Part I
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HACCP and ISO 22000 – A Comparison of the Two Systems
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1.1 HACCP
1.1.1 Introduction to HACCP

Food safety in the early twenty-first century is an international challenge requiring close cooperation between countries in agreeing standards and in setting up transnational surveillance systems. The lessons of the past two decades are plain to those engaged in the food industry. No longer can farmers grow just what they want or use technical aids to farming without taking into account the effect on the quality of the food produced (Rooney and Wall, 2003). The behaviour of European consumers has been gradually changing. They currently require not only much higher dietary quality, hygiene and health standards in the products they purchase, but they also look for certification and reassurance of products’ origins (national or geographical) and production methods. This heightened consumer awareness is reflected in the demand for products endowed with individual characteristics due to specific production methods, composition or origin (national or geographic; Anon, 2004).

No matter how professional and effective a company may be, there is always the possibility of a serious problem arising which is unforeseen or eventually develops into a major crisis. However, thinking through the possible ramifications of such an eventuality and preparing responses and scenarios to deal with it, always ensures that an organisation is better prepared for the unexpected (Doeg, 1995). The Hazard Analysis and Critical Control Point (HACCP) system is a science-based system created to identify specific hazards and actions to control them in order to ensure food safety and quality. It can be considered an efficient tool for both the food industry and health authorities in preventing foodborne diseases (Vela and Fernandez, 2003). A ‘hazard’ is ‘a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect’ (Codex Alimentarius, 1997). A HACCP system should be developed for every food production line and adapted for the individual products and processes (da Cruz et al., 2006). HACCP systems have become mandatory for food industry in the European Union (European Community Directive, 1993).

Food complaints fall into 7 broad categories within which there are a number of possible subcategories:

1. A complaint from a consumer
   (a) Food complaints fall into four broad categories:
      (i) foreign objects found in food or food not meeting the consumers’ expectations
      (ii) poor premises conditions
      (iii) poor food handling practices, or
      (iv) alleged cases of food poisoning

2. A complaint from the regulatory authorities
   (a) Often instigated by a complaint from consumers and falling into the same broad sub-categories as given above
   (b) As a result of routine monitoring and premise visits
   (c) As a result of investigations into events such as outbreaks of ‘food poisoning’

3. A phone call from the police
   (a) For example, warning of
      (i) an incidence of food poisoning in the area
      (ii) detection of ‘food fraud’
      (iii) malicious action or intended action against the company or its products.

4. A threatening message direct to the company as per 3 (iii) above
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5. An enquiry from the media
6. The knock-on effect of a problem in another country
7. An industry issue, such as the use of an ingredient (Doig, 1995).

To be effective, a food safety management system (FSMS) as exemplified by HACCP and mandatory under 2001/47/EC requires monitoring and control (of critical limits) of those process stages deemed critical to food safety. These process stages, identified as critical control points (CCPs), should be monitored and all non-compliance immediately corrected by removing the offending material, by re-skilling staff and by rectifying identified process or equipment faults (Ryan, 2007). HACCP procedures should be documented at all times. Record keeping is essential for providing documentation to the HACCP system and to verify the proper functioning of the system. Documentation and record keeping examples are given in Codex Alimentarius (2001).

Consumer awareness of the benefits that the HACCP approach provides is absolutely essential for effective implementation of HACCP programmes. What should be avoided is a consumer’s misconception that HACCP represents only an extension of industry self-certification programmes without food authority control over the process (Kvenberg, 1998). HACCP systems are often seen as unnecessary, burdensome and bureaucratic in the food industry. They are often ineffective because the premise of the system is not emphasised. HACCP was intended to be ‘a minimal system that ensures maximum control’. It is important that employees understand its many benefits, including reduced waste and downtime. The system can become overly complicated due to a lack of internal knowledge of microbiological and toxicological issues, forcing those involved to seek advice from outside sources (Mortimore, 2003). A study revealed that in companies with less than 50 employees, HACCP implementation decreased proportionally as the number of employees decreased (Pansuello et al., 1999).

An analysis of the barriers to HACCP implementation which include availability of appropriate training in HACCP methodology, access to technical expertise and the required resources (infrastructure and personnel) is available. The burden that this places on the small business are documentation, validation and verification (Taylor, 2001).

