10
Safety in Food Processing

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10.1
Introduction

It is a fundamental requirement of any food process that the food produced should be safe for consumption. Food safety is a basic need but there is a danger that it may be overlooked in the development of effective and efficient processes.

There are three key elements to ensuring food safety is achieved in food manufacture:

1. safe design of the process, recipe and packaging format;
2. prerequisite programmes or good manufacturing practice to control the manufacturing environment;
3. use of the HACCP system of food safety management.

This chapter will outline these current approaches to effective food safety management and consider how they fit with the design and use of different food processing technologies.

10.2
Safe Design

"When designing a new food product it is important to ask if it is possible to manufacture it safely. Effective HACCP systems (and prerequisite programmes) will manage and control food safety but what they cannot do is make safe a fundamentally unsafe product" [1].

It is important, therefore, to understand the criteria involved in designing and manufacturing a safe product. These include:

- an understanding of the likely food safety hazards that may be presented through the ingredients, processing and handling methods;
- the intrinsic factors involved in developing a safe recipe;
- a thorough knowledge of the chosen food processing and packaging technologies;

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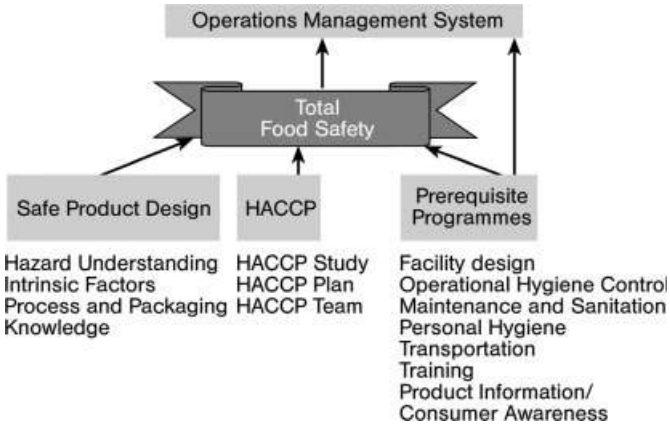

Fig. 10.1 Safe food processing achievement model; adapted from [3].

- manufacturing in a facility operating to prerequisite good manufacturing practice systems;
- management of production within the framework of a validated HACCP programme.

Prerequisite good manufacturing practice programmes and HACCP will be covered in Sections 10.3 and 10.4, respectively. Before further considering the design of safe products, we can look at how these different criteria fit together to ensure safe food processing. Fig. 10.1 shows a model for the achievement of safe food processing. The safety management criteria, i.e. safe product design, HACCP and Prerequisite Good Manufacturing Practice programmes are all managed within the framework of the Operational Management system, which could be a Quality Management system such as ISO 9000:2000 [2].

10.2.1 Food Safety Hazards

Food safety hazards are contaminants that may cause a food product to be unsafe for production. Hazards are defined by Codex 1997 [4] as follows:

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

Hazards may enter a food product from its ingredients or may contaminate during processing or handling. Table 10.1 shows examples of common hazard types for consideration.

At the product design stage, it is important to understand the likely hazards that might be encountered in the chosen ingredient types, or that might be present in the processing environment. This allows the development team to identify the best ways to control these hazards, either by preventing their entry to the process, destroying them or reducing the contamination to a level where

Table 10.1 Examples of food safety hazards. Note: this table provides examples only and is not intended to be an exhaustive list of food safety hazards.

	Type of hazard		
	Biological	**Chemical**	**Physical**
Considerations	Organisms that can cause harm through infection or intoxication	Chemicals that can cause harm through toxic effects, either immediate or long-term	Items that can cause harm through direct injury or choking
Examples	Pathogenic bacteria, e.g. *Escherichia coli*, *Bacillus cereus*, *Campylobacter jejuni*, *Clostridium botulinum*, *C. botulinum* (non-proteolytic), *C. perfringens*, *Salmonella* spp, *Shigella* spp, *Staphylococcus aureas*, *Vibrio parahaemoliticus*; Viruses, Protozoan parasites, e.g. *Cryptosporidium parvum*, *Giardia intestinalis*, *Cyclospora cayetanensis*	Mycotoxins, e.g. aflatoxins, patulin, vomitoxin, fumonisin; pesticides, allergenic materials, heavy metals, PCBs dioxins, cleaning chemicals	Glass, metal, stones, wood, plastic, pests, intrinsic natural materials, e.g. bone, nut shell

it no longer poses a food safety risk. This information on likely hazards and proposed control options should link with the prerequisite good manufacturing practice programmes and HACCP systems to ensure everyday control is established in the manufacturing operation.

Consideration of likely hazards at an early stage in the development process can also, in some cases, help to design these hazards out of the product, either through careful choice and sourcing of ingredients or through identification of appropriate processing technologies and/or equipment. For example, if there is a concern about physical hazards gaining entry to a product during manufacture due to the use of open vessels, the redesign of the equipment to use enclosed vessels would prevent this hazard from ever occurring at that processing step. Similarly, if there is concern about pathogen contamination in a raw ingredient, e.g. *Salmonella* spp contamination in coconut that is to be used as a topping ingredient after heat processing, it may be possible to replace this ingredient with a preprocessed ingredient, in this example pasteurized coconut.

10.2.2 Intrinsic Factors

Intrinsic factors are the formulation criteria that control the ability of microorganisms to survive and grow in foods. These factors have been used traditionally to prevent problems with spoilage organisms and pathogens in a wide variety of foodstuffs. The most commonly used intrinsic factors in food processing are water activity, pH, organic acids and preservatives.

