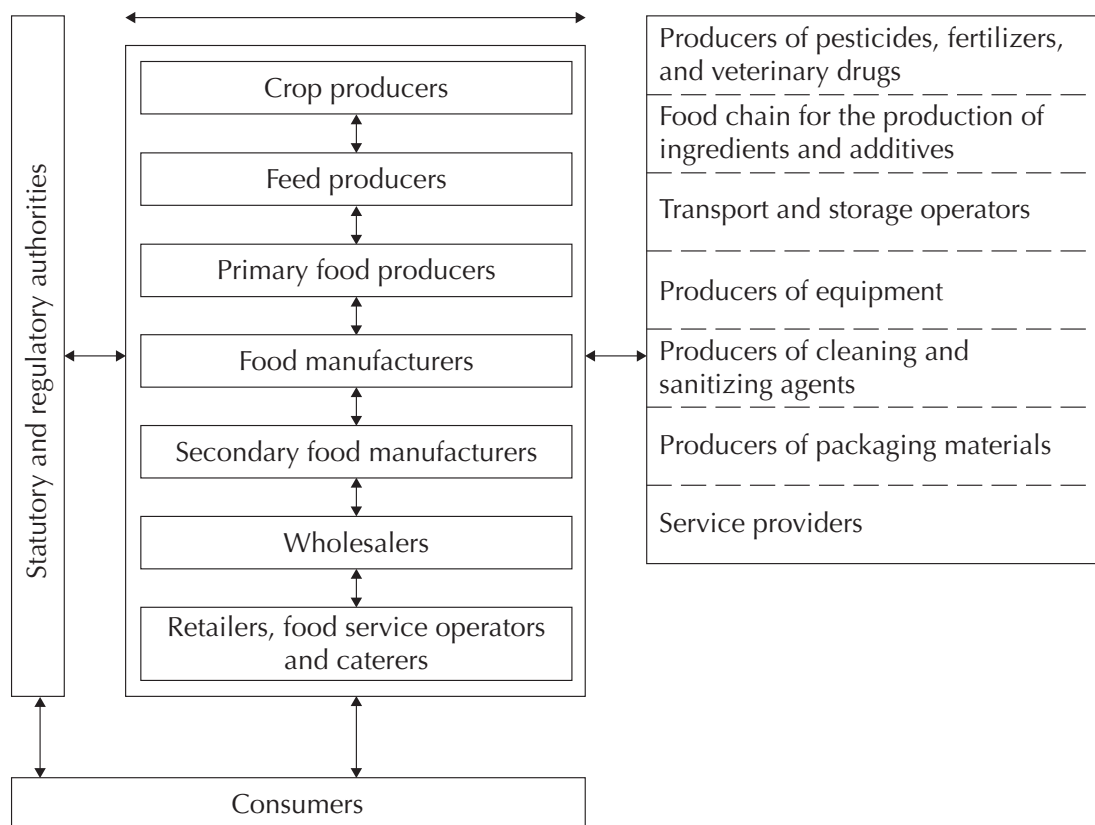
- There is a general requirement to document the FSMS (4.1).
- Processes that are outsourced are documented within the FSMS (4.1, 4.2.1 and 5.3).
- The food safety policy and associated objectives are fully documented (4.2.1 and 5.2).
- There shall be a documented procedure to define the controls required over all documentation within the FSMS (4.2.2).
- Records shall be established and maintained to provide evidence of conformity to requirements and evidence of the effective operation of the FSMS. These records shall remain legible, readily identifiable and retrievable (4.2.3).
- There shall be a documented procedure to define controls needed for identification, storage, protection, retrieval, retention time and disposition of records (4.2.3).
- Where external communication to other organizations in the food chain (concerning food safety) has been undertaken records of this communication shall be maintained (5.6.1).
- Records of management reviews shall be maintained (5.8.1).
- Records of agreements and contracts defining the responsibilities of external experts who have provided assistance in the development, implementation, operation or assessment of the FSMS shall be available (6.2.1).
- Records of training shall be maintained (6.2.2).
- Records of verification and modifications of PRPs shall be maintained (7.2.3).
- Details of how activities included in PRPs are managed are documented (7.2.3).
- Relevant information needed to conduct hazard analysis shall be documented. Records shall be maintained (7.3.1).
- Records shall be maintained that demonstrate that the food safety team has the required knowledge and experience (7.3.2).
- All raw materials, ingredients and product-contact materials shall be documented (7.3.3.1).
- Characteristics of end products shall be described in documents (7.3.3.2).
- Intended use, reasonably expected handling of the end product and any unintended but reasonably expected mishandling and misuse of the end product shall be documented (7.3.4).
- After verification, flow diagrams shall be maintained as records (7.3.5.1).
- A documented description of the existing control measures, process parameters and/or the rigour with which they are applied shall be kept and updated (7.3.5.2).
- All food safety hazards that are reasonably expected to occur shall be recorded (7.4.2.1).
- The evaluation of food safety hazards shall be recorded including a description of the methodology used and the results of the hazard assessment (7.4.3).
- The methodology and parameters used for the categorization of control measures shall be documented (7.4.4).
- Records shall be maintained of the results of assessments (7.4.4).
- Operational PRPs shall be documented and record(s) of monitoring maintained (7.5).

- The HACCP plan shall be documented and records of monitoring maintained (7.6.1).
- The rationale for the determination of critical limits for critical control points (CCPs) shall be documented (7.4.2.3 and 7.6.3).
- The system for monitoring CCPs shall include records that cover: measurements or observations that provide results within an adequate time frame; monitoring devices used; applicable calibration methods; monitoring frequency; responsibility and authority related to monitoring and evaluation of results; records requirements and methods (7.6.4).
- Procedures for the handling of potentially unsafe products shall be established (7.6.5).
- Documentation specifying PRPs and the HACCP plan shall be updated (7.7).
- Verification plans shall be documented and results of verification shall be recorded (7.8).
- Records that support the traceability system shall be maintained in accordance with statutory and regulatory requirements and customer requirements (7.9).
- A documented procedure shall be established defining the identification and assessment of end products where CCPs are exceeded. Records of evaluation shall be maintained (7.10.1).
- A documented procedure(s) shall be established that specifies appropriate actions to identify and eliminate the cause of detected nonconformances. Results of corrective actions taken shall be recorded (7.10.2).
- Controls and authorization for dealing with potentially unsafe products shall be documented (7.10.3.1 and 5.7).
- A documented procedure shall be established for notification to interested parties, handling of products and the sequence of actions to be taken in the event of a withdrawal of a product. The cause, extent and result of a withdrawal shall be recorded (7.10.4).
- Following verification of a withdrawal programme the effectiveness shall be recorded (7.10.4).
- Records of the results of calibration and verification shall be maintained. Where equipment is found to be nonconforming records of the assessment and resulting actions shall be maintained (8.3).
- A documented procedure shall be established outlining responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (8.4.1).
- The results of the analysis of verification activities shall be recorded (8.4.3).
- Systems updating activities shall be recorded (8.5.2 and 5.6.2).

5.4 Communication

Effective communication arrangements throughout the organization are essential for the efficient running of any management system. Food safety is no different in this respect.

It is important to establish effective communication arrangements with all interested parties, e.g. customers, suppliers, trade associations, regulatory bodies. It is particularly important to have effective arrangements with your immediate suppliers and your direct customers. It may be useful to draw up an internal communications flow diagram that shows the sources of key data, where it is recorded, who it is reported to and what part of the management system it feeds into.



NOTE The figure does not show the type of interactive communications along and across the food chain that by-pass immediate suppliers and customers.

Source: ISO 22000:2005

Figure 5.1 – Example of communication within the food chain

Arrangements need to be made for:

- identifying and receiving relevant food safety information from outside the organization, e.g. changes in legislation, information on new developments, codes of hygienic practice;
- ensuring that any pertinent food safety information is communicated to those within the organization who need to know;
- ensuring that relevant information is communicated to people outside the organization who require it;
- encouraging feedback and suggestions from staff on food safety matters.

5.4.1 External communication

In the current world it is particularly important to be responsive to issues arising that are of concern to the consumer. These need to be addressed quickly in order to ensure that consumers do not respond adversely to the food products supplied by the organization.

Information can arise from many sources including the media, customers, suppliers, government agencies, the World Health Organization, etc. The organization needs to develop its capacity for receiving information and acting upon it and also communicating to external parties. A person should be appointed to deal with all aspects of external communication concerning food safety matters.

Arrangements also need to be established to deal with any emergency such as production loss or product failure.

5.4.2 Internal communication

The commitment of employees throughout the organization to food safety is essential. They are a valuable source of information in identifying hazards and assessing risk and their cooperation is essential in implementing control measures.

Employees should be encouraged to report shortcomings in the food safety arrangements and be involved, where appropriate, in the development of food safety procedures. There are a number of ways of involving staff and consulting with them on food safety issues. One very effective method is to set up a food safety committee to act as a vehicle for active participation.

In addressing internal communication issues it is necessary to take account of literacy skills and the first language of those working within the organization. It may well be beneficial if universally understood pictures are used as a means of communicating procedures and instructions.



Polly Porkers

This business was set up by the second generation of a family of immigrants from eastern Europe. The son set up a pig-breeding establishment that reflected his grandparent's business in his native Poland. Following expansion of the operation he now runs a production and wholesale butchers supplying pork and related products.

Many of the workers he employs do not have English as their first language and this proved to be a barrier as he tried to implement a sound FSMS. Despite the background of the manager, his knowledge of the language of his heritage was restricted to a few words when dealing with the different languages encountered within the 50-strong workforce.


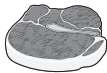


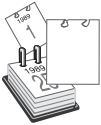



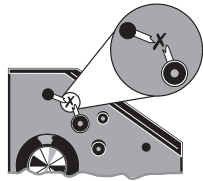
The need for effective communication with the restrictions placed upon the business was a major barrier as he needed to communicate key requirements to meet the needs of his supermarket clients and regulators.

The organization carried out a number of initiatives to address this need, as follows:

- introduced signs in the workplace that used pictograms rather than words;
- training information and instructions produced in a pictogram format;
- provided free of charge English lessons;
- encouraged workers to bring matters to the attention of line managers in their native language and arranged for translation services to provide urgent support for such communications.

POLLY PORKERS' CHECKLIST

To assist the operatives who did not have English as their first language, all products were assigned a number and each production line a letter. The production line had the letters permanently assigned but the numbers changed with the product variant being manufactured at the time. The operators were able to indicate problems on the simple form and convey information quickly.

Production Line 		A	B	C
Product		 1	 2	 3
Date 				
Time 				
Problem				
				
				
Corrected or needs action ✓ / ✗				

The food safety team need to be made aware of a whole variety of changes through effective communication systems and these may include:

- products or new products;
- raw materials, ingredients and services;

- production systems and equipment;
- production premises, location of equipment, surrounding environment;
- cleaning and sanitation programmes;
- packaging, storage and distribution systems;
- personnel qualification levels and/or allocation of responsibilities and authorizations;
- statutory and regulatory requirements;
- knowledge regarding food safety hazards and control measures;
- customer, sector and other requirements that the organization observes;
- relevant enquiries from external interested parties;
- complaints indicating food safety hazards associated with the product;
- other conditions that have an impact on food safety. (5.6.2).

The checklist below is provided to help the reader indicate where requirements have been met (Yes) or need to be addressed (No).

CHECKLIST

We have arrangements for:	Yes	No
A designated person who has responsibility for external communication.	<input type="checkbox"/>	<input type="checkbox"/>
Identifying and receiving food safety information from external parties.	<input type="checkbox"/>	<input type="checkbox"/>
Ensuring that food safety information is communicated internally.	<input type="checkbox"/>	<input type="checkbox"/>
Ensuring that relevant information is communicated to relevant external parties.	<input type="checkbox"/>	<input type="checkbox"/>
Encouraging and responding to suggestions from staff on food safety matters.	<input type="checkbox"/>	<input type="checkbox"/>
A food safety committee.	<input type="checkbox"/>	<input type="checkbox"/>
Ensuring that personnel have appropriate qualifications for their job.	<input type="checkbox"/>	<input type="checkbox"/>
Making all staff aware of complaints and any subsequent corrective actions.	<input type="checkbox"/>	<input type="checkbox"/>

5.5 Monitoring and measuring

Monitoring the system to make sure that everything is working as intended is obviously an essential activity. Much of this monitoring will involve measurement of one kind or another, and it is necessary to ensure that the measurements are appropriate and that the instruments used are accurate. The monitoring and measuring methods and equipment to be used should be determined by the food safety team when developing the HACCP plan and detailed on the HACCP control charts.

ISO 22000 states that 'monitoring procedures that demonstrate that the operational PRPs are implemented' (7.5c) shall be included in the programme, 'a monitoring system shall be established for each CCP to demonstrate that the CCP is in control' (7.6.4) and evidence that 'specified monitoring and measuring methods and equipment are adequate to ensure the performance of the monitoring and measuring procedures' (8.3) shall be provided.