1.1.2 History of HACCP – outbreaks

The acronym HACCP is one which evokes ‘food safety’. Originally developed to ensure microbiological safety of foodstuffs, HACCP has been broadened to include chemical and physical hazards in foods. The recent growing worldwide concern about food safety amongst public health authorities, consumers and other concerned parties, fuelled by the continuous reports of foodborne ‘disease’ outbreaks have been a major impetus in the introduction and widespread application of the HACCP system (http://www.unido.org/userfiles/cracknej/fgs1.pdf). HACCP is merely a tool and is not designed to be a stand-alone programme. To be effective, other tools should include adherence to good manufacturing practices (GMPs), use of standard sanitation operating procedures and personal hygiene programmes (Rushing and Ward, 1999).

The HACCP system for managing food safety concerns grew from two major developments. The first breakthrough was associated with W.E. Deming, whose theories of quality management are widely regarded as a major factor in turning around the quality of Japanese products in the 1950s. Dr Deming and others developed Total Quality Management (TQM) systems, which emphasised a total systems approach to manufacturing that could improve quality while lowering costs (FAO, 1998). The second breakthrough was the HACCP proposal by the Pillsbury Company, NASA and the US Army laboratories. This was based on the Failure, Mode and Effect analysis (FMEA) as used by engineers in construction designs. The HACCP concept was introduced in the United States in 1971 at the Conference of Food Protection where it was ‘recommended for widespread use’ (Bauman, 1974; FDA, 1972). The call for change was galvanised in the early 1990s with a tragic outbreak of Escherichia coli O157:H7 foodborne illness in the Northwest of the United States. Four children died and hundreds of people were taken ill in this outbreak, which resulted from the consumption of undercooked, contaminated ground beef. Food Safety and Inspection Services (FSIS) developed the regulatory proposal that became the Pathogen Reduction/HACCP System Rule (published as a final rule in 1996; Hulebak and Schlosser, 2002). Subsequently, as a means of safe food production, HACCP principles were adopted worldwide as given in Codex Alimentarius Commission (1997) and the National Advisory Committee on Microbiological Criteria for foods (NACMCF, 1992).

HACCP became a mandatory programme for approximately 4000 seafood processors in December 1997 and also for foreign processors that ship seafood to the United States (FDA, 2001). The following month, in January 1998, the USDA’s Food Safety and Inspection Service (FSIS) began implementing HACCP in the meat and poultry industry, starting with the largest...
Table 1.1 Overview of HACCP systems.

<table>
<thead>
<tr>
<th>Date</th>
<th>Highlights of HACCP</th>
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<tbody>
<tr>
<td>1959</td>
<td>The Pillsbury Company develops concept for NASA</td>
</tr>
<tr>
<td>1971</td>
<td>US national conference on food protection (1st mention of HACCP)</td>
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<tr>
<td>1972</td>
<td>The Pillsbury Company in the United States began the application of its HACCP concept to the manufacture of its consumer food products</td>
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<tr>
<td>1973</td>
<td>The Pillsbury Company published the first HACCP text in ‘Food Safety Through the Hazard Analysis and Critical Control Point System’</td>
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<td>1980</td>
<td>WHO/ICMSF report on HACCP</td>
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<td>1983</td>
<td>WHO Europe recommends HACCP</td>
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<td>1985</td>
<td>National Academy of Science report on HACCP</td>
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<tr>
<td>1988</td>
<td>Formation of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF)</td>
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<td>1989</td>
<td>National Advisory Committee of Microbiological Specification for Food document endorsing HACCP approach</td>
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<td>1990</td>
<td>Richmond Report advocated use of HACCP</td>
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<td>1991</td>
<td>Codex HACCP draft</td>
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<tr>
<td>1992</td>
<td>The NACMCF system defined HACCP as ‘a systematic approach to be used in food production as a means to assure food safety’</td>
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<tr>
<td>1993</td>
<td>EU Commission 93/43/ECC recommended use of 5 HACCP principles</td>
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<tr>
<td>1995</td>
<td>Codex Document on HACCP principles and application</td>
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<tr>
<td>1998</td>
<td>FAO/WHO provide guidance for regulatory assessment of HACCP</td>
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<td>2003</td>
<td>FAO/WHO develop HACCP guidelines</td>
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<td>2004</td>
<td>EC 852/2004 requirement for all food businesses to adopt HACCP principles in EU</td>
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<tr>
<td>2006</td>
<td>Legal requirements to apply HACCP in food businesses (other than primary production) across EU</td>
</tr>
<tr>
<td>2006+</td>
<td>Increased worldwide use of HACCP in food safety legislation</td>
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plants (FSIS, 1996). Meat and poultry HACCP implementation was completed in January 2000 (FSIS, 2000a, b). At the 35th Session of the Codex Committee on Food Hygiene in 2003, it was agreed that FAO and WHO would develop HACCP guidelines for small and/or less developed businesses (SLDBs), highlighting potential obstacles and approaches to overcome these obstacles. The FDA defines the term ‘small and/or less developed businesses’ shall mean businesses because of their size, lack of technical expertise, economic resources, or the nature of their work, encounter difficulties in implementing HACCP in their food business. The term ‘less developed business’ refers to the status of the FSMS and not to the number of staff or volume of production (FAO/WHO, 2006a).