Water activity (a_w) is a measure of the amount of water available in a foodstuff for microbial growth. Pure water has an a_w of 1.0 and, as solutes such as salt and sugar are added to make a more concentrated solution, the a_w decreases. Table 10.2 shows the a_w limit for growth of a number of key microbial pathogens. There is a characteristic pH range across which microorganisms can grow; and the limiting pH for growth varies widely between species. The use of pH to control the growth of microorganisms is very common in food processing, finding uses in pickled foods such as pickled vegetables and fermented foods such as cheese and yoghurt. The pH limit for growth of a number of key microbial pathogens is also given in Table 10.2.

Organic acids, such as acetic, citric, lactic and sorbic acids, are widely used as preserving factors in food processing. The antimicrobial effect of organic acids is due to undissociated molecules of the acid and, since the dissociation of the molecules is pH-dependent, the effectiveness is related to pH.

Chemical preservatives may be added to food products to prevent the growth of pathogens and spoilage organisms. The use of preservatives is normally controlled by legislation, with different levels of various preservatives allowed for use in different groups of foodstuffs. Further detailed information on the effects of intrinsic factors on a wide range of microorganisms can be found in other publications, such as ICMSF [6], Kyriakides [19].

Table 10.2 Control of key microbiological hazards through intrinsic factors (adapted from [5, 6]).

Organism	Minimum pH for growth	Minimum water activity (a_w) for growth
Bacillus cereus	5.0	0.93
Campylobacter jejuni	4.9	0.99
Clostridium botulinum	4.7	0.94
Clostridium botulinum (non-proteolitic)	5.0	0.97
Clostridium perfringens	5.5	0.93
Escherichia coli	4.4	0.95
Listeria monocytogenes	4.4	0.92
Salmonella spp	3.8	0.94
Shigella spp	4.9	0.97
Staphylococcus aureuas	4.0	0.85
Vibrio parahaemoliticus	4.8	0.94

10.2.3
Food Processing Technologies

A wide variety of food processing technologies is available, as highlighted in the other chapters of this book. It is important for food safety that the chosen food process is thoroughly understood so that any potential food safety hazards can be effectively controlled. Table 10.3 shows the effects of various food processing techniques on food safety hazards.

It can be seen that most types of food processing illustrated in Table 10.3 are designed to control microbiological hazards and involve either destruction, reduction of numbers or prevention from growth of various foodborne pathogens. To a lesser extent, a number food processing techniques, e.g. cleaning and separation, involve the removal of physical hazards. Very few food processing techniques are designed to control chemical hazards in foods; and therefore it is important to source high quality ingredients that are free from chemical hazards.

10.2.4
Food Packaging Issues

The chosen packaging type should also be evaluated as part of the 'Safe Design' process. Food packaging systems have evolved to prevent contamination and ensure achievement of desired shelf life; however there may be hazard considerations if inappropriate to the type of food or proposed storage conditions. Table 10.4 lists a number of considerations for choosing a safe packaging system.

10.3
Prerequisite Good Manufacturing Practice Programmes

Prerequisite programmes or 'Good Manufacturing Practice' (GMP) provide the hygienic foundations for any food operation. The terms 'prerequisite programmes' and 'Good Manufacturing Practice' are used interchangeably in different parts of the world but have the same general meaning. For simplicity, the term prerequisite programmes will be used in this chapter.

Several groups have suggested definitions for the term prerequisites and the most commonly used are reproduced here. Prerequisite programmes are:

- practices and conditions needed prior to and during the implementation of HACCP and which are essential to food safety (World Health Organisation WHO [7]);
- universal steps or procedures that control the operating conditions within a food establishment, allowing for environmental conditions that are favourable for the production of safe food (Canadian Food Inspection Agency [8]);
- procedures, including GMP, that address operational conditions, providing the foundation for the HACCP system (USA National Advisory Committee for Microbiological Criteria for Foods [9]).

Table 10.3 Effects of food processing on food safety hazards.

Processing operation		Intended effect on food safety hazards	Example food types
Cleaning	Dry	Removal of foreign material and dust	Grain crops
	Wet	Reduction in level of micro-organisms and foreign material	Raw foods, e.g. vegetables, fruit, dried fruit
Antimicrobial dipping/spraying		Reduction in levels of micro-organisms	Fruit and vegetables
Fumigation		Destruction of certain micro-organisms and pests	Nuts, dried fruit, cocoa beans
Thermal processing	Pasteurisation/ cooking	Destroys vegetative pathogens, e.g. *Salmonella* spp, *Listeria monocytogenes*	Milk products, meat, fish, ready meals
	Sterilisation: UHT/aseptic	Destroys pathogens and prevents recontamination in packaging system	UHT milk, fruit juices
	Sterilisation: cans/pouches	Destroys pathogens	Canned meats, soups, pet food, etc.
Evaporation/dehydration		Halts growth of pathogenic bacteria at a_w 0.84, all microorganisms at a_w 0.60	Various foodstuffs, e.g. dried fruit, milk powder, cake mixes, etc.
Salt preserving		Halts growth of pathogenic bacteria at a_w 0.84, all micro-organisms at a_w 0.60; growth of many microorganisms halted at ca. 10% salt	Fish, meats, vegetables
Sugar preserving		Halts growth of pathogenic bacteria at a_w 0.84, all micro-organisms at a_w 0.60	Jam, fruits, syrups, jellies, confectionery
Chilling (<5 °C)		Slows or prevents growth of most pathogens	Cooked meats, dairy products, fruit juices
Freezing (at least –10 °C)		Prevents growth of all micro-organisms. Destroys some parasites	Many foodstuffs, e.g. fruit, vegetables, meat, fish, ice cream, etc.
Irradiation		Destroys microorganisms	Can be used for various products, e.g. fruit, shellfish, however consumer pressure has limited its application
High pressure processing		Destroys/inactivates micro-organisms; affects functional and organoleptic properties	Fruit juice, guacomole, yoghurt, oysters