The purpose of monitoring systems is to give assurance that critical limits are not being exceeded and the process is under control. The monitoring and measuring methods and equipment should also enable speedy detection of the process going out of control and enable rapid corrective action to be taken to bring the process back under control. Where possible, monitoring should be able to indicate if there is a trend towards nonconformity so that adjustments can be made to avoid exceeding a critical

limit before this happens. To ensure that this is effective, the team must consider method (including equipment), frequency and recording/reporting.

The type of monitoring method and equipment used will of course depend on what is being monitored. Some monitoring may be *quantitative measurement*, e.g. temperature checks on hot food holding or refrigeration; time checks on cooling of hot food. Some monitoring may be *qualitative observation*, e.g. visual checks on cleaning standards. Other monitoring may be confirmation of a procedural requirement, e.g. 'continued approved supplier status' for raw materials supplies. The equipment used for quantitative checks must be adequate for its intended use and should be regularly calibrated/verified to ensure that it is accurate. Qualitative observation can be subjective, so requirements must be explicit and staff carefully trained to ensure effectiveness. Regular proficiency testing of staff conducting visual monitoring should be carried out to ensure that standards are maintained.

The frequency of monitoring will depend on the nature of the activity and the monitoring method being used. It is imperative that an appropriate frequency is determined for each monitoring activity to maintain control. Off-line testing, such as microbiological analysis, does not usually provide a sufficiently rapid result to ensure that a process remains in control, but may be used at scheduled intervals to support other, more frequent, monitoring methods.

Recording and reporting is the essential final part of the monitoring activity, without which the checks have no lasting value. It is as important to document visual observations as it is to record measurements and readings, if they are specified control measures either for PRPs or CCPs. Such records provide not only system data for audit and inspection, but also evidence of due diligence for legal purposes. Records must therefore be legible and complete, and be signed by the person doing the monitoring as well as the person responsible for reviewing the record. The reporting procedure for deviations or nonconformities must be clear and well understood by everyone.

A final point to consider is any monitoring that may be contracted out by your organization, for example pest control. It should be understood that where a programme of monitoring (and associated corrective action) is conducted by a contractor, overall responsibility remains with the food safety team. A designated individual within the organization should supervise the contractor's activities and the programme conducted should be consistent with the procedures laid down within the FSMS. Failures on the part of the contractor will be nonconformities in *your* system and management should take prompt, documented action to ensure that such instances do not compromise ISO 22000 accreditation status.

The checklist below is provided to help the reader indicate where requirements have been met (Yes) or need to be addressed (No).

CHECKLIST

Do you:	Yes	No
Specify monitoring procedures for all PRPs and CCPs?	<input type="checkbox"/>	<input type="checkbox"/>
Ensure that monitoring methods are adequate and that monitoring frequencies are appropriate to maintain control?	<input type="checkbox"/>	<input type="checkbox"/>
Ensure that monitoring checks are signed by the monitor and also by a designated reviewer?	<input type="checkbox"/>	<input type="checkbox"/>
Have prompt reporting procedures for nonconformities that are clear and well understood?	<input type="checkbox"/>	<input type="checkbox"/>
Calibrate measuring equipment at specified intervals against agreed standards?	<input type="checkbox"/>	<input type="checkbox"/>
Make adjustments to equipment as necessary and record status?	<input type="checkbox"/>	<input type="checkbox"/>
Ensure equipment is safeguarded from adjustments that would invalidate results?	<input type="checkbox"/>	<input type="checkbox"/>
Ensure that equipment is protected from damage and deterioration?	<input type="checkbox"/>	<input type="checkbox"/>
Keep records of calibration and verification?	<input type="checkbox"/>	<input type="checkbox"/>

5.6 Contingency planning

5.6.1 Emergency preparedness and response

All organizations need to make arrangements for dealing with emergencies, whether fire evacuation or first aid. Food safety is no different in this respect. A product that has reached the consumer market that is deficient in some way poses a major problem to those in the food supply industry. The logistics of dealing with faulty products is also a considerable problem. Moreover the withdrawal of the product is not the only major difficulty should this happen. It is now a legal requirement to notify consumers and regulatory bodies that an incident has occurred. In the event of an incident the following questions should be addressed.

- What is the nature of the problem?
- How much product has been affected?
- How far into the marketplace has it been distributed?
- What steps should we take to isolate and recall?
- What public notification should we issue and to whom?
- How is the cause of the problem to be rectified?

ISO 22000:2005 states:

Top management shall establish, implement and maintain procedures to manage potential emergency situations and accidents that can impact food safety and which are relevant to the role of the organization in the food chain (5.7).

Withdrawn products shall be secured or held under supervision until they are destroyed, used for purposes other than originally intended, determined to be safe for the same (or other) intended use, or reprocessed in a manner to ensure they become safe. The cause, extent and result of a withdrawal should be recorded and reported to top management as input to the management review (5.8.2).

The organization needs to verify and record the effectiveness of the withdrawal programme through the use of appropriate techniques (e.g. mock withdrawal or practice withdrawal).

The checklist below is provided to help the reader indicate where requirements have been met (Yes) or need to be addressed (No).

CHECKLIST

	Yes	No
Has the organization established contingency arrangements for product withdrawal?	<input type="checkbox"/>	<input type="checkbox"/>
Has the organization set up a communication system with its customers in the case of such an emergency?	<input type="checkbox"/>	<input type="checkbox"/>
Have there been any trial runs?	<input type="checkbox"/>	<input type="checkbox"/>
Have lessons been learnt from real events and trial runs and corrective action taken?	<input type="checkbox"/>	<input type="checkbox"/>
Have top management appointed personnel with the authority to initiate a withdrawal?	<input type="checkbox"/>	<input type="checkbox"/>
Have top management appointed personnel responsible for executing the withdrawal?	<input type="checkbox"/>	<input type="checkbox"/>
Has a documented procedure been produced for notification to relevant interested parties?	<input type="checkbox"/>	<input type="checkbox"/>
Has a documented procedure been produced for handling the withdrawal of products?	<input type="checkbox"/>	<input type="checkbox"/>
Has a documented procedure been produced for dealing with affected products in stock?	<input type="checkbox"/>	<input type="checkbox"/>
Does the procedure identify the sequence of events that need to be initiated?	<input type="checkbox"/>	<input type="checkbox"/>

5.7 Internal audit

One of the core management system requirements in all the established management systems standards/specifications is the internal audit. A similar requirement exists for those implementing ISO 22000. The audit is the process that tests the system and establishes that it is working effectively and identifies where there may be opportunities for improvement. A system for routinely monitoring performance is insufficient in itself to ensure that the FSMS is effective and the audit needs to be recognized as an important activity for this purpose. Only in this way will it be possible to judge whether the system is adequate to meet the requirements expressed in the stated policy and objectives of the organization.

To achieve this in practice requires that the operation of the system is checked in all areas and applications by auditors who are not directly involved in the audited work. The object is not to find fault. The purpose is to help, not to criticize.

Both validation and verification should be included in the audit process. Validation is obtaining evidence that the elements and the scope of the HACCP plan are an accurate reflection of the food operation. Verification is confirmation through objective evidence that the system is in control of food safety. Examples of verification and validation checklists are provided in Section 3.

Although the primary purpose of auditing is to check that the system is being followed and is effective, it is also a primary means of achieving continual improvement of the system, another essential requirement. If the audit is to be done by employees of the organization (in most cases the best way) they need to be selected with care and given the necessary training. This will consist of systems auditing in general and of FSMSs in particular. If there are experienced quality systems auditors in the organization, they may well be suitable for the task after training on the specialist food safety management aspects. An essential requirement is that whoever is performing the audit does not themselves have direct responsibility for the function being audited, as otherwise the integrity of the audit may be compromised.

All parts of the system need to be audited regularly – customarily in the course of a year – but not all parts of the system need to be audited at the same time nor at the same frequency. Those areas where the risk is greatest should be audited more frequently than those where the risk is less, and the audit programme should recognize this requirement.

The results of audits should be communicated to all relevant personnel immediately on completion of the audit so that any necessary corrective action can be taken and improvements made. These results will be an important input to the annual management review. If the auditor finds some serious problem in the course of the audit this should immediately be raised with the appropriate manager without waiting for the formal report.

The checklist below is provided to help the reader indicate where the key issues in auditing the FSMS have been addressed (Yes) or need to be addressed (No).

CHECKLIST: Auditing in your organization

	Yes	No
Regular, periodic audits of the FSMS are taking place.	<input type="checkbox"/>	<input type="checkbox"/>
Staff conducting audits are competent to perform this task.	<input type="checkbox"/>	<input type="checkbox"/>
Staff conducting audits are independent from the activity being audited.	<input type="checkbox"/>	<input type="checkbox"/>
Audits verify that the organization is fulfilling its food safety management obligations.	<input type="checkbox"/>	<input type="checkbox"/>
Audits identify strengths and weaknesses in the FSMS.	<input type="checkbox"/>	<input type="checkbox"/>
Audits verify whether the organization is achieving its food safety management performance targets.	<input type="checkbox"/>	<input type="checkbox"/>
Audit results are communicated to all relevant personnel.	<input type="checkbox"/>	<input type="checkbox"/>

	Yes	No
Audit results are the basis for corrective action.	<input type="checkbox"/>	<input type="checkbox"/>
Audit results are monitored to ensure food safety management improvement, i.e. there are no repetitions of failures revealed by previous reports.	<input type="checkbox"/>	<input type="checkbox"/>

5.7.1 Organizing an audit

Figure 5.2 shows the steps to be followed during an audit and each step is further elaborated below.

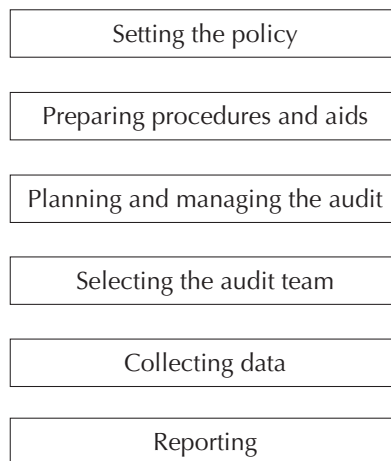


Figure 5.2 – Audit process

Stage 1. Setting the policy

In developing an audit policy, the issues which need to be considered include:

- the objectives and purpose of auditing;
- the standards, procedures and aids to be used;
- who is to undertake audits (or be part of a team) and the training needed;
- the arrangements for managing the audit, including budget provisions;
- formulating the audit programme;
- the format of audit reports and arrangements for responding to them;
- performance standards for planning and implementing the audit programme and arrangements to monitor it;
- arrangements for the review of the audit policy and its implementation and for revision, as necessary.

Stage 2. Preparing procedures and aids

Issues to consider in preparing for the audit are:

- the elements of the audit process, preparation, on-site work and follow up programme;
- the key elements of the FSMS and any other topics that the audit programme will address and the criteria against which the performance will be judged;

- means of ensuring that the audit includes a representative sample of activities to be included;
- how key questions should be framed;
- the need for auditing aids, e.g. checklists, aides-memoir, inspection procedures.

Stage 3. Planning and managing the audit

Audits cost money. Apart from the direct costs of the auditors (even if they are your own staff who have been seconded to do the audit), all staff and managers will be involved, so there is a significant indirect cost arising from the disruption and distraction from people's normal duties.

Effective planning should cover:

- preparing the programme;
- the scope of the audit;
- establishing terms of reference;
- establishing a timetable;
- selecting an appropriate audit team.

Stage 4. Selecting the audit team

The auditors should be:

- competent;
- independent of the area being audited;
- able to communicate;
- good listeners;
- able to assess information.

Stage 5. Collecting data

There are a number of stages involved, including:

- carrying out structured interviews with key personnel throughout the business area to determine that robust procedures are in place and that they are understood and are being followed;
- examining accident and incident reports for the area;
- examining other relevant documentation, including policy statements, risk assessment reports, audit records, manuals, etc.
- confirming the statements made by observation and examining documents;
- analysing and interpreting the data;
- maintaining records.

Stage 6. Reporting

For each department or section audited, the auditor should prepare a written report. This should be in a standard format and should specify the processes audited, the problems found and details of the actions agreed to overcome them (together with names and dates). The auditor and the person responsible for the activity should sign the report, to indicate mutual agreement of the facts of the situation and any remedial actions. The report should then be passed to the audit manager or whoever is in charge of the process. The audit manager may accept responsibility for checking that the necessary corrective action has been taken to ensure no recurrence of the problems that have been reported, or this may be left with the individual auditors to clear with the appropriate managers.

To assist further in the audit process, Section 3 contains example validation and verification checklists.

5.8 Reviewing

The management review is the opportunity to review the continuing suitability, adequacy and effectiveness of the system. It is essential that the system is reviewed from time to time as this provides the mechanism for continual improvement, which is a requirement of ISO 22000.

A management review is quite different to an audit. An audit is to see if the system is being followed. The review is to see whether the system is still appropriate to the organization and in what respects it can be improved.

A management review should be undertaken by senior management at least once a year and the outcome may include a revision to the policy as well as changes to the actual management system.