The highlights of the HACCP system are presented in Table 1.1.

1.1.3 Codex Alimentarius

A Codex Alimentarius programme was initiated in the early 1960s under FAO/WHO control with the specific aim of getting international agreements on food standards and codes of practice which would safeguard the health of consumers and generally encourage good practices in the food trade (Forsythe and Hayes, 1998). The Codex Alimentarius (Latin, meaning Food Law or Code) is a collection of internationally adopted food standards presented in a uniform manner. It also includes provisions of an advisory nature in the form of codes of practice, guidelines and other recommended measures to assist in achieving the purposes of the Codex Alimentarius (FAO/WHO, 2005). The Codex Alimentarius has gained a greater significance since the formation of the World Trade Organisation (WTO). The Agreement on the Technical Barriers to Trade (TBT), which was introduced following the Tokyo Round on World Trade in 1979, had a substantial impact on the establishment of policies on food control. The TBT agreement did not specifically mention Codex but dealt with the aspects of food not directly related to safety such as labelling, quality and packaging and thus impinged on Codex. The WTO, however, recognised Codex as the preferred international organisation for the arbitration and settlement of disputes related to food trade (Ottaway, 2003).

The Codex Alimentarius Commission is committed to protecting the health of consumers, ensuring fair practices in the food trade and facilitates international trade in food. The Codex General Principles of Food Hygiene has recommended a HACCP-based approach as a means to enhance food safety and has indicated...
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how to implement the principles (Codex Alimentarius, 1997). All member nations and associate members of the FAO and WHO can become members of Codex. The membership has increased over the years and 165 countries were Codex members in 2000, representing 97% of the world's population (Ottaway, 2003). The Codex Guidelines for the application of the HACCP system published in 1993 have been revised and the revised text entitled Hazard Analysis and Critical Control Point (HACCP) system and guidelines for its application was adopted by the Codex Alimentarius Commission in June 1997 in the document 'Codex Alimentarius Commission, Report of the Twenty-Second Session of the Codex Alimentarius Commission, Geneva, June 1997' (http://www.unido.org/userfiles/cracknej/fgfs1.pdf).

The Codex general principles of food hygiene are as follows:

1. Identify the essential principles of food hygiene applicable throughout the food chain, in order to achieve the goal of ensuring that food is safe and suitable for human consumption.
2. Recommend a HACCP-based approach as a means of enhancing food safety.
3. Indicate how to implement those principles.
4. Provide guidance to specific codes which may be needed for sectors of the food chain, processes or commodities, to amplify the hygiene requirements specific to those areas (FAO/WHO, 2005).

Although Codex claims to have 'broad community involvement' to increase consumer protection with internationally recognised scientific food standards, its achievements fall flat under scrutiny. The Codex does not rely on community involvement in its decision-making process; decisions are made by governmental appointees behind closed doors (http://www.citizen.org/documents/codexfactsheet.pdf).

1.1.4 The need for HACCP

To successfully implement HACCP in the food supply system, authorities responsible for food safety should first be aware of the need to move to a system such as HACCP. Until this need is acknowledged, it is unlikely that a commitment at any level can be expected (http://www.unido.org/userfiles/cracknej/fgfs1.pdf). In a survey conducted to find out whether HACCP was a more effective strategy than their current or other method(s) industry groups had used to secure food hygiene, 41% strongly agreed, 50% agreed, while only 9% did not think that the strategy was more effective than their current provisions (Ehiri et al., 1997).