Table 10.3 (continued)

Processing operation	Intended effect on food safety hazards	Example food types
Pulsed electric field processing	Destroys microorganisms, inactivates some enzymes	Potential applications include fruit juice, milk
Fermentation/acidification	Halts growth of pathogens; destroys some organisms, depending on pH/acid used	Cheese, yogurt, vegetables, fruit, etc.
Separation (e.g. filtration)	Removes physical hazards and/or pathogens (depending on filter pore size), adjusts chemical concentration (e.g. reverse osmosis)	Various foodstuffs, e.g. sugar, grains, water, etc.

A number of groups have published helpful material on prerequisite programmes; however the internationally accepted requirements for prerequisites are defined in the Codex general principles of food hygiene [10]. Box 10.1 shows the section headings from this Codex document.

10.3.1 Prerequisite Programmes – The Essentials

Using the headings given in [10], the following notes describe the general requirements for prerequisite programmes in each area. Further, more detailed, information can be found in other publications such as the Codex document itself [10], CFIA [8], IFST [11], Sprenger [12], Engel [18], Mortimore [20], and Wallace [21].

Establishment: Design and Facilities The location of food premises is important and care should be taken to identify and consider the risks of potential sources of contamination in the surrounding environment. Suitable controls to prevent contamination should be developed and implemented.

The design and layout of the premises and rooms should permit good hygiene and protect the products from cross-contamination during operation. Internal structures and equipment should be built of materials able to be easily cleaned/disinfected and maintained. Surfaces should be smooth, impervious and able to withstand the normal conditions of the operation, e.g. moisture and temperature ranges.

Facilities should be provided to include adequate potable water supplies, suitable drainage and waste disposal, appropriate cleaning facilities, storage areas, lighting, ventilation and temperature control. Suitable facilities should also be provided to promote personal hygiene for the workforce, including adequate changing areas, lavatories and hand washing and drying facilities.

Table 10.4 Food packaging considerations.

Packaging type	Considerations
Retortable containers: cans	Hygienic container suitable for a wide range of foods. Suitable for retort sterilisation/pasteurisation and ambient storage, dependant on formulation suitability (pasteurisation). Careful handling required after sealing and retorting. Type of can and inner laquer needs to be matched to food type to prevent degradation and leaching of metal into the product.
Retortable containers: pouches	Hygienic container suitable for a wide range of foods. Suitable for retort sterilisation/pasteurisation and ambient storage, dependant on formulation suitability (pasteurisation). Careful handling required after sealing and retorting. Need to check that film constituents, e.g. plasticisers and additives, cannot transfer to food during packaging use.
Glass	Hygienic container suitable for a wide range of foods. Suitable for hot and cold fill. For ambient storage, need to ensure that the recipe intrinsic factors keep the product safe over the shelf-life. High quality glass required and container design for strength necessary. Careful handling required to prevent breakage and glass hazards. Glass breakage procedures needed.
Gas-flushed containers	Intended to extend life of product by preventing growth of spoilage organisms. Need to ensure that any pathogens present, e.g. anaerobic spore formers, cannot grow in the chosen gas mix.
Vacuum packaging	Intended to extend life of product by preventing growth of spoilage organisms. Anaerobic conditions provided can allow growth of some pathogens, e.g. *Clostridium botulinum*. May need to use vacuum packaging in conjunction with additional control measures such as chilling.
Gas-permeable packaging	Is it possible for other materials, e.g. moisture, to pass through into the product and cause contamination?
Product contact films and plastics	Need to check that constituents, e.g. plasticisers and additives, cannot transfer to food during packaging use.
Paper/cardboard	Most suitable for secondary/tertiary packaging. Need to ensure that inks and adhesives cannot transfer to foodstuff.
Wood	May introduce hazards, e.g. splinters. In most cases wood is best kept for secondary/tertiary packaging rather than direct product contact.

Box 10.1 Prerequisite programme topics for manufacturing facilities (adapted from [10], which also includes recommended general principles of food hygiene for primary production facilities).

Establishment: design and facilities
Location
Premises and rooms
Equipment
Facilities

Establishment: maintenance and sanitation
Maintenance and cleaning
Cleaning programmes
Pest control systems
Waste management
Monitoring effectiveness

Transportation
General
Requirements
Use and maintenance

Training
Awareness and responsibilities
Training programmes
Instruction and supervision
Refresher training

Control of operation
Control of food hazards
Key aspects of hygiene control systems
Incoming material requirements
Packaging
Water
Management and supervision
Documentation and records
Recall procedures

Establishment: personal hygiene
Health status
Illness and injuries
Personal cleanliness
Personal behaviour
Visitors

Product information and consumer awareness
Lot identification
Product information
Labelling
Consumer education

Control of Operation The rationale for operational control listed in [10] is "to reduce the risk of unsafe food by taking preventive measures to assure the safety and suitability of food at an appropriate stage in the operation by controlling food hazards". This includes the need to control potential food hazards by using a system such as HACCP.