5.8.1 Management review inputs

Some additional guidance is given below about the reasoning behind the various inputs where it may not be obvious what is required (see Checklist: Management review inputs).

5.8.1.1 Input items 1–3

Regulation and codes of practice form a very important role in the driving of standards in the food industry. Customer expectations, social change, fashion, legislative requirements, technological developments and new sources of supply, etc. are constantly changing and from time to time a new 'scare' arises, which results in new issues being identified. Organizations need to be in a position such that they know what is coming and are proactive in their approach. For this reason it is essential to track emerging directives from the EU, UK legislation and regulations, and new codes of practice. It may be you track these from the Food Standards Agency or trade associations. The input of information on these changes should be reviewed in the management review process to determine what the organization should do to respond – if the information relates to their activities. This may need major investment or a change of strategy that only senior management can deal with effectively.

5.8.1.2 Input items 4–8

Effective resourcing in the organization is essential and the management review provides an opportunity to consider this. Items 4 to 8 all relate to resource issues. Organizations exist in a climate of constant change: expanding production lines, changes to equipment needs and changes of management structure, etc. to respond to items 1–3. There may be supply problems and the need to review suppliers or find new ones for new products. These issues can have significant implications for other resource issues and storage, etc.

Any changes arising from amendments to the operating arrangements may necessitate a review of the competency of the various employees affected, with respect to their experience, expertise and training needs.

5.8.1.3 Input items 9–10

These relate to the outputs from staff and other management meetings. It may also include feedback from customers. Reports from groups dealing with quality and occupational health and safety issues may be important if they impact on the product safety.

5.8.1.4 Input items 11–13

These items all relate to activities that should be undertaken routinely to ensure the food product is safe. The outputs from these processes should be input to the management review process in case there is an opportunity for improving the current arrangements.

The checklist below of the key issues in reviewing the FSMS is provided to help the reader indicate those issues you are already addressing (Yes) or need to address (No).

CHECKLIST: Management review inputs

	Yes	No
1 Amendments and changes to regulations and legislation.	<input type="checkbox"/>	<input type="checkbox"/>
2 Potential impact of emerging legislation, e.g. EC directives.	<input type="checkbox"/>	<input type="checkbox"/>
3 New or revised codes of practice or industry guidance.	<input type="checkbox"/>	<input type="checkbox"/>
4 Changes (present and future) to internal organizational structure/staffing levels and responsibilities.	<input type="checkbox"/>	<input type="checkbox"/>
5 Competence reports/training needs.	<input type="checkbox"/>	<input type="checkbox"/>
6 Changes (present and future) to the products/services of the organization.	<input type="checkbox"/>	<input type="checkbox"/>
7 Changes (present and future) to the suppliers to the organization.	<input type="checkbox"/>	<input type="checkbox"/>
8 Changes (present and future) in equipment, plant, buildings, infrastructure, etc.	<input type="checkbox"/>	<input type="checkbox"/>
9 Output from management meetings or other committees.	<input type="checkbox"/>	<input type="checkbox"/>
10 Reports from other management key discipline areas such as quality, safety.	<input type="checkbox"/>	<input type="checkbox"/>
11 Food safety monitoring and compliance data.	<input type="checkbox"/>	<input type="checkbox"/>
12 Revalidation of the HACCP system including process flow charts, hazards and control measures.	<input type="checkbox"/>	<input type="checkbox"/>
13 Findings and recommendations of the organization's verification programme (audits, product testing, etc.).	<input type="checkbox"/>	<input type="checkbox"/>

5.8.2 Management review outputs

Following the management review process, there should be outputs reflecting the decisions made on the various inputs and management commitment to improve continually. These outputs should be documented.

The outputs from the review process should result in the following.

CHECKLIST: Management review outputs

	Yes	No
14 Assurance of food safety legal compliance and due diligence.	<input type="checkbox"/>	<input type="checkbox"/>
15 Decisions and actions on food safety performance.	<input type="checkbox"/>	<input type="checkbox"/>
16 Revision of the organization's food safety policy.	<input type="checkbox"/>	<input type="checkbox"/>
17 Decisions and actions on the organization's FSMS.	<input type="checkbox"/>	<input type="checkbox"/>

	Yes	No
18 Decisions, actions and any revisions of food safety objectives.	<input type="checkbox"/>	<input type="checkbox"/>
19 Decisions and actions on resource needs including skills and training.	<input type="checkbox"/>	<input type="checkbox"/>
20 Decisions on improving the effectiveness of the FSMS.	<input type="checkbox"/>	<input type="checkbox"/>

5.9 Improvement

It is a requirement of the standard that top management ensure that the system continually improves. It is likely that this improvement will be in a series of steps that may involve both small and large changes within the business, for example the purchase of new equipment, improved training, etc. The aim is to improve the effectiveness of the FSMS through:

- communication;
- management review;
- internal audit;
- evaluation of verification results;
- analysis of results of verification activities;
- validation of control measure combinations;
- corrective actions.

It is important that the FSMS continues to grow and develop to reflect changes in the organization and its operating environment. The members of the food safety team play an important part in this improvement process, which is an ongoing process of collection and assessment of data and information providing a current evaluation of performance and trends. The evaluation process focuses on outputs and inputs from various information sources including:

- internal and external communication;
- other information arising from day-to-day activities and observations;
- verification activities;
- management review.

It is essential to recognize that before implementing any changes to an existing, stable system the full implications and consequences should be considered carefully for impacts upon the present arrangements.

When completed, the update activities should be recorded and reported as input to subsequent management reviews.

The final point above refers to the management review requirement that the FSMS should be continually updated. In order to achieve this there is a need to evaluate the system and its effectiveness at planned intervals. The food safety team should review all aspects of the system and consider whether it is necessary to revise any specific part. In particular they should review the hazard analysis, established operational PRPs and the HACCP plan.

Section 2

Self-assessment of your organization's system for food safety

6

How to use the self-assessment questionnaire

What follows is a series of questions covering the various aspects of food safety management in your organization. Each of the questions is answered by two statements (1) and (4), which describe two extreme positions. Numbers (2) and (3) should be ticked if your organization occupies the 'middle ground', nearer to (1) or to (4). Tick one number for each question. As you progress through this workbook there are a variety of checklists you may have completed. These checklists will help you assess your score in this self-assessment section. Once you have answered each question, add your score to the box on page 61, total the score, then see how your organization rates, using the performance rating system on page 62.

7

Self-assessment questionnaire

a. Management commitment

Does your organization recognize food safety management as an integral part of business performance by allocating responsibility at the most senior level for ensuring continual improvement in food safety performance?

1. There is no clear management responsibility.
4. We have defined and documented responsibility and authority for food safety management. Ultimate responsibility is allocated to a manager at the most senior level but all managers and staff are actively involved and encouraged in the continual improvement of food safety performance.

a.	1	2	3	4
----	---	---	---	---

b. Food safety team leader

Does your organization have a food safety team leader?

1. We have not appointed a food safety team leader.
4. We have appointed a food safety team leader who meets the requirements of ISO 22000 and ensured that their training needs have been fully met. A food safety team has also been appointed.

b.	1	2	3	4
----	---	---	---	---

c. Food safety team

Does your organization have a food safety team?

1. We have not appointed a food safety team.
4. We have appointed a food safety team that meets the requirements of ISO 22000 and ensured that their training needs have been fully met to reflect the food safety operations that exist within the organization.

c.	1	2	3	4
----	---	---	---	---

d. Identification and definition of processes

Has your organization identified all its processes, mapped and defined them?

- 1. We have not identified all the processes or mapped and defined them.
- 4. We have identified all the processes from start to finish. These have been mapped and all the inputs and outputs defined.

d.	1	2	3	4
-----------	----------	----------	----------	----------

e. Food safety policy

Does your organization define and document its food safety policy?

- 1. We do not have a food safety policy.
- 4. We have a comprehensive and documented policy that clearly defines the organization's commitment to food safety. It is communicated to employees and other relevant, interested parties. It expresses a clear commitment by top management to continual improvement of food safety performance and meets the requirements of 5.2 of ISO 22000.

e.	1	2	3	4
-----------	----------	----------	----------	----------

f. Resources

Does your organization provide adequate resources for food safety management?

- 1. We do not allocate any resources.
- 4. We allocate resources and make budget provisions to ensure continual improvement in food safety performance.

f.	1	2	3	4
-----------	----------	----------	----------	----------

g. Product specifications

Does your organization have a specification for each of its products?

- 1. We do not have specification for any of our products.
- 4. We have full specification for all of our products and variants and review them regularly.

g.	1	2	3	4
-----------	----------	----------	----------	----------

h. Prerequisite programmes

Does your organization have operational PRPs?

- 1. We do not have any operational PRPs.
- 4. We have fully implemented operational PRPs that are routinely monitored and audited at regular intervals.

h.	1	2	3	4
-----------	----------	----------	----------	----------

i. Hazard analysis

Has the organization carried out comprehensive hazard analysis?

- 1. We have not carried out any hazard analysis programme.
- 4. Our hazard analysis programme is comprehensive and covers all activities in the food catering operations.

i.	1	2	3	4
-----------	----------	----------	----------	----------

j. Risk assessment

Does your organization carry out food safety risk assessments?

- 1. We do not carry out food safety risk assessments.
- 4. Our FSMS includes a thorough risk assessment programme covering all activities and processes undertaken by the organization.

j.	1	2	3	4
-----------	----------	----------	----------	----------

k. Legal and other requirements

Does your organization identify all legal and other requirements that apply to it?

- 1. We have little knowledge about legislation that might apply to our activities.
- 4. We operate procedures and implement controls to ensure regulatory compliance and meet the customer requirements and all voluntary programmes, etc. that the organization subscribes to.

k.	1	2	3	4
-----------	----------	----------	----------	----------

l. Best practice

Does your organization identify and embrace any codes of practice and/or other guidance relevant to its activities?

- 1. We have no knowledge about codes of practice or other guidance that may be relevant to our activities.
- 4. We have embraced within our procedures what we consider to be the best practice on the basis of relevant industry guidance.

l.	1	2	3	4
-----------	----------	----------	----------	----------

m. Objectives

Does your organization set objectives to ensure continual improvement of food safety performance?

- 1. We never set objectives.
- 4. We set and publish objectives consistent with our policy to ensure continual improvement of food safety performance, and these are regularly reviewed.

m.	1	2	3	4
-----------	----------	----------	----------	----------

n. Employee responsibility

Does the organization assign food safety responsibility to its employees?

- 1. We do not assign any food safety responsibility to our employees.
- 4. Every employee is aware of their responsibility for the food safety of those they manage, themselves, others with whom they work and anyone else who visits the site.

n.	1	2	3	4
----	---	---	---	---

o. Training

Does your organization carry out training to increase the awareness and knowledge of employees about food safety issues?

- 1. We do not carry out any food safety training.
- 4. We have a continual staff training programme to ensure employees are aware of current food safety issues and legal requirements. Staff are competent for the tasks they have to undertake and understand their individual responsibilities.

o.	1	2	3	4
----	---	---	---	---

p. Internal communications

Does your organization provide information about food safety matters to employees?

- 1. We do not provide employees with information on any food safety issue.
- 4. We have an established communication system to keep employees informed about food safety issues, including policy, objectives, performance, remedial actions and future plans.

p.	1	2	3	4
----	---	---	---	---

q. External communications

Does your organization provide information about food safety matters to relevant interested parties, i.e. customers, etc.?

- 1. We do not disclose information.
- 4. We have established procedures to inform all relevant interested parties about the organization's food safety-related matters.

q.	1	2	3	4
----	---	---	---	---

r. Traceability

Does your organization have a comprehensive documented system for traceability of its products?

- 1. We don't know what happens to our stuff after we've loaded it on the lorry, and don't care!
- 4. We have a comprehensive traceability system that embraces incoming supplies, food preparation processes and the output of products.

r.	1	2	3	4
----	---	---	---	---

s. Documentation

Does your organization have a documented system for gathering and communicating relevant food safety information?

- 1. We do not have a system.
- 4. We maintain a comprehensive system, appropriate to the organization, including a food safety management manual and supporting records.

s.	1	2	3	4
-----------	----------	----------	----------	----------

t. Operational control measures and CCPs

Does your organization embrace food safety issues in its operational control system?

- 1. We focus exclusively on ‘business’ issues, e.g. products, processes or services, and have no CCPs identified.
- 4. We have operational control measures in place for all identified hazards with CCPs determined and fully implemented.

t.	1	2	3	4
-----------	----------	----------	----------	----------

u. Emergency preparedness and response

Does your organization have a procedure(s) for responding to emergency situations that might endanger food safety?

- 1. We do not have any procedures for responding to emergency situations.
- 4. We have an emergency response plan that is tested to adequately respond to food safety incidents and communicate them accordingly. Employees are aware of their role and responsibilities in implementing the plan.

u.	1	2	3	4
-----------	----------	----------	----------	----------

v. Internal audits

Does your organization carry out food safety audits?