Motivations for adopting HACCP may include the need to:
- reduce the incidence of foodborne disease
- ensure a safe food supply for the population
- promote (facilitate) trade in food products

1.1.5 Hazards (physical, chemical, microbiological)

The regulation defines a food safety hazard as ‘Any biological, chemical or physical property that may cause a food to be unsafe for human consumption' (USDA, 1997). While consumers have historically been most concerned with chemical hazards such as pesticide residues and heavy metal contamination, microbiological contaminants and allergens have been the recent focus of public health officials' concerns (Fig. 1.1). The HACCP system addresses and controls all significant hazards associated with a particular product (Goodrich et al., 2005). At a cost of about $1000 per case of disease (Canadian and USA estimates), the economic impact in the Federal Republic of Germany had been valued at more than 10 billion DM (Untermann, 1995). There are three categories of hazards that are considered in a HACCP plan. These are physical, chemical and biological. All types of hazard can enter a food product at any stage during processing (Harris, 1999). Potentially hazardous foods include meats, dairy products, poultry, eggs, cooked foods (beans, pasta, rice and potatoes), cut cantaloupe and raw seed sprouts (McSwane et al., 2000).

1.1.5.1 Physical hazards

Physical hazards include glass, metal, stones, wood, plastic, rubber or pests (typically larger pests). Sand may also be an undesirable foreign material in a prepared salad but it is not likely to cause human illness (Harris, 1999). However, foreign objects which cannot or do not cause illness or injury are not hazards, even though they may not be aesthetically pleasing to the consumers (USDA, 1997). Physical hazards commonly result from accidental contamination and poor food handling practices that can occur at various points in the food chain from harvest to consumer (McSwane et al., 2000). Confirmed cases of foreign materials in US food versus time are presented in Fig. 1.2.

The Canadian Food Inspection Agency (CFIA) defines three classes of physical hazards depending on their likelihood and the severity of the consequences:
- Category I (high likelihood)
- Category II (moderate likelihood)
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Fig. 1.1 Problems in the international trade in food that are related to deficiencies in basic hygienic measures (FAO, 2000; Orriss and Whitehead, 2000).


To prevent physical hazards, wash raw fruits and vegetables thoroughly and visually inspect foods that cannot be washed (such as ground beef). Food workers should be taught to handle food safely to prevent contamination by unwanted foreign objects. Finally, food workers should not wear jewelry when involved in the production of food, except for a plain wedding band (McSwane et al., 2000). Nowadays, there are various methods for the detection of foreign materials such as metal detectors, low-energy X-rays etc. which are used in the food industry.

1.1.5.2 Chemical hazards

Chemical hazards include cleaning chemicals, pesticides (including those not applied in or around food processing establishments), allergens, toxic metals, nitrites and nitrates (when added to the product),

Fig. 1.2 Determined cases of foreign materials in United States versus time. (Adapted from Arvanitoyannis et al., 2006)
plastics and packaging migration, veterinary residues (when animals have been given drugs to treat disease in the animal, e.g. antibiotics treatments for mastitis in cows) and chemical additives (when added; Harris, 1999). Between 5 and 8% of children and 1–2% of adults are allergic to certain chemicals in foods and food ingredients. These chemicals are commonly referred to as food allergens (McSwane et al., 2000).

Chemical hazards fall into two categories:

- Naturally occurring poisons, chemicals or deleterious substances are those that are natural constituents of foods and are not the result of environmental, agricultural, industrial or other contamination (e.g. aflatoxins, mycotoxins, shellfish toxins).
- Added poisonous chemicals or deleterious substances are those which are intentionally or unintentionally added to foods at some point in growing, harvesting, storage, processing, packing, or distribution (e.g. pesticides, fungicides, insecticides, fertilisers, drug residues, antibiotics, food additives, lubricants, cleaners, paints, coatings; USDA, 1997).

Because it is impossible to provide a comprehensive list of contaminants, it would be much better to focus on purity of water, raw material supply, workers’ poor hygiene