Codex also describes key aspects of hygiene control systems, including:

- time and temperature control;
- microbiological and other specifications;
- microbiological cross-contamination risks;
- physical and chemical contamination.

Incoming material requirements and systems to ensure the safety of materials and ingredients at the start of processing are necessary, along with a suitable packaging design (see also Section 10.2.4).

Codex [10] also lists the importance of hygienic control of water, ice and steam, appropriate management and supervision, the need to keep adequate documentation and records and the need to develop and test suitable recall procedures so that product can be effectively withdrawn and recalled in the event of a food safety problem.

Establishment: Maintenance and Sanitation Maintenance and cleaning are important both to keep the processing environment, facilities and equipment in a good state of repair where they function as intended and to prevent cross-contamination with food residues and microorganisms that might otherwise build up. Facilities should operate preventative maintenance programmes as well as attending to breakdowns and faults without delay.

Cleaning programmes should be developed to encompass all equipment and facilities as well as general environmental cleaning. Cleaning methods need to be developed that are suitable for the item to be cleaned, including the use of appropriate chemical cleaning agents, disinfectants, hot/cold water and cleaning tools, e.g. brushes, scrapers, cloths, etc. Methods should describe how the item is to be cleaned and personnel should be trained to apply the methods correctly. A cleaning schedule should also be developed to identify the frequency of cleaning needed in each case and records of cleaning and monitoring should be kept.

Cleaning in place (CIP) solutions may be used in certain types of equipment, e.g. tanks and lines. Here it is important that the CIP programme is properly designed for the equipment to be cleaned, taking into account the flow rates, coverage and the need for rinsing and disinfection cycles.

Pest control systems are important to prevent the access of pests that might cause contamination to the product. Pest management is often contracted out to a professional pest control contractor. Buildings need to be made pestproof and regularly inspected for potential ingress points. Interior and exterior areas need to be kept clean and tidy to minimise potential food and harbourage sources. Suitable interior traps and monitoring devices should also be considered and any pest infestations need to be dealt with promptly, without adversely affecting food safety.

Waste management should ensure that waste materials can be removed and stored safely so that they do not provide a cross-contamination risk or become a food or harbourage source for pests.

All maintenance and sanitation systems should be monitored for effectiveness, verified and reviewed, with changes made to reflect operational changes.

Establishment: Personal Hygiene The objectives for personal hygiene stated in [10] are: "To ensure that those who come directly or indirectly into contact with food are not likely to contaminate food by:

- maintaining an appropriate degree of personal cleanliness;
- behaving and operating in an appropriate manner."

Food companies should, therefore, have standards and procedures in place to define the requirements for personal hygiene and staff responsibility; and staff

should be appropriately trained. This should include the establishment of health status where individuals may be carrying disease that can be transmitted through food, a consideration of illness and injuries where affected staff members may need to be excluded or wear appropriate dressings, the need for good personal cleanliness and effective hand washing, the wearing of adequate protective clothing and the prevention of inappropriate behaviour such as smoking, eating or chewing in food handling areas. Visitors to processing and product handling areas should be adequately supervised and required to follow the same standards of personal hygiene as employees.

Transportation To ensure continuation of food safety throughout transportation, transport facilities need to be designed and managed to protect food products from potential contamination and damage and to prevent the growth of pathogens. This includes the need for cleaning and maintenance of vehicles and containers and the use of temperature control devices where appropriate.

Product Information and Consumer Awareness It is important that sufficient information is easily identifiable on the products so that the lot or batch can be identified for recall purposes and that the product can be handled correctly, e.g. stored at $<5\,^{\circ}C$. Product information and labelling should be clear such that it facilitates consumer choice and correct storage/use.

Codex [10] also highlights the importance of consumer education, particularly the importance of following handling instructions and the link between time/temperature and foodborne illness.

Training Food hygiene training is essential to make personnel aware of their roles and responsibilities for food control. Companies should develop and implement appropriate training programmes and should include adequate supervision and monitoring of food hygiene behaviour. Training should be evaluated and reviewed with refresher or update training implemented as necessary.

10.3.2 Validation and Verification of Prerequisite Programmes

Prerequisite programmes are the basic standards for the food facility, in which the safely designed product can be manufactured. They form the hygiene foundations on which the HACCP System is built to control food safety every day of operation. As such, it is essential that prerequisite programmes are working effectively at all times and it is therefore necessary that each prerequisite element is validated to establish that it will be effective and that an ongoing programme of monitoring and verification is developed and implemented.

10.4
HACCP, the Hazard Analysis and Critical Control Point System

The acronym HACCP stands for the 'hazard analysis and critical control point' system, a method of food control based on the prevention of food safety problems. The HACCP story began in the early 1960s, when the Pillsbury Company was working with NASA and the US Army Natick laboratories to provide food for the American manned space programme. Up until this time, most food safety control systems had been based on end product testing but it was realised that this would not give enough assurance of food safety for such an important mission. Taking the failure mode and effect analysis (FMEA) approach as a starting point, the team adapted this into the basis of the HACCP system that we know today: a system that looks at what can go wrong at each step in the process and builds in control to prevent the problem from occurring.

The HACCP system has become the internationally accepted approach to food safety management [4, 9]. It is based on the application of seven principles (Box 10.2) that show how to develop, implement and maintain a HACCP system.

The use of HACCP is promoted by the WHO and is increasingly being seen by government groups worldwide as a cornerstone of food safety legislation.