- 1. We do not carry out audits.
- 4. We have a programme of regular audits undertaken by at least one auditor who is both competent and independent. Remedial action is initiated where deficiencies are found.

v.	1	2	3	4
-----------	----------	----------	----------	----------

w. Management review

Does your organization carry out management reviews of its food safety activities?

- 1. We do not carry out management reviews of food safety activities.
- 4. We undertake comprehensive regular reviews using a designated senior manager to ensure the efficiency and effectiveness of our FSMS.

w.	1	2	3	4
-----------	----------	----------	----------	----------

8

Assessment of performance

Topic	Score
a. Management commitment	<input type="text"/>
b. Food safety team leader	<input type="text"/>
c. Food safety team	<input type="text"/>
d. Identification and definition of processes	<input type="text"/>
e. Food safety policy	<input type="text"/>
f. Resources	<input type="text"/>
g. Product specifications	<input type="text"/>
h. Prerequisite programmes	<input type="text"/>
i. Hazard analysis	<input type="text"/>
j. Risk assessment	<input type="text"/>
k. Legal and other requirements	<input type="text"/>
l. Best practice	<input type="text"/>
m. Objectives	<input type="text"/>
n. Employee responsibility	<input type="text"/>
o. Training	<input type="text"/>
p. Internal communications	<input type="text"/>
q. External communications	<input type="text"/>
r. Traceability	<input type="text"/>
s. Documentation	<input type="text"/>
t. Operational control measures and CCPs	<input type="text"/>
u. Emergency preparedness and response	<input type="text"/>
v. Internal audits	<input type="text"/>
w. Management review	<input type="text"/>

9

Overall performance

Performance rating

Score

- 23 Your organization has little commitment at present to food safety. You are likely to be in breach of current UK legislation and open to prosecution.
- 24–69 A level of food safety management exists but full commitment by the organization is not evident.
- 70–92 Provided you score not less than 3 in any area, your organization has a comprehensive FSMS in place. This should not invite complacency, and continuous management and development of the system should always be the number one aim of your organization.

In order to assess performance at the start of an implementation programme and as you progress blank assessment charts are provided below.

Day 1

4																									
3																									
2																									
1																									
	a	b	c	d	e	f	g	h	i	j	k	l	m	n	o	p	q	r	s	t	u	v	w		

Day X

4																								
3																								
2																								
1																								
	a	b	c	d	e	f	g	h	i	j	k	l	m	n	o	p	q	r	s	t	u	v	w	

Section 3

Useful forms and pro formas

10

Example monitoring forms

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Stage	Week													
	1	2	3	4	5	6	7	8	9	10	11	12	13	14
1 Select team leader	█													
2 Scope and plan the project	█	█												
3 Select HACCP team		█												
4 Train HACCP team			█											
5 Develop/define product definitions and intended use			█	█										
6 HACCP team construct and check process flow charts			█	█	█									
7 Undertake hazard analysis			█	█	█	█								
8 Complete risk assessment					█	█								
9 Decide on critical control points (CCPs)							█	█	█					
10 Determine critical limits and corrective actions and complete HACCP control charts							█	█	█	█				
11 Develop and establish monitoring sheets									█	█				
12 Complete HACCP plan										█	█			
13 Train auditors and key staff												█	█	
14 HACCP team conduct Validation of above steps														█

Figure 10.1 – HACCP implementation plan

Process step	Hazard	Control measure	CCP (Yes/no)	Reason (Decision tree/risk assessment?)

Issue: (Date) (Issue No.)

Record ref:

Figure 10.2 – Hazard analysis record

Process step	Hazard	Controls	Critical limits	Monitor/check	Corrective action	Responsibility

Issue: (Date) (Issue No.)

Chart ref:

Figure 10.3 – HACCP control chart

CHILL 5 °C to 8 °C
FROZEN -16 °C to -18 °C

WEEK ENDING:

Supplier	Product	Time	Temp	Sign	Comments/Action	Vehicle check & Temp

Issue: (Date) (Issue No.)

Authorized by:

Figure 10.4 – Delivery checks

Device Type:
Target/Limit:
Corrective Action:

Location:
Frequency:

Date	Time	Temp	Comments	Corrective Actions (if required)	Signature

Issue: (date) (issue no.)

Ref.:

Figure 10.5 – Temperature control logsheet

Refrigerator 5 °C to 8 °C
Freezers -18 °C

DATE:

Appliance details	FIRST CHECK			SECOND CHECK		
	Time	Temp	Sign	Time	Temp	Sign
Fridge 1						
Fridge 2						
Fridge 3						
Fridge 4						
Freezer 1						
Freezer 2						
Freezer 3						
Freezer 4						
Blast Chiller						
Hot Cupboard 1						
Hot Cupboard 2						
Dishwasher						
Rinse Cycle						

Issue: (Date) (Issue No.)

Authorized by:

Figure 10.6 – Equipment temperature monitoring form (1)

APPLIANCE: _____
Refrigerator 5 °C to 8 °C
Freezers -18 °C

WEEK ENDING:

Appliance details	FIRST CHECK				SECOND CHECK		
	Time	Temp	Sign	Time	Temp	Sign	

Issue: (Date) (Issue No.)

Authorized by:

Figure 10.7 – Equipment temperature monitoring form (2)

**CHILL TO 3 °C WITHIN 90 MINUTES
FREEZE TO -5 °C WITHIN 90 MINUTES**

DATE:

PRODUCT	COOKING		BLAST CHILLERS/BLAST FREEZER			REHEAT TEMPERATURE		
	Time	Temp	Start	End	Temp	Time	Temp	Sign

Issue: (Date) (Issue No.) _____ Authorized by: _____

Figure 10.8 – Blast chill/freeze monitoring form

COOL TO 10 °C + 15 °C WITHIN 90 MINUTES AND REFRIGERATE

DATE:

PRODUCT	COOKING		COOLING PERIOD 90 MINUTES			REHEAT TEMPERATURE		
	Time	Temp	Start	End	Temp	Time	Temp	Sign

Issue: (Date) (Issue No.)

Authorized by:

Figure 10.9 – Retained food (without the aid of a blast chiller)

Cook 75 °C and above
Hold at 64 °C and above

Unit: _____

Shift: _____

Date: _____

Dish	Cooking			Service			Service			Samples Yes/No	Check Sign
	Time	Temp	Sign	Time	Temp	Sign	Time	Temp	Sign		

Issue: (Date) (Issue No.)

Authorized by:

Figure 10.10 – Temperature monitoring form (1)

Cook 75 °C and above
 Hold at 64 °C and above

Unit: _____ Shift: _____ W/E: _____

Date	Dish	Cooking			Service			Service			Samples Yes/No	Check Sign
		Time	Temp	Sign	Time	Temp	Sign	Time	Temp	Sign		

Issue: (Date) (Issue No.) _____ Authorized by: _____

Figure 10.11 – Temperature monitoring form (2)

Company			
Unit Name		Unit No	
Unit Address			
Unit Tel Number			
Manager		Area Manager	

DETAILS OF CONSUMER(S)

Number of persons with symptoms	
Name(s) of consumer(s)	1
	2

ILLNESS DETAILS

First report of illness	Date	Time	To whom
Symptoms of illness (delete if N/A)	Diarrhoea	Vomiting	Nausea
	Abdominal Pain	Headache	
Symptoms started	Date	Time	
Duration of Symptoms			

DETAILS OF SUSPECTED FOOD MADE ON SITE

Food suspected		Number of portions served	
Date and time produced		Date and time consumed	
Food samples available	Yes or No	Are any of the food handlers ill?	
Number of portions served		Temperature Records available	Yes or No

DETAILS OF SUSPECTED FOOD BOUGHT IN

Name and Address of Supplier			
Telephone Number			
Time and date of delivery		Packing date mark or code	
Has the Supplier been informed?	YES	NO	
If yes, give Date		Person	
Temperature records available	YES or NO		
Has the Supplier sent temperature records?			

ENVIRONMENTAL HEALTH OFFICER INVOLVEMENT

EHO involved	Yes or No
Name of EHO	Tel No
Local Authority	

RESULTS

Results of Investigation			
Manager's Signature		Date	

Issue: (Date) (Issue No.)

Authorized by:

Figure 10.12 – Alleged/suspected food poisoning incident form

ALLEGED FOOD POISONING – Multiple Numbers DETAILS OF CONSUMERS

Name	Address	Symptoms	Duration of symptoms	Time and date started	Food consumed within 48 hours

Issue: (Date) (Issue No.)

Authorized by:

Figure 10.13 – Multiple food poisoning

Company			
Unit Name			
Unit Address			
Unit Telephone Number			
Manager			
Description of Complaint/Foreign Body			
Food Involved			

Complete Part A in all instances

PART A

CUSTOMER DETAILS	
Name and address of customer	_____
Was the contaminated food returned?	YES _____ NO _____
Where is the food now?	_____
Date of Discussion _____	Who spoke to the customer? _____
Has the Customer suffered any injury/damage?	YES _____ NO _____
If yes, give details _____	
Has the customer informed the Environmental Health Officer/Trading Standards Officer? _____	

PART B

BOUGHT-IN PRODUCT	
Name and Address of Supplier	_____
Telephone Number	_____
Time and date of delivery _____	Packing date mark or code _____
Has the Supplier been informed?	YES _____ NO _____
If yes, give Date _____	Person _____
Has the body/product been returned to or collected by the supplier?	YES _____ NO _____

PART C

UNIT MADE PRODUCT		
Time and date of product	_____	
Ingredients	Supplier	Product Code
_____	_____	_____
_____	_____	_____
Where is the product now?	_____	

RESOURCES INFORMATION

Results of Investigation	

Manager signature	Date
_____	_____

Issue: (Date) (Issue No.)

Authorized by:

Figure 10.14 – Food complaint form (contaminated food)

Confidential Pre-employment Health Questionnaire

Post Applied for:

Surname: Forename(s): Date of Birth:
(Dr/Mr/Mrs/Miss/Ms) (Day) (Month) (Year)

Address: Telephone number:

Present Post: For How Long:

Name/Address of General Practitioner:

Have you suffered from any of the following? Please provide details, continuing if necessary, on a separate sheet

	YES	NO
1. Any skin disease(s)	<input type="checkbox"/>	<input type="checkbox"/>
2. Discharge or infection of the ears or hearing defect	<input type="checkbox"/>	<input type="checkbox"/>
3. Asthma or hay fever of sufficient severity to require time off work (or school)	<input type="checkbox"/>	<input type="checkbox"/>
4. Any allergies (including sensitivity to antibiotics or other drugs)	<input type="checkbox"/>	<input type="checkbox"/>
5. Recurrent sore throats or sinusitis	<input type="checkbox"/>	<input type="checkbox"/>
6. Bronchitis or pneumonia	<input type="checkbox"/>	<input type="checkbox"/>
7. Tuberculosis	<input type="checkbox"/>	<input type="checkbox"/>
8. Heart disease	<input type="checkbox"/>	<input type="checkbox"/>
9. Headache or migraine requiring time off work (or school)	<input type="checkbox"/>	<input type="checkbox"/>
10. Fits, blackouts or epilepsy	<input type="checkbox"/>	<input type="checkbox"/>
11. Depression, nervous breakdown or mental illness; psychiatric treatment, including anorexia	<input type="checkbox"/>	<input type="checkbox"/>
12. Backache or sciatica requiring time off work (or school)	<input type="checkbox"/>	<input type="checkbox"/>
13. Rupture, varicose veins or foot ailments	<input type="checkbox"/>	<input type="checkbox"/>
14. Indigestion or stomach pains requiring time off work (or school)	<input type="checkbox"/>	<input type="checkbox"/>
15. Kidney or bladder infection	<input type="checkbox"/>	<input type="checkbox"/>
16. Eye disease, injury or significant defect of vision not corrected by spectacles	<input type="checkbox"/>	<input type="checkbox"/>
17. Diabetes	<input type="checkbox"/>	<input type="checkbox"/>
18. Serious injury or operation	<input type="checkbox"/>	<input type="checkbox"/>

Have you ever been admitted to hospital? If so provide details below

19. Do you suffer from any disability not included in the above?	<input type="checkbox"/>	<input type="checkbox"/>
20. Roughly how many days have you had off work or school from illness over the past two years	Days	
	<input style="width: 50px;" type="text"/>	

21. Are you regularly receiving injections, pills, tablets or medicines from a doctor (other than contraceptives)? Please give details

22. What is your height?	<input style="width: 50px;" type="text"/>
23. What is your weight?	<input style="width: 50px;" type="text"/>
24. Number of days sick in previous 12 months	<input style="width: 50px;" type="text"/>

Any further details in respect of the above questions:

I understand and acknowledge that should I knowingly make a false statement regarding my medical history either in answering the above questions or to any medical examiner, or should I wilfully conceal any material fact, I will, if engaged, be liable to have my contract terminated. In the event of any health queries, I consent to my General Practitioner supplying relevant information to the professional Medical Advisor.