HACCP systems can be linear, where the principles are applied to the whole operation from ingredients to end product, or modular, where the operation is split into process stages or modules and HACCP plans [1)] are developed for each module. Modular systems are common in complex manufacturing operations and are practical to develop; however a key point is to ensure that the modules add up to the entire operation and that no process stages are missed out. Fig. 10.2 shows the linear and modular approaches to HACCP.

10.4.1
Developing a HACCP System

In order to develop a HACCP system, a food company applies the Codex HACCP principles to its operations. This is most easily achieved using the following logic sequence (Box 10.3), also proposed by Codex [4].

Step 1. Assemble HACCP Team HACCP is normally applied by a multidisciplinary team, so that the system is the output of a group with the necessary combined experience and knowledge to take decisions about product safety. This approach works well in manufacturing operations and normally includes, as a minimum, the following disciplines:

- manufacturing or operations personnel who understand the process operations on site;

1) HACCP plan: A document prepared in accordance with the principles of HACCP to ensure control of hazards that are significant for food safety in the segment of the food chain under consideration [4]. The HACCP plan is simply the documentation produced that shows how significant hazards will be controlled.

Box 10.2 The HACCP principles (from [4]).

Principle 1
Conduct a hazard analysis.

Principle 2
Determine the critical control points (CCPs).

Principle 3
Establish critical limit(s).

Principle 4
Establish a system to monitor control of the CCP.

Principle 5
Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.

Principle 6
Establish procedures for verification to confirm that the HACCP system is working effectively.

Principle 7
Establish documentation concerning all procedures and records appropriate to these principles and their application.

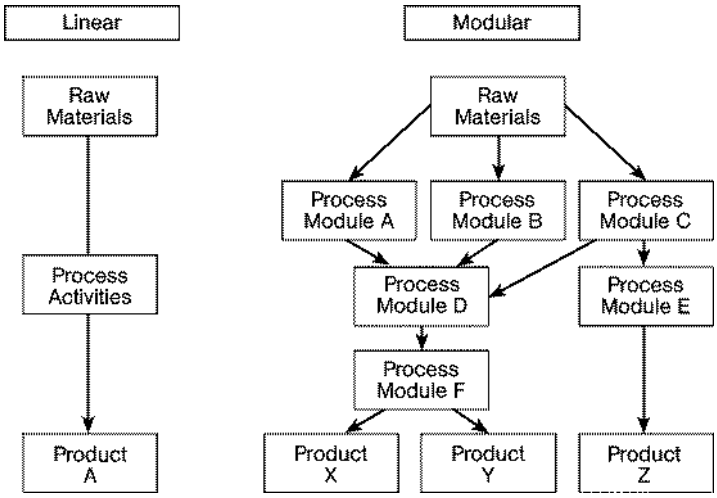

Fig. 10.2 Linear and modular HACCP system example layouts.

- quality or technical personnel who understand the product's technical characteristics regarding hazard control and have up to date information on likely hazards in that sector of the food industry;
- engineering personnel who have knowledge and experience of the equipment and process operations in use on site.

Box 10.3 Logic sequence for application of the Codex HACCP principles (adapted from [4]).

Logic sequence for application of HACCP	
Step 1	Assemble HACCP team
Step 2	Describe product
Step 3	Identify intended use
Step 4	Construct flow diagram
Step 5	On-Site confirmation of flow digram
Step 6	List all potenzial hazards, conduct a hazard analysis and consider control measures
Step 7	Determine CCPs
Step 8	Establish critical limits for each CCP
Step 9	Establish a monitoring system for each CCP
Step 10	Establish corrective actions
Step 11	Establish verification procedures
Step 12	Establish documentation and record keeping

In addition to the above disciplines, it can be helpful to include personnel from the following areas; however the total size of a HACCP team is best kept to 4–6 personnel for ease of management:

- microbiology;
- supplier/vendor assurance;
- storage and distribution;
- product development.

Step 2. Describe Product It is important for all members of the HACCP team to understand the background to the product/process that they are about to study. This is achieved by constructing a product description (also known as a process description). The product description is not simply a specification for the product, but rather contains information important to making safety judgments. The following criteria are normally included:

- hazard types to be considered;
- main ingredient groups to be used in the product/process line;
- main processing technologies;
- key control measures;
- intrinsic (recipe) factors;
- packaging system;
- start and end points of the study.

The task of constructing a product description helps to familiarize all HACCP team members with the product/process under study. It is normal practice to document the product description and include it with the HACCP plan paperwork. The document is also useful at later stages as a familiarization tool for HACCP system auditors or any personnel who need to gain an understanding of the HACCP plan.

Step 3. Identify Intended Use It is necessary to identify the intended use of the product, including the intended consumer target group, because different uses may involve different hazard considerations and different consumer groups may have varying susceptibilities to the potential hazards. This information is usually included as part of the product description (Step 2).

Step 4. Construct Flow Diagram A process flow diagram, outlining all the process activities in the operation being studied, needs to be constructed. This should list all the individual activities in a stepwise manner and should show the interactions of the different activities. The purpose of the process flow diagram is to document the process and provide a foundation for the hazard analysis (Step 5). A simple example of a process flow diagram is shown in Fig. 10.3. This shows a process module taken from a modular HACCP system at a milk processing plant.

Notice that the steps are shown as activities. A common error in HACCP is to list the names of the process equipment rather than the process activity (Fig. 10.4). This error can cause difficulties, particularly where more than one process activity takes place in the same piece of equipment, since different haz-

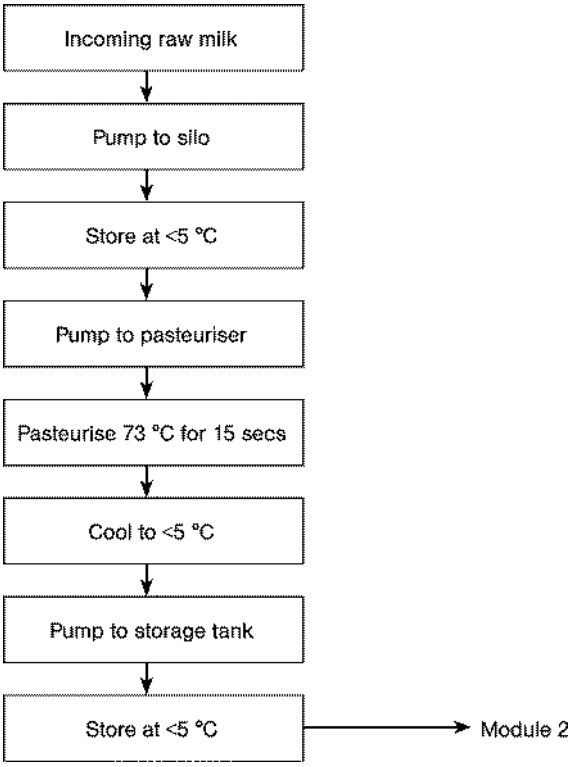

Fig. 10.3 Example of a process flow diagram.

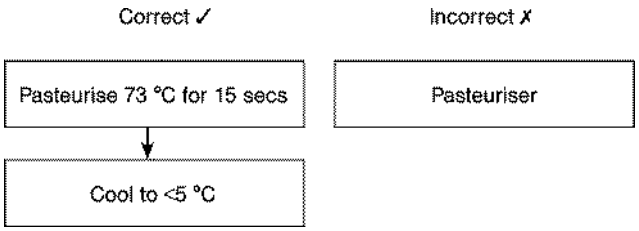

Fig. 10.4 Process flow diagrams – process activities vs equipment names.

ards can apply. The example shown in Fig. 10.4 is for the pasteurisation process where two different steps, the pasteurisation heat treatment and the cooling process, take place in the same piece of equipment: the pasteuriser. These steps have different potential hazards, the former being survival of vegetative pathogens if the heat process is not effective and the latter being potential cross-contamination with pathogens from raw milk during cooling due to inadequate pressure differential in the pasteuriser.

Step 5. On Site Confirmation of Flow Diagram Since the process flow diagram is used as a tool to structure the hazard analysis, it is important to check and confirm that it is correct. This is done by walking the line and comparing the documented diagram with the actual process activities, noting any changes necessary. This exercise is normally done by members of the HACCP team but could also be done by process line operators. The completed process flow diagram should be signed off as valid by a responsible member of staff, e.g. the HACCP team leader.

Step 6. List all Potential Hazards, Conduct a Hazard Analysis and Consider Control Measures Using the process flow diagram, the HACCP team now needs to consider each step in turn and list any potential hazards that might occur. They should then carry out an analysis to identify the significant hazards and identify suitable control measures. These terms are defined by Codex [4] as follows:

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

Hazard Analysis: the process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan;

Control Measure: an action or activity that can be used to prevent, eliminate or reduce a hazard to an acceptable level.

An example of hazard analysis for two steps from the milk process flow diagram (see Fig. 10.3) is given in Table 10.5. Note, only one potential hazard has been detailed for each process step – there may be others.

The process of hazard analysis requires the team to transcribe each process activity to a table such as the example given, consider any potential hazards

Table 10.5 Example of hazard analysis process.

Process step	Hazard and source/cause	Significant hazard? (yes or no)	Control measure
Incoming raw milk	Presence of vegetative pathogens, e.g. *Salmonella,* due to contamination from animal	Yes	Control by pasteurisation step in process
Pasteurisation	Survival of vegetative pathogens, e.g. *Salmonella,* due to incorrect heat process	Yes	Effective heat process (correct time/temperature combination)

along with their sources or causes and then evaluate their significance. To identify the significant hazards, it is necessary to consider the likelihood of occurrence of the hazard in the type of operation being studied as well as the severity of the potential adverse effect. This may be done using judgement and experience or using a structured 'risk assessment' method, where different degrees of likelihood and severity are weighted to help with the significance decision. Effective control measures then need to be identified for each significant hazard.

Step 7. Determine CCPs Critical control points (CCPs) are the points in the process where the hazards must be controlled in order to ensure product safety. They are defined by Codex [4] as follows:

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

It is important to identify the correct points as CCPs so that resource can be focused on their management during processing. CCPs can be identified using HACCP team knowledge and experience or by using tools such as the Codex CCP decision tree (see Fig. 10.5). More detailed explanations on the identification of CCPs and use of decision trees can be found in other publications, e.g. [1, 13].

Step 8. Establish Critical Limits for each CCP Critical limits are the safety limits that must be achieved for each CCP to ensure that the products are safe. As long as the process operates within the critical limits, the products will be safe but if it goes beyond the critical limits then the products made will be potentially unsafe. Critical limits are defined by Codex [4] as follows:

Critical limit: a criterion that separates acceptability from unacceptability.

Critical limits are expressed as absolute values (never a range) and often involve criteria such as temperature and time, pH and acidity, moisture, etc.