Signed: _____ Date: _____

Figure 10.15 – Health questionnaire

**PRE-EMPLOYMENT QUESTIONNAIRE
FOR AGENCY & CASUAL CATERING STAFF**

Surname:	Forenames:	
Address	Date of Birth:	Telephone:
Name and Address of your own General Practitioner:		

Have you ever had any of the following?		If YES	
		How long off work?	Name of Dr and Hospital
Typhoid, Paratyphoid or Enteric fever	Yes/No		
Dysentery	Yes/No		
Food poisoning	Yes/No		
Persistent diarrhoea or infection of the bowels	Yes/No		
Tuberculosis	Yes/No		
Tropical disease, e.g. Hookworm, Bilharzia, etc.	Yes/No		
Have you suffered from any of the following within the last two years?			
Chronic bronchitis with spit	Yes/No		
Diarrhoea and/or vomiting for more than 2 days	Yes/No		
Skin rash or any skin disease	Yes/No		
Recurrent boils/septic fingers	Yes/No		
Discharge from:			
Ear	Yes/No		
Eye	Yes/No		
Nose	Yes/No		
Have you ever lived or been abroad in the last 10 years?		Yes/No	
If yes, where and when			
I declare that all of the above statements are true and completed to the best of my knowledge and belief			
Signed:		Date:	

Figure 10.16 – Medical screening (pre-employment questionnaire)

To be completed at commencement of employment
Duplicate copy to be retained by the employee

1. I will report to my Manager or Supervisor as soon as possible, and make myself available for medical examination, if required, should I suffer any illness involving:
 - a vomiting
 - b diarrhoea
 - c septic skin lesions (boils, infected cuts, etc. however small)
 - d discharge from ear, nose or any other site
2. After returning, and before commencing work, following an illness or any of the above conditions.
3. If any member of my household is suffering from diarrhoea and/or vomiting.
4. After returning from a holiday during which I suffered an attack of vomiting and/or diarrhoea.
5. After returning from a holiday during which any member of my party had an attack of vomiting and/or diarrhoea.

I declare that all of the above statements are true and completed to the best of my knowledge and belief	
Signed:	Date:

Figure 10.17 – Agreement to report infections

RETURN TO WORK QUESTIONNAIRE

This form is to be completed by all catering staff on return to work after absence due to illness, injury or holidays abroad, under the supervision of the manager.	
Name of Employee	
Address	
Absent from	
Absent to	
Reason for absence – sickness/holiday	
Holidays only – Countries Visited	
Since you have been away, have you suffered from sickness, diarrhoea or any stomach disorder in the last 48 hrs?	Yes/No
Have you had any 'flu-like' symptoms in the last 48 hrs?	Yes/No
Have you been in contact with anyone with Typhoid, Paratyphoid, Cholera, Dysentery, Salmonella infections?	Yes/No
Are you suffering from any infectious conditions of the skin, nose, throat, eyes or ears in the last 48 hrs?	Yes/No
Have you suffered from any of these conditions since you have been away?	Yes/No
Signature of Employee	
Job Title:	Date
Signature of Supervisor/Manager	Date
If the answer to any of these questions is yes, the person must not be allowed to return to work until medical clearance has been given by a qualified doctor and the results from a stool test.	

Figure 10.18 – Medical screening (return to work questionnaire)

DATE:

Item	Person responsible	Product & Dosage Date	Signature	Safety Information	Method

Issue: (Date) (Issue No.) Authorized by:

Figure 10.19 – Daily cleaning schedule

W/E:

Item	Person responsible	Day	Product & Dosage Date	Signature	Safety Information	Method

Authorized by:

Issue: (Date) (Issue No.)

Figure 10.20 – Weekly cleaning schedule

DATE:

Item	Person responsible	Frequency	Product & Dosage Date	Signature	Safety Information	Method

Issue: (Date) (Issue No.)

Authorized by:

Figure 10.21 – Cleaning schedule (general)

DATE:

Item	Person responsible	Frequency	Product & Dosage Date	Sig.	Safety Information	Method
Floors		Daily				Sweep up debris. Apply hot solution using clean mop or long handle scrubber; paying attention to floor/wall joint around equipment and under rear of equipment. Rinse and mop over with fresh clean water. Allow to dry.
Walls, doors and paint work		Monthly				Apply solution with sponge, cloth or hand sprayer. Work down from higher areas. Rinse with clean water. Allow to air dry.
Work surfaces		After use				Remove debris. Apply solution with a cloth or hand sprayer, or apply powder directly on to the dampened surface and spread over with a damp cloth. Ensure that attention is given to legs and under edges. Rinse and allow to air dry or dry with paper towels.
Cutting boards		After use				Remove debris. Sprinkle sanitizer powder or apply sanitizer solution on to moistened board and scrub. Wipe surface and rinse. Allow to air dry. Can be routinely washed in dishwasher if suitable, but additional weekly clean with sanitizer solution to reduce surface staining. Cutting boards should be stacked vertically with cutting surfaces separated after cleaning and sanitizing.
Refrigerators		Daily Weekly				Check and organize fridges daily. Check for spillages and wipe up (spillages should be wiped up immediately). Clean door seals, shelves and all internal surfaces.
Blast chillers		Weekly				Transfer foods to cool place. Remove shelving and wash in solution. Wipe interior with solution. Pay particular attention to base section. Wipe seals and door handles. Rinse with clean water. Replace shelving and foods.
Deep freezers		Daily				Check and organize freezers daily. Wipe down external surfaces and door seals. [Wipe up spillages immediately. Do not allow to freeze.]

Issue: (Date) (Issue No.)

Authorized by:

Figure 10.22 – Generic cleaning record (1)

DATE:

Item	Person responsible	Frequency	Product & Dosage Date	Sig.	Safety Information	Method
Deep freezers		Monthly				Remove contents and store in fridge or alternative freezer. Turn off power and leave lid or door open (follow manufacturer's instructions if appliance is provided with a defrost facility). Remove shelves and baskets if fitted and clean with solution. When the ice comes off the shelves easily, scrape away with a plastic implement. Remove ice and other debris. Wipe surfaces with a warm damp cloth. Replace shelves and baskets. Turn appliance back on to normal operation. Replace food when temperature has reduced to proper level.
Can opener		Daily				Remove from bench mounting. Soak in hot general purpose detergent solution. Scrub cutter blade and assembly with a brush. Check for uneven blade wear or loose blade mount and report to supervisor where necessary. Scrub the base plate mount at the table. Rinse and air dry.
Slicer		After use				Zero the slice thickness plate. Remove detachable parts. Blade must only be removed with the use of the specific blade removing tools. Soak and wash in sanitizer solution. Carefully brush or sponge all pans. Clean the blade separately. Rinse, air dry and reassemble. Clean the slicer casing with damp cloth and sanitizer solution. Clean the work surface under the slice and adjacent walls likely to be soiled. Do not reconnect power supply until required for use. N.B. Refer to manufacturer's instructions accompanying the slicer for detailed cleaning information specific to the slicer model.
Mixer		After use				Remove beater, extension ring and mixing bowl and transfer to pan wash. Scrub or wipe down mixer thoroughly using sanitizer solution. Rinse and air dry. Clean underneath and adjacent walls likely to be soiled. Do not reconnect power supply until required for use.
Food processor		After use				Detach removable pans, soak and wash in sanitizer solution. Wash casing. Rinse and air dry. Stack cutting blades in the storage rack provided with the appliance after cleaning and sanitizing. Clean work table and adjacent walls where likely to be soiled. Do not reconnect power supply until required for use.

Issue: (Date) (Issue No.)

Authorized by:

Figure 10.23 – Generic cleaning record (2)

DATE:

Item	Person responsible	Frequency	Product & Dosage Date	Sig.	Safety Information	Method
Potato peeler		After use				Detach removable parts, soak and wash in sanitizer solution. Wash casing. Rinse and air dry. Stack cutting blades in the storage rack provided with the appliance after cleaning and sanitizing. Clean work table and adjacent walls where likely to be soiled. Do not reconnect power supply until required for use.
Potato chipper		After use				Detach removable parts, soak and wash in sanitizer solution. Scrub cutting blades and hopper attachment using hard brush. Wipe down exterior casing. Rinse thoroughly, allow to air dry and reassemble. Clean underneath and adjacent walls where likely to be soiled. Do not re-connect power supply until required for use.
Fryer		After use				Switch off appliance and allow oil to cool. Remove food particles with fine wire mesh web. Wipe outside of fryer to remove spilt oil. Wash frying buckets in general purpose detergent. Dry and replace. Top up oil to required level if necessary.
						Switch off appliance and allow oil to cool. Drain and strain oil into a receptacle. Fill fryer with warm water to level required. Add cleaning chemical powder and stir well to dissolve. Boil for 15 to 20 minutes. Submerge all baskets and utensils in solution, soak for 5 to 10 minutes. Remove carbonized deposits from top of fryer with a stiff brush. Drain and rinse thoroughly, allow to air dry. Refill with strained oil and top up level. Clean outer casing, lid and surround to drain tap. Replace lid in position.
Ovens and grills		Weekly				Ensure appliances are switched off. Spray neat on to warm surfaces and allow contact time of 5 to 20 minutes. Thoroughly cover all surfaces to be cleaned, starting from the top and working downwards. Rinse off with water and allow to air dry. For stubborn soilage, repeat application and use scouring pad or brush.
		As required				Remove detachable parts of oven tops and soak in hot detergent solution.

Issue: (Date) (Issue No.)

Authorized by:

Figure 10.24 – Generic cleaning record (3)

DATE:

Item	Person responsible	Frequency	Product & Dosage Date	Sig.	Safety Information	Method
Combi-oven/ Steamer		After use				Switch off equipment. Turn off water supply. Remove trays and shelving for cleaning in pan wash. Scrub all surfaces with solution. Rinse and air dry. Leave door slightly ajar to ventilate.
		Period				To descale: brush surfaces with descaling solution, rinse with warm water and allow to air dry.
Tea/Coffee boiling urns		After use				Ensure appliance is switched off. Fill with solution and leave to soak for 10 to 15 minutes. Scrub out and drain. Rinse thoroughly and allow to air dry.
		After use				Switch off power supply and allow to cool. Remove containers and transfer to pan wash. Where a water bath is incorporated, drain to waste and clean out the bath. Wash down all surfaces and rinse. Remove deposits from door runners with a stiff brush. Brush floor under appliance and clean up spillages.
Bain Marie and hot cupboards		Weekly				Dismantle the shelves and doors if detachable. Scrub all parts with solution, rinse and air dry. Reassemble.
						To descale: brush surfaces with descaling solution, rinse with warm water and allow to air dry.
Display cabinet		Daily				Remove all unsold items. Carefully remove doors and take out detachable shelving. Remove all food particles. Brush out solution, rinse and air dry. Replace doors and shelving but leave doors open to assist in air drying, until next use.
		Daily				Remove turntable plate (if applicable) and wash in solution. Wash out interior, paying particular attention to the top surface and to the corner joins. Wipe down exterior casing and door. Rinse and allow to air dry. Leave door slightly ajar until next use.
Sinks and wash hand basins		Daily				Clean with the general-purpose detergent. Remove tide marks from the bowl and drainer with a scouring pad or cloth. Include taps, waste outlets and splashbacks in cleaning programme. Rinse thoroughly with cold water. Ensure sufficient supply of towels, soap and a clean nail-brush are maintained at the wash hand basin.

Issue: (Date) (Issue No.)

Authorized by:

Figure 10.25 – Generic cleaning record (4)

DATE:

Item	Person responsible	Frequency	Product & Dosage Date	Sig.	Safety Information	Method
Waste disposal unit		Daily				Disconnect the baffle plate (restrictor plate) and remove if possible. Remove strainer if fitted and clean in solution. Remove solid waste from machine and scrub all parts with solution. Do not access the blades. Clean exterior casing and adjacent wall surfaces. Reassemble, reconnect power supply and operate water supply only, for one minute. Switch off and isolate from power supply until next required for use.
Waste bins		Daily				Empty bins frequently throughout the day. Do not allow contents to overflow. Wash out empty bin or bin liner holder with solution. Clean external casing and the elide, paying attention to underside of lid and the handle (if fitted). Rinse and allow to dry.
Equipment racks and shelving		Weekly				Remove stock and utensils/equipment from shelves and racking. Sweep debris off surfaces and sweep floor under. Clean with solution, rinse and allow to air dry. Replace stock and utensils/equipment. Ensure equipment is placed inverted as far as practicable.
Dining room table and chairs		Daily Weekly (chair legs)				Apply with sponge, cloth or hand sprayer. Wipe down tabletops, edges, under edges, seats and chair-lets. Check that cruets, condiments and sauce bottles are clean and well stocked.
Vending machines						Follow clean instructions as per manufacturer's cleaning schedule posted inside the vending machine, or in accordance with manufacturer's cleaning manual. Complete the cleaning record card.

Issue: (Date) (Issue No.)

Authorized by:

Figure 10.2.6 – Generic cleaning record (5)

Name				
Job title				
Department				
Employment start date				
Training programme	Date	Details/comments	Employee initials	Mgmt initials

Issue: (Date) (Issue No.)

Authorized by:

Figure 10.27 – Employee training record

11

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12

Validation and verification checklists

The following validation and verification checklists are provided to support internal audit procedures.

12.1 HACCP validation audit checklist

HACCP principle	Audit checklist
<p>Preparation</p>	<p>What evidence is there of management commitment to HACCP?</p> <p><i>HACCP team</i></p> <ul style="list-style-type: none"> • Who is on the team? • Are all appropriate disciplines represented? • What is the knowledge level of the team members? (Evidence of training, experience, etc.) • Has external expertise been sought where necessary? • What is the decision-making leverage of the HACCP team leader? <p><i>HACCP system</i></p> <ul style="list-style-type: none"> • How does the system fit with the overall food safety control programme? • Does the company have a food safety policy? • Has the scope been clearly defined? • How is the system structured?
<p>Principle 1</p> <p>'conduct a hazard analysis'</p>	<p>Has the product been properly described?</p> <ul style="list-style-type: none"> • Are intrinsic control measures identified? <p>Is the process flow diagram comprehensive?</p> <ul style="list-style-type: none"> • How was the process flow diagram validated for accuracy and by whom? • Are all raw materials and process/storage activities included in the flow diagram? (Rework can be included as an ingredient.) • Have all activities been included? • Is the process flow diagram correct? • Have changes been made since the process flow diagram was drawn up? • How does the HACCP team get notified of changes to the process or product parameters? • How were the changes recorded and approved? • Were any changes discussed with the HACCP team before implementation? • Are there rework opportunities and have they been included?

	<p>How was the hazard analysis conducted?</p> <ul style="list-style-type: none"> • Were only significant hazards identified? • Have all raw materials (including rework) been included? • Have all process steps been considered? • Have the hazards been specifically identified by type/source or have they been generalized? • How did the team assess likelihood of occurrence? • What information sources were utilized? <p>Have appropriate control measures been identified for each hazard?</p> <ul style="list-style-type: none"> • Will the control measures control the hazards and how was this validated? • Are all of the control measures in place and actually being operated?
<p>Principle 2</p> <p><i>‘determine the critical control points (CCPs)’</i></p>	<p>How were the CCPs identified?</p> <ul style="list-style-type: none"> • By expert judgement? • By the use of a decision tree? (Has the decision tree been used correctly?) • By the use of consultants? • Have all necessary CCPs been identified? <p>Did each identified hazard undergo a systematic consideration?</p> <p>How are hazards not controlled by CCPs addressed?</p>
<p>Principle 3</p> <p><i>‘establish critical limits’</i></p>	<p>How were the critical limits established?</p> <ul style="list-style-type: none"> • Is there evidence (experimental data, literature, references, etc.)? • What validation exists to confirm that the critical limits control the identified hazards? • Have critical limits been established for every CCP? • How do they differ from operational limits?
<p>Principle 4</p> <p><i>‘establish a system to monitor the control of the CCP’</i></p>	<p>Have realistic monitoring schedules been established?</p> <ul style="list-style-type: none"> • Do they cover all CCPs? • Has the reliability of monitoring procedures been assessed where appropriate? • What is the status of monitoring equipment? • Is it evidenced as being in place and calibrated appropriately? • Are the CCP log sheets being used at all CCPs? • Is there any evidence that procedures are not being followed consistently? • Check that records agree with stated activities. <p>Are monitoring personnel and their deputies properly identified and trained?</p> <ul style="list-style-type: none"> • How was the training undertaken? • Are the monitoring records being reviewed by designated appropriate reviewers?
<p>Principle 5</p> <p><i>‘establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control’</i></p>	<p>Have the corrective actions been properly defined such that control is regained?</p> <ul style="list-style-type: none"> • What evidence is there to demonstrate that this is being done in the event of a CCP deviation? • Has corrective action been recorded and how is effectiveness being verified? <p>How has the authority for corrective action been assigned?</p> <p>How is nonconforming product controlled and is this clearly recorded?</p>
<p>Principle 6</p> <p><i>‘establish procedures for verification to confirm that the HACCP system is working effectively’</i></p>	<p>Have verification procedures been clearly and appropriately established?</p> <ul style="list-style-type: none"> • How are these procedures communicated throughout the business? • Have responsibilities for verification procedures been allocated? • Are they being carried out effectively? • Are all CCPs covered by the verification programme? • Is the information on the HACCP control chart(s) up to date? • Is there a formal system to trigger amendments? • Are control parameters being achieved?

	<p>Have process capability studies been carried out?</p> <p>How is food safety data being used to improve the system?</p> <p>How is consumer complaint data being used within the verification system?</p> <p>Is there a regular review of CCP failure and scrapped product?</p> <p>Are prerequisite programmes included within the verification programme?</p>
<p>Principle 7</p> <p><i>‘establish documentation concerning all procedures and records appropriate to these principles and their application’</i></p>	<p>What format is being used to document the system?</p> <ul style="list-style-type: none"> • Does the documentation cover all of the HACCP system? • How is the documentation controlled with regard to update and issue, etc.? • Are the records accessible? • Are the HACCP records clearly identified by unique reference numbers? • Are all documents accurate and current? • Are verification procedures documented? • How is change control managed?

12.2 HACCP verification audit checklist

Document review

I. Documents provided for review		
Type of document	Reviewed (Y or N)	Comments/strengths/weaknesses noted
Prerequisite programmes (list them below)		
Menu or food preparation process		
Flow diagrams		
Equipment layout		
Training records		
HACCP plan and documents		
Other		

2. List critical control points (CCPs) and critical limits identified by the HACCP plan			
Food item or process step	Critical control point	Critical limits	Comments/problems noted

3. What monitoring records are required by the plan?

Type of record (PRP monitoring, corrective action, CCP monitoring, etc.)	Monitoring frequency and procedure (How often? Signed and dated? etc.)	Record location (where kept?)

4. Describe the strengths or weaknesses with the current monitoring or record-keeping regimen.

5. Who is responsible for verification that the required records are being completed and being properly maintained?

6. Describe the training that has been provided to support the system.

7. Describe examples of any documentation showing that the training was completed.

Record review and on-site inspection

(Choose at random one week from the previous four.)

8. Are monitoring actions performed according to the plan?	<input type="checkbox"/> Full compliance <input type="checkbox"/> Partial compliance <input type="checkbox"/> Non-compliance
9. When critical limits established by the plan are not met, are immediate corrective actions taken and recorded?	<input type="checkbox"/> Yes <input type="checkbox"/> No
10. Do the corrective actions taken reflect the same actions described in the plan?	<input type="checkbox"/> Yes <input type="checkbox"/> No
11. Are routine calibrations required and performed according to the plan?	<input type="checkbox"/> Yes <input type="checkbox"/> No
For the next two points, examine the current day's records, if possible.	
12. Are the records for the present day accurate for the observed situation?	<input type="checkbox"/> Yes <input type="checkbox"/> No
13. Do managers and employees demonstrate knowledge of the system?	
Managers:	<input type="checkbox"/> Yes <input type="checkbox"/> No
Employees:	<input type="checkbox"/> Yes <input type="checkbox"/> No
Additional considerations	
14. Have there been any changes to the product specification or process since the last verification?	<input type="checkbox"/> Yes <input type="checkbox"/> No
15. Was the control system modified because of these changes?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Additional comments or recommendations	

Section 4

ISO 22000:2005 extracts

13

ISO 22000:2005 extracts, including terms and definitions

To assist the users of this workbook, extracts from the terms and definitions and Clause 7 of ISO 22000:2005 are given below. The user should refer to the specific wording in Clause 7 when developing and implementing their system. A copy of the standard is needed for reference purposes within the organization to ensure all issues are addressed in line with the standard.

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000 and the following apply.

For the convenience of the users of this International Standard, some of the definitions in ISO 9000 are quoted with added notes that are applicable only to this special application.

NOTE Terms are not defined where they retain their normal dictionary definition. Where bold type is used in a definition, this indicates a cross-reference to another term defined in this clause, and the number reference for the term is given in parentheses.

3.1 food safety

concept that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use

NOTE 1 Adapted from Reference [11].

NOTE 2 Food safety is related to the occurrence of **food safety hazards** (3.3) and does not include other human health aspects related to, for example, malnutrition.

3.2 food chain

sequence of the stages and operations involved in the production, processing, distribution, storage and handling of a food and its ingredients, from primary production to consumption

NOTE 1 This includes the production of feed for food-producing animals and for animals intended for food production.

NOTE 2 The food chain also includes the production of materials intended to come into contact with food or raw materials.

3.3

food safety hazard

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

NOTE 1 Adapted from Reference [11].

NOTE 2 The term “hazard” is not to be confused with the term “risk” which, in the context of food safety, means a function of the probability of an adverse health effect (e.g. becoming diseased) and the severity of that effect (death, hospitalization, absence from work, etc.) when exposed to a specified hazard. Risk is defined in ISO/IEC Guide 51 as the combination of the probability of occurrence of harm and the severity of that harm.

NOTE 3 Food safety hazards include allergens.

NOTE 4 In the context of feed and feed ingredients, relevant food safety hazards are those that may be present in and/or on feed and feed ingredients and that may subsequently be transferred to food through animal consumption of feed and may thus have the potential to cause an adverse human health effect. In the context of operations other than those directly handling feed and food (e.g. producers of packaging materials, cleaning agents, etc.), relevant food safety hazards are those hazards that can be directly or indirectly transferred to food because of the intended use of the provided products and/or services and thus can have the potential to cause an adverse human health effect.

3.4

food safety policy

overall intentions and direction of an organization related to **food safety** (3.1) as formally expressed by top management

3.5

end product

product that will undergo no further processing or transformation by the organization

NOTE A product that undergoes further processing or transformation by another organization is an end product in the context of the first organization and a raw material or an ingredient in the context of the second organization.

3.6

flow diagram

schematic and systematic presentation of the sequence and interactions of steps

3.7

control measure

<food safety> action or activity that can be used to prevent or eliminate a **food safety hazard** (3.3) or reduce it to an acceptable level

NOTE Adapted from Reference [11].

3.8

PRP

prerequisite programme

<food safety> basic conditions and activities that are necessary to maintain a hygienic environment throughout the **food chain** (3.2) suitable for the production, handling and provision of safe **end products** (3.5) and safe food for human consumption

NOTE The PRPs needed depend on the segment of the food chain in which the organization operates and the type of organization (see Annex C). Examples of equivalent terms are: Good Agricultural Practice (GAP), Good Veterinarian Practice (GVP), Good Manufacturing Practice (GMP), Good Hygienic Practice (GHP), Good Production Practice (GPP), Good Distribution Practice (GDP) and Good Trading Practice (GTP).

3.9

operational PRP

operational prerequisite programme

PRP (3.8) identified by the hazard analysis as essential in order to control the likelihood of introducing **food safety hazards** (3.3) to and/or the contamination or proliferation of food safety hazards in the product(s) or in the processing environment

3.10

CCP

critical control point

<food safety> step at which control can be applied and is essential to prevent or eliminate a **food safety hazard** (3.3) or reduce it to an acceptable level

NOTE Adapted from Reference [11].

3.11

critical limit

criterion which separates acceptability from unacceptability

NOTE 1 Adapted from Reference [11].

NOTE 2 Critical limits are established to determine whether a **CCP** (3.10) remains in control. If a critical limit is exceeded or violated, the products affected are deemed to be potentially unsafe.

3.12

monitoring

conducting a planned sequence of observations or measurements to assess whether **control measures** (3.7) are operating as intended

3.13

correction

action to eliminate a detected nonconformity

[ISO 9000:2000, definition 3.6.6]

NOTE 1 For the purposes of this International Standard, a correction relates to the handling of potentially unsafe products, and can therefore be made in conjunction with a **corrective action** (3.14).

NOTE 2 A correction may be, for example, reprocessing, further processing, and/or elimination of the adverse consequences of the nonconformity (such as disposal for other use or specific labelling).

3.14

corrective action

action to eliminate the cause of a detected nonconformity or other undesirable situation

NOTE 1 There can be more than one cause for a nonconformity.

[ISO 9000:2000, definition 3.6.5]

NOTE 2 Corrective action includes cause analysis and is taken to prevent recurrence.

3.15

validation

<food safety> obtaining evidence that the **control measures** (3.7) managed by the HACCP plan and by the **operational PRPs** (3.9) are capable of being effective

NOTE This definition is based on Reference [11] and is more suitable for the field of **food safety** (3.1) than the definition given in ISO 9000.

3.16 verification

confirmation, through the provision of objective evidence, that specified requirements have been fulfilled [ISO 9000:2000, definition 3.8.4]

3.17 updating

immediate and/or planned activity to ensure application of the most recent information

7 Planning and realization of safe products

7.1 General

The organization shall plan and develop the processes needed for the realization of safe products.

The organization shall implement, operate and ensure the effectiveness of the planned activities and any changes to those activities. This includes PRP(s) as well as operational PRP(s) and/or the HACCP plan.

7.2 Prerequisite programmes (PRPs)

7.2.1 The organization shall establish, implement and maintain PRP(s) to assist in controlling

- a) the likelihood of introducing food safety hazards to the product through the work environment,
- b) biological, chemical and physical contamination of the product(s), including cross contamination between products, and
- c) food safety hazard levels in the product and product processing environment.

7.2.2 The PRP(s) shall

- a) be appropriate to the organizational needs with regard to food safety,
- b) be appropriate to the size and type of the operation and the nature of the products being manufactured and/or handled,
- c) be implemented across the entire production system, either as programmes applicable in general or as programmes applicable to a particular product or operational line, and
- d) be approved by the food safety team.

The organization shall identify statutory and regulatory requirements related to the above.

7.2.3 When selecting and/or establishing PRP(s), the organization shall consider and utilize appropriate information [e.g. statutory and regulatory requirements, customer requirements, recognized guidelines, Codex Alimentarius Commission (Codex) principles and codes of practices, national, international or sector standards].

NOTE Annex C gives a list of relevant Codex publications.

The organization shall consider the following when establishing these programmes:

- a) construction and lay-out of buildings and associated utilities;
- b) lay-out of premises, including workspace and employee facilities;
- c) supplies of air, water, energy and other utilities;

- d) supporting services, including waste and sewage disposal;
- e) the suitability of equipment and its accessibility for cleaning, maintenance and preventative maintenance;
- f) management of purchased materials (e.g. raw materials, ingredients, chemicals and packaging), supplies (e.g. water, air, steam and ice), disposals (e.g. waste and sewage) and handling of products (e.g. storage and transportation);
- g) measures for the prevention of cross contamination;
- h) cleaning and sanitizing;
- i) pest control;
- j) personnel hygiene;
- k) other aspects as appropriate.

Verification of PRP(s) shall be planned (see 7.8) and PRP(s) shall be modified as necessary (see 7.7). Records of verifications and modifications shall be maintained. Documents should specify how activities included in the PRP(s) are managed.

7.3 Preliminary steps to enable hazard analysis

7.3.1 General

All relevant information needed to conduct the hazard analysis shall be collected, maintained, updated and documented. Records shall be maintained.

7.3.2 Food safety team

A food safety team shall be appointed.

The food safety team shall have a combination of multi-disciplinary knowledge and experience in developing and implementing the food safety management system. This includes, but need not be limited to, the organization's products, processes, equipment and food safety hazards within the scope of the food safety management system.

Records shall be maintained that demonstrate that the food safety team has the required knowledge and experience (see 6.2.2).

7.3.3 Product characteristics

7.3.3.1 Raw materials, ingredients and product-contact materials

All raw materials, ingredients and product-contact materials shall be described in documents to the extent needed to conduct the hazard analysis (see 7.4), including the following, as appropriate:

- a) biological, chemical and physical characteristics;
- b) composition of formulated ingredients, including additives and processing aids;
- c) origin;
- d) method of production;
- e) packaging and delivery methods;
- f) storage conditions and shelf life;
- g) preparation and/or handling before use or processing;
- h) food safety-related acceptance criteria or specifications of purchased materials and ingredients appropriate to their intended uses.

The organization shall identify statutory and regulatory food safety requirements related to the above. The descriptions shall be kept up-to-date including, when required, in accordance with 7.7.

7.3.3.2 Characteristics of end products

The characteristics of end products shall be described in documents to the extent needed to conduct the hazard analysis (see 7.4), including information on the following, as appropriate:

- a) product name or similar identification;
- b) composition;
- c) biological, chemical and physical characteristics relevant for food safety;
- d) intended shelf life and storage conditions;
- e) packaging;
- f) labelling relating to food safety and/or instructions for handling, preparation and usage;
- g) method(s) of distribution.

The organization shall identify statutory and regulatory food safety requirements related to the above. The descriptions shall be kept up-to-date including, when required, in accordance with 7.7.

7.3.4 Intended use

The intended use, the reasonably expected handling of the end product, and any unintended but reasonably expected mishandling and misuse of the end product shall be considered and shall be described in documents to the extent needed to conduct the hazard analysis (see 7.4).

Groups of users and, where appropriate, groups of consumers shall be identified for each product, and consumer groups known to be especially vulnerable to specific food safety hazards shall be considered. The descriptions shall be kept up-to-date including, when required, in accordance with 7.7.

7.3.5 Flow diagrams, process steps and control measures

7.3.5.1 Flow diagrams

Flow diagrams shall be prepared for the products or process categories covered by the food safety management system. Flow diagrams shall provide a basis for evaluating the possible occurrence, increase or introduction of food safety hazards.

Flow diagrams shall be clear, accurate and sufficiently detailed. Flow diagrams shall, as appropriate, include the following:

- a) the sequence and interaction of all steps in the operation;
- b) any outsourced processes and subcontracted work;
- c) where raw materials, ingredients and intermediate products enter the flow;
- d) where reworking and recycling take place;
- e) where end products, intermediate products, by-products and waste are released or removed.

In accordance with 7.8, the food safety team shall verify the accuracy of the flow diagrams by on-site checking. Verified flow diagrams shall be maintained as records.

7.3.5.2 Description of process steps and control measures

The existing control measures, process parameters and/or the rigorousness with which they are applied, or procedures that may influence food safety, shall be described to the extent needed to conduct the hazard analysis (see 7.4).

External requirements (e.g. from regulatory authorities or customers) that may impact the choice and the rigorousness of the control measures shall also be described.

The descriptions shall be updated in accordance with 7.7.

7.4 Hazard analysis

7.4.1 General

The food safety team shall conduct a hazard analysis to determine which hazards need to be controlled, the degree of control required to ensure food safety, and which combination of control measures is required.

7.4.2 Hazard identification and determination of acceptable levels

7.4.2.1 All food safety hazards that are reasonably expected to occur in relation to the type of product, type of process and actual processing facilities shall be identified and recorded. The identification shall be based on

- a) the preliminary information and data collected according to 7.3,
- b) experience,
- c) external information including, to the extent possible, epidemiological and other historical data, and
- d) information from the food chain on food safety hazards that may be of relevance for the safety of the end products, intermediate products and the food at consumption.

The step(s) (from raw materials, processing and distribution) at which each food safety hazard may be introduced shall be indicated.

7.4.2.2 When identifying the hazards, consideration shall be given to

- a) the steps preceding and following the specified operation,
- b) the process equipment, utilities/services and surroundings, and
- c) the preceding and following links in the food chain.

7.4.2.3 For each of the food safety hazards identified, the acceptable level of the food safety hazard in the end product shall be determined whenever possible. The determined level shall take into account established statutory and regulatory requirements, customer food safety requirements, the intended use by the customer and other relevant data. The justification for, and the result of, the determination shall be recorded.

7.4.3 Hazard assessment

A hazard assessment shall be conducted to determine, for each food safety hazard identified (see 7.4.2), whether its elimination or reduction to acceptable levels is essential to the production of a safe food, and whether its control is needed to enable the defined acceptable levels to be met.

Each food safety hazard shall be evaluated according to the possible severity of adverse health effects and the likelihood of their occurrence. The methodology used shall be described, and the results of the food safety hazard assessment shall be recorded.

7.4.4 Selection and assessment of control measures

Based on the hazard assessment of 7.4.3, an appropriate combination of control measures shall be selected which is capable of preventing, eliminating or reducing these food safety hazards to defined acceptable levels.

In this selection, each of the control measures as described in 7.3.5.2 shall be reviewed with respect to its effectiveness against the identified food safety hazards.

The control measures selected shall be categorized as to whether they need to be managed through operational PRP(s) or by the HACCP plan.

The selection and categorization shall be carried out using a logical approach that includes assessments with regard to the following:

- a) its effect on identified food safety hazards relative to the strictness applied;
- b) its feasibility for monitoring (e.g. ability to be monitored in a timely manner to enable immediate corrections);
- c) its place within the system relative to other control measures;
- d) the likelihood of failure in the functioning of a control measure or significant processing variability;
- e) the severity of the consequence(s) in the case of failure in its functioning;
- f) whether the control measure is specifically established and applied to eliminate or significantly reduce the level of hazard(s);
- g) synergistic effects (i.e. interaction that occurs between two or more measures resulting in their combined effect being higher than the sum of their individual effects).

Control measures categorized as belonging to the HACCP plan shall be implemented in accordance with 7.6. Other control measures shall be implemented as operational PRPs according to 7.5.

The methodology and parameters used for this categorization shall be described in documents, and the results of the assessment shall be recorded.

7.5 Establishing the operational prerequisite programmes (PRPs)

The operational PRPs shall be documented and shall include the following information for each programme:

- a) food safety hazard(s) to be controlled by the programme (see 7.4.4);
- b) control measure(s) (see 7.4.4);
- c) monitoring procedures that demonstrate that the operational PRPs are implemented;
- d) corrections and corrective actions to be taken if monitoring shows that the operational PRPs are not in control (see 7.10.1 and 7.10.2, respectively);
- e) responsibilities and authorities;
- f) record(s) of monitoring.

7.6 Establishing the HACCP plan

7.6.1 HACCP plan

The HACCP plan shall be documented and shall include the following information for each identified critical control point (CCP):

- a) food safety hazard(s) to be controlled at the CCP (see 7.4.4);
- b) control measure(s) (see 7.4.4)
- c) critical limit(s) (see 7.6.3);
- d) monitoring procedure(s) (see 7.6.4);
- e) corrections and corrective action(s) to be taken if critical limits are exceeded (see 7.6.5);
- f) responsibilities and authorities;
- g) record(s) of monitoring.

7.6.2 Identification of critical control points (CCPs)

For each hazard that is to be controlled by the HACCP plan, CCP(s) shall be identified for the control measures identified (see 7.4.4).

7.6.3 Determination of critical limits for critical control points

Critical limits shall be determined for the monitoring established for each CCP.

Critical limits shall be established to ensure that the identified acceptable level of the food safety hazard in the end product (see 7.4.2) is not exceeded.

Critical limits shall be measurable.

The rationale for the chosen critical limits shall be documented.

Critical limits based on subjective data (such as visual inspection of product, process, handling, etc.) shall be supported by instructions or specifications and/or education and training.

7.6.4 System for the monitoring of critical control points

A monitoring system shall be established for each CCP to demonstrate that the CCP is in control. The system shall include all scheduled measurements or observations relative to the critical limit(s).

The monitoring system shall consist of relevant procedures, instructions and records that cover the following:

- a) measurements or observations that provide results within an adequate time frame;
- b) monitoring devices used;
- c) applicable calibration methods (see 8.3);
- d) monitoring frequency;
- e) responsibility and authority related to monitoring and evaluation of monitoring results;
- f) record requirements and methods.

The monitoring methods and frequency shall be capable of determining when the critical limits have been exceeded in time for the product to be isolated before it is used or consumed.

7.6.5 Actions when monitoring results exceed critical limits

Planned corrections and corrective actions to be taken when critical limits are exceeded shall be specified in the HACCP plan. The actions shall ensure that the cause of nonconformity is identified, that the parameter(s) controlled at the CCP is (are) brought back under control, and that recurrence is prevented (see 7.10.2).

Documented procedures shall be established and maintained for the appropriate handling of potentially unsafe products to ensure that they are not released until they have been evaluated (see 7.10.3).

7.7 *Updating of preliminary information and documents specifying the PRPs and the HACCP plan*

Following the establishment of operational PRP(s) (see 7.5) and/or the HACCP plan (see 7.6), the organization shall update the following information, if necessary:

- a) product characteristics (see 7.3.3);
- b) intended use (see 7.3.4);
- c) flow diagrams (see 7.3.5.1);
- d) process steps (see 7.3.5.2);
- e) control measures (see 7.3.5.2).

If necessary, the HACCP plan (see 7.6.1) and the procedures and instructions specifying the PRP(s) (see 7.2) shall be amended.

7.8 Verification planning

Verification planning shall define the purpose, methods, frequencies and responsibilities for the verification activities. The verification activities shall confirm that

- a) the PRP(s) are implemented (see 7.2),
- b) input to the hazard analysis (see 7.3) is continually updated,
- c) the operational PRP(s) (see 7.5) and the elements within the HACCP plan (see 7.6.1) are implemented and effective,
- d) hazard levels are within identified acceptable levels (see 7.4.2), and
- e) other procedures required by the organization are implemented and effective.

The output of this planning shall be in a form suitable for the organization's method of operations. Verification results shall be recorded and shall be communicated to the food safety team. Verification results shall be provided to enable the analysis of the results of the verification activities (see 8.4.3).

If system verification is based on testing of end product samples, and where such test samples show nonconformity with the acceptable level of the food safety hazard (see 7.4.2), the affected lots of product shall be handled as potentially unsafe in accordance with 7.10.3.

7.9 Traceability system

The organization shall establish and apply a traceability system that enables the identification of product lots and their relation to batches of raw materials, processing and delivery records.

The traceability system shall be able to identify incoming material from the immediate suppliers and the initial distribution route of the end product.

Traceability records shall be maintained for a defined period for system assessment to enable the handling of potentially unsafe products and in the event of product withdrawal. Records shall be in accordance with statutory and regulatory requirements and customer requirements and may, for example, be based on the end product lot identification.

7.10 Control of nonconformity

7.10.1 Corrections

The organization shall ensure that when critical limits for CCP(s) are exceeded (see 7.6.5), or there is a loss of control of operational PRP(s), the products affected are identified and controlled with regard to their use and release.

A documented procedure shall be established and maintained defining

- a) the identification and assessment of affected end products to determine their proper handling (see 7.10.3), and
- b) a review of the corrections carried out.

Products manufactured under conditions where critical limits have been exceeded are potentially unsafe products and shall be handled in accordance with 7.10.3. Products manufactured under conditions

where operational PRP(s) have not been conformed with shall be evaluated with respect to the cause(s) of the nonconformity and to the consequences thereof in terms of food safety and shall, where necessary, be handled in accordance with 7.10.3. The evaluation shall be recorded.

All corrections shall be approved by the responsible person(s), and shall be recorded together with information on the nature of the nonconformity, its cause(s) and consequence(s), including information needed for traceability purposes related to the nonconforming lots.

7.10.2 Corrective actions

Data derived from the monitoring of operational PRPs and CCPs shall be evaluated by designated person(s) with sufficient knowledge (see 6.2) and authority (see 5.4) to initiate corrective actions. Corrective actions shall be initiated when critical limits are exceeded (see 7.6.5) or when there is a lack of conformity with operational PRP(s).

The organization shall establish and maintain documented procedures that specify appropriate actions to identify and eliminate the cause of detected nonconformities, to prevent recurrence, and to bring the process or system back into control after nonconformity is encountered. These actions include

- a) reviewing nonconformities (including customer complaints),
- b) reviewing trends in monitoring results that may indicate development towards loss of control,
- c) determining the cause(s) of nonconformities,
- d) evaluating the need for action to ensure that nonconformities do not recur,
- e) determining and implementing the actions needed,
- f) recording the results of corrective actions taken, and
- g) reviewing corrective actions taken to ensure that they are effective.

Corrective actions shall be recorded.

7.10.3 Handling of potentially unsafe products

7.10.3.1 General

The organization shall handle nonconforming products by taking action(s) to prevent the nonconforming product from entering the food chain unless it is possible to ensure that

- a) the food safety hazard(s) of concern has(ve) been reduced to the defined acceptable levels,
- b) the food safety hazard(s) of concern will be reduced to identified acceptable levels (see 7.4.2) prior to entering into the food chain, or
- c) the product still meets the defined acceptable level(s) of the food safety hazard(s) of concern despite the nonconformity.

All lots of product that may have been affected by a nonconforming situation shall be held under control of the organization until they have been evaluated.

If products that have left the control of the organization are subsequently determined to be unsafe, the organization shall notify relevant interested parties and initiate a withdrawal (see 7.10.4).

NOTE The term "withdrawal" includes recall.

The controls and related responses and authorization for dealing with potentially unsafe products shall be documented.

7.10.3.2 Evaluation for release

Each lot of product affected by the nonconformity shall only be released as safe when any of the following conditions apply:

- a) evidence other than the monitoring system demonstrates that the control measures have been effective;
- b) evidence shows that the combined effect of the control measures for that particular product complies with the performance intended (i.e. identified acceptable levels as identified in accordance with 7.4.2);
- c) the results of sampling, analysis and/or other verification activities demonstrate that the affected lot of product complies with the identified acceptable levels for the food safety hazard(s) concerned.

7.10.3.3 Disposition of nonconforming products

Following evaluation, if the lot of product is not acceptable for release it shall be handled by one of the following activities:

- a) reprocessing or further processing within or outside the organization to ensure that the food safety hazard is eliminated or reduced to acceptable levels;
- b) destruction and/or disposal as waste.

7.10.4 Withdrawals

To enable and facilitate the complete and timely withdrawal of lots of end products which have been identified as unsafe

- a) top management shall appoint personnel having the authority to initiate a withdrawal and personnel responsible for executing the withdrawal, and
- b) the organization shall establish and maintain a documented procedure for
 - 1) notification to relevant interested parties (e.g. statutory and regulatory authorities, customers and/or consumers),
 - 2) handling of withdrawn products as well as affected lots of the products still in stock, and
 - 3) the sequence of actions to be taken.

Withdrawn products shall be secured or held under supervision until they are destroyed, used for purposes other than originally intended, determined to be safe for the same (or other) intended use, or reprocessed in a manner to ensure they become safe.

The cause, extent and result of a withdrawal shall be recorded and reported to top management as input to the management review (see 5.8.2).

The organization shall verify and record the effectiveness of the withdrawal programme through the use of appropriate techniques (e.g. mock withdrawal or practice withdrawal).

Section 5

Other sources of information

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Introduction

There is a huge amount of information available from both governmental and trade associations to support organizations where they wish to have more detailed specific information on aspects of managing food safety. A principal source of information is British Standards Institution which, in addition to publishing the ISO 22000:2005 standard itself, also publishes a huge number of other standards used extensively across the food industry. They also publish additional guidance in the area of which this workbook is one example.

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Good practice

The Codex Alimentarius Commission is an international body responsible for the development of a range of international food codes and standards. The *Codex Alimentarius*, or the food code, has become the global reference point for consumers, food producers and processors, national food control agencies and the international food trade.

<http://www.codexalimentarius.net>

Standards and codes can be also downloaded from this site.

Internationally recognized science-based guidance on the microbiological safety of foods – to inform hazard analysis, risk assessment, control measures and critical limits for microbiological hazards: International Commission on Microbiological Specifications for Foods (ICMSF) is available from:

<http://www.icmsf.iit.edu/main/home.html>

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Legislation and regulation

Copies of the regulations in pdf format can be accessed from the Food Standards Agency's (FSA's) website <http://www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg/>

An electronic version of the EU *Official Journal* (where the adopted EU Regulations are published) can be found on the European Union website <http://www.europa.eu.int/eur-lex/lex/JOIndex.do?ihmlang=en>

Key pieces of legislation that apply in the UK are:

- The Food Safety Act 1990;
- The Food Labelling Regulations 1996;
- The Food Labelling (Amendment) (No 2) Regulations 2004;
- The Food Labelling (Amendment) (No 2) Regulations 2005;
- The Food Hygiene (England) Regulations 2006 (and equivalent for Scotland, Wales and Northern Ireland);
- EU Regulation No. 852/2004;
- EU Regulation No. 178/2002;
- EU Directive No. 2000/13/EC;
- EU Directive No. 2003/89/EC;
- EU Directive No. 2005/26/EC;
- EU Regulation No 2073/2005 on The Microbiological Criteria for Foodstuffs.

In addition to the above, there are other specific regulations and industry guidance relating to particular issues or specific product types.

A detailed list of the legislation applicable across the food industry can be found in the *Food Law Guide*, published by the Food Standards Agency <http://www.food.gov.uk>

Copies are obtainable from the Office of Public Sector Information (OPSI).

You can access these from the OPSI website <http://www.opsi.gov.uk>

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Background information

Background to the new legislation and copies of the EU texts can be found on the FSA website <http://www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg/>

Information for businesses and enforcement practitioners in the form of a Q&A on the new food hygiene legislation can be accessed at <http://www.food.gov.uk/foodindustry/>

Other sources of information for small businesses from the government agencies:

The Small Business Service
<http://www.sbs.gov.uk>

Business Link
<http://www.businesslink.gov.uk>

The statutory *Food Law Code of Practice* and accompanying *Practice Guidance* for England and for Wales can be found respectively on the FSA website <http://www.food.gov.uk/enforcement/foodlaw/foodlawcop/copengland> and <http://www.food.gov.uk/enforcement/foodlaw/foodlawcop/copwales>

Hard copies of the above documents can be obtained from the FSA on 020 7276 8455 or 020 7276 8454, or from FSA Wales on 029 2067 8902.

You may also wish to contact environmental/port health representative bodies.

Local Authorities Coordinators of Regulatory Services
<http://www.lacors.gov.uk>
tel: 020 7840 7200

Chartered Institute of Environmental Health
<http://www.cieh.org>
tel: 020 7928 6006
email: info@cieh.org

Chartered Institute for Environmental Health Cymru-Wales

<http://www.cieh-cymruwales.org>

tel: 01766 810081

email: ciehcymruwales@cieh.net

Association of Port Health Authorities

<http://www.apha.org.uk>

tel: 08707 444505

email: APHA@cieh.org.uk

The draft *Code of Practice* and *Practice Guidance for Scotland* can be found on the FSA website

<http://www.food.gov.uk/enforcement/foodlaw/foodlawcop/copscotland>

Hard copies of the above documents can be obtained from Food Standards Agency Scotland on 01224 285118.

You may also wish to contact environmental health representative bodies.

Royal Environmental Health Institute of Scotland

<http://www.rehis.org/>

tel: 0131 225 6999

email: rehis@rehis.org.uk

Industry Organizations and Associations

The British Association for Shooting and Conservation

<http://www.basc.org.uk>

British Egg Industry Service

<http://www.britegg.co.uk>

tel: 020 7808 9790

British Hospitality Association

<http://www.bha-online.org.uk>

tel: 0845 880 7744

email: info@bha.org.uk

British Institute of Innkeeping

<http://www.bii.org>

tel: 01276 684449

email: reception@bii.org

British Meat Processors Association

<http://www.bmpa.uk.com>

tel: 020 7329 0776

email: info@bmpa.uk.com

British Poultry Council
<http://www.poultry.uk.com>
tel: 020 7202 4760
email: white@poultry.uk.com

British Retail Consortium
<http://www.brc.org.uk>
tel: 020 7854 8900

British Sandwich Association
<http://www.sandwich.org.uk>
email: admin@sandwich.org.uk

Campden and Chorleywood Food Research Association
<http://www.campden.co.uk>
tel: 01386 842000

Chilled Food Association
<http://www.chilledfood.org>
email: cfa@chilledfood.org

Farmers Union of Wales
<http://www.fuw.org.uk/>

Food and Drink Federation
<http://www.fdf.org.uk>
tel: 020 7836 2460

Scottish Food and Drink Federation
<http://www.sfdf.org.uk>
tel: 0131 229 9415

Freight Transport Association
<http://www.fta.co.uk>
tel: 08717 112222

Hospital Caterers Association
<http://www.hospitalcaterers.org>
email: alison.mccree@cddah.nhs.uk

Hotel & Catering International Management Association
<http://www.hcima.org.uk>
tel: 020 8661 4900
email: commdept@hcima.co.uk

Leatherhead Food International
<http://www.lfra.co.uk>
tel: 01372 376761
email: help@leatherheadfood.com

Meat and Livestock Commission
<http://www.mlc.org.uk>
tel: 01908 677577

National Association of Catering Butchers
<http://www.nacb.co.uk>
Tel: 020 7248 1896
email: info@nacb.co.uk

National Farmers' Union
<http://www.nfu.org.uk/>

National Farmers' Union of Scotland
<http://www.nfus.org.uk/>

National Farmers' Union (Cymru)
<http://www.nfu-cymru.org.uk/>

National Pig Association
<http://www.npa-uk.net>
tel: 020 7331 7650

Nationwide Caterers Association
<http://www.ncass.org.uk>
tel: 0871 504 1780
email: info@ncass.org.uk

People1st, the Sector Skills Council (for hospitality, leisure, travel and tourism)
<http://www.people1st.co.uk>
tel: 0870 060 2550

Royal Association of British Dairy Farmers
<http://www.rabdf.co.uk>
tel: 0845 458 2711
email: office@rabdf.co.uk

Scottish Association of Meat Wholesalers
<http://www.scottish-meat-wholesalers.org.uk/>

Sea Fish Industry Authority
<http://www.seafish.org>
tel: 01482 327837

Advice for caterers and consumers is provided on the FSA's websites <http://www.food.gov.uk> and <http://www.eatwell.gov.uk>

If you wish to order any of the publications, please contact FSA Publications
tel: 0845 606 0667
minicom: 0845 606 0678
fax: 020 8867 3225
email: foodstandards@ecgroup.uk.com

Other general sources of information

To locate your nearest Environmental Health Department please go to
<http://www.food.gov.uk/enforcement/laresource/yourarea/>

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References

- BIP 2078, *Managing Food Safety the 22000 Way*
BIP 2128, *ISO 22000 Food Safety: Guidance and Workbook for the Manufacturing Industry*
BIP 2129, *ISO 22000 Food Safety: Guidance and Workbook for the Retail Industry*
Codex Alimentarius: Recommended International Code of Practice – General Principles of Food Hygiene
– CAC/RCP 1-1969, Rev. 4 – 2003
ISO 9001:2000, *Quality management systems — Requirements*
ISO 14001:2004, *Environmental management systems — Requirements with guidance for use*
ISO 22000:2005, *Food safety management systems — Requirements for any organization in the food chain*
ISO/TS 22004:2005, *Food safety management systems — Guidance on the application of ISO 22000:2005*
OHSAS 18001:1999, *Occupational health and safety management systems*
PAS 99:2006, *Specification of common management systems requirements as a framework for integration*