Step 9. Establish a Monitoring System for each CCP Monitoring is necessary to demonstrate that the CCPs are being controlled within the appropriate critical limits. Monitoring requirements are specified by the HACCP team during the

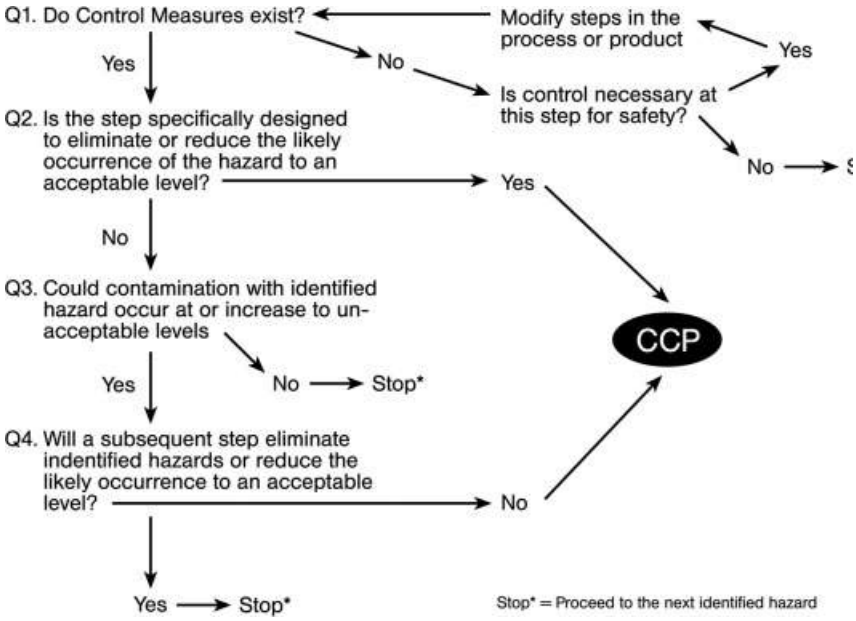

Fig. 10.5 CCP decision tree; from [4].

HACCP study but will usually be done by the process operators when the HACCP plan is implemented in the operation.

Monitoring: the act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control; Codex [4].

Monitoring should be defined in terms of the monitoring activity itself, along with the frequency and responsibility for doing the task.

Step 10. Establish Corrective Actions Corrective action needs to be taken where monitoring shows that there is a deviation from a defined critical limit. Corrective actions will deal with the material produced while the process is out of control and will also bring the process back under control.

Corrective action: any action to be taken when the results of monitoring at the CCP indicate a loss of control; Codex [4].

As for monitoring, the corrective action procedures and responsibility need to be identified by the HACCP team during the HACCP study, but will be implemented by the appropriate operations personnel if deviation occurs.

A completed table demonstrating control of CCPs using critical limits, monitoring and corrective action is shown as Table 10.6.

Step 11. Establish Verification Procedures The HACCP team needs to consider how to determine if the HACCP system is valid and working effectively over

Table 10.6 Example of CCP control.

Process step	Hazard	Control measure	Critical Limit	Monitoring			Corrective Action	
				Procedure	Frequency	Responsibility	Activity	Responsibility
Pasteurisation	Survival of vegetative pathogens, e.g. *Salmonella*	Correct temperature and time regime: effective heat process	71.7 °C for 15 s	Chart recorder: visual check and sign off	Each batch	Pasteuriser operator	Report to supervisor, contact QA and discuss; ensure divert working correctly; if not, dump/re-process	Pasteuriser operator, production supervisor, QA manager, plant engineer
				Check auto-divert function	Daily at start up and shutdown	Pasteuriser operator	Hold product until correct heat process verified; dump/reprocess if not	Pasteuriser operator, production supervisor, QA manager, plant engineer

time. Verification procedures are the methods that will be used to demonstrate compliance and verification is defined by Codex [4] as:

Verification; the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine compliance with the HACCP plan.

Commonly used verification procedures include:

- HACCP audits;
- review of CCP monitoring records;
- validity assessment of HACCP plan elements;
- product testing – microbiological and chemical;
- review of deviations, including product disposition and customer complaints.

Step 12. Establish Documentation and Record Keeping It is important to document the HACCP system and to keep adequate records. The HACCP plan will form a key part of the documentation, outlining the CCPs and their management procedures (critical limits, monitoring, corrective action). It is also necessary to keep documentation describing how the HACCP plan was developed, i.e. the hazard analysis, CCP determination and critical limit identification processes.

When the HACCP plan is implemented in the operation, records will be kept on an ongoing basis. Essential records include:

- CCP monitoring records;
- records of corrective actions associated with critical limit deviation;
- records of verification activities;
- records of modifications to processes and the HACCP plans.

10.4.2
Implementing and Maintaining a HACCP System

The twelve steps of the HACCP logic sequence outlined above describe how to develop HACCP plans and their associated verification and documentation requirements. However they do not describe how to implement the HACCP plans into everyday practice. Implementing HACCP requires careful preparation and training of the workforce and is, perhaps, best managed as a change management process. Depending on the maturity of the operation, this may be a straightforward implementation of the HACCP requirements or may require a culture change.

The implementation stage is where the HACCP plans are handed over from the HACCP team(s) that worked on the development process to the operations personnel who will manage the CCPs on a day to day basis. Training for the personnel who will monitor CCPs and take corrective action is essential and HACCP awareness training for the operations workforce is advisable. HACCP monitoring personnel need to understand the monitoring procedures and frequency, as well as how to record results and when corrective action must be taken.

After implementation, the HACCP verification procedures identified in Step 11 of the HACCP logic sequence need to commence. Results of verification should be reviewed regularly and actions should be taken where necessary to strengthen the HACCP system.

10.4.3
Ongoing Control of Food Safety in Processing

In order to ensure ongoing control of food safety, the prerequisite programmes, HACCP and safe design processes need to work together as a cohesive system. The keys points to ongoing control of food safety are:

- verification of food safety system elements effectiveness;
- review of system elements and their suitability for food safety;
- change control procedures that require safety assessment and approval for all proposed changes to ingredients, process activities and products;
- ongoing management and update of system elements;
- training of staff.

As shown at the start of this chapter (see Fig. 10.1), the management of food safety system elements is often done using an overall operations management system, e.g. the quality management framework ISO 9001:2000 [2]. At the time

of writing, a new ISO standard for food safety management, ISO 22000 [14], is at the draft stage. This document includes HACCP, quality management and prerequisite programme requirements. It remains to be seen what the take up of this ISO Standard will be by food processing companies. Other external Standards also require food companies to manage food safety through prerequisite programmes, management practices and HACCP. These include retail-driven Standards such as the BRC Global Technical Standard – Food [15], manufacturing Standards such as the American NFPA-Safe Program [16] and national expert Standards such as the Netherlands National Board of HACCP Experts HACCP Code [17].

External standards for food safety management can be helpful in giving an external perspective as well as keeping the requirements for food safety in the forefront of people's minds. These schemes are now a requirement for doing business in many areas, required by manufacturers and retailers alike.

The essential requirement for any food processor is that they can manage their facility, ingredients, processes and products to ensure that only safe products reach the customer. The food safety system elements – safe design, prerequisite programmes and HACCP – described in this chapter will allow the requirement for safe food to be achieved. The use of an external audit standard to assess the operation of system elements may be a business requirement for some companies or may be regarded as an optional extra by others. Either way, it is important to assess regularly whether the systems are working and therefore that there is ongoing control of food safety.

References

1 Mortimore, S. E., Wallace, C. A. **1998**, *HACCP: A Practical Approach*, 2nd edn, Aspen Publishers, Gaithersburgh.

2 International Organisation for Standardisation **2000**, *ISO 9001:2000, Quality Managment Systems – Requirements*, International Organisation for Standardisation, London.

3 Mortimore, S. E. **2001**, How to Make HACCP Work in Practice, *Food Control* 12, 209–215.

4 Codex Committee on Food Hygiene **1997**, HACCP System and Guidelines for its Application, in *Food Hygiene Basic Texts*, ed. Food and Agriculture Organisation of the United Nations, World Health Organisation, Rome, pp 33–45.

5 Kyriakides, A. L. **2005**, The Principles of Food Safety, in *Training and Education for Food Safety*, ed. C. A. Wallace, Blackwell Science, Oxford.

6 International Commission on Microbiological Specifications of Foods **1996**, *Microbiological Specifications of Food Pathogens* (*Microorganisms in Foods 5*), Blackie Academic & Professional, London.

7 World Health Organisation **1999**, *Strategies for implementing HACCP in small and/or less developed businesses* (Report of a WHO consultation, WHO/SDE/PHE/FOS/99.7), WHO, Geneva.

8 Canadian Food Inspection Agency **2000**, Prerequisite Programs, in *Guidelines and Principles for the Development of HACCP Generic Models*, 2nd edn (*Food Safety Enhancement Program Implementation Manual*, vol. 2), available at: www.inspection.gc.ca/english/fssa/polstrat/haccp/manu/vol2/volii/pdf.

9 NACMCF **1997**, *Hazard Analysis and Critical Control Point Principles and Appli-*

cations Guidelines, www.seafood_ucdavis.edu/Guidelines/nacmcfl.htm.

10 Codex Committee on Food Hygiene **1999**, *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969, rev. 3-1997, amended 1999), Food and Agriculture Organisation of the United Nations, Rome.

11 Institute of Food Science and Technology **1998**, *Food & Drink – Good Manufacturing Practice: A Guide to its Responsible Management*, 4th edn, Institute of Food Science and Technology, London.

12 Sprenger, R. **2003**, *Hygiene for Management*, Highfield Publications, Doncaster.

13 Mortimore, S. E., Wallace, C. A. **2001**, *HACCP – Food Industry Briefing*, Blackwell Science, Oxford.

14 International Organisation for Standardisation **2003**, *Food Safety Management Systems – Requirements* (*ISO/CD 22000, draft*), ISO/TC 34 N60, International Organisation for Standardisation, London.

15 British Retail Consortium **2003**, *BRC Global Standard – Food* (Issue 3), The Stationery Office, London.

16 National Food Processors Association **2004**, *NPFA – Safe Program Policies and Procedures Manual,* National Food Processors Association, Washington D.C., available at: www.nfpa-safe.org.

17 Netherlands National Board of HACCP Experts **2002**, *Dutch HACCP Code* (*Requirements for a HACCP Based on Food Safety System*, Ver. 3), Netherlands National Board of HACCP Experts, The Hague, available at: www.foodsafetymanagement.info.

18 Engel, D., MacDonald, D. **2001**, *Managing Food Safety*, Chadwick House Group, London.

19 Kyriakides, A., Bell, C. **1999–2005**, *The Practical Food Microbiology Series (Listeria 2005, E. coli 1999, Clostridium botulinum 2000, Salmonella 2001*), Blackwell Publications, Oxford.

20 Mortimore, S. E., Mayes, T. **2001**, *Making the Most of HACCP – Learning from Others' Experience,* Woodhead Publishing, Cambridge.

21 Wallace, C. A., Williams, A. P. **2001**, Pre-Requisites – a Help or a Hindrance to HACCP, *Food Control* 12, 235–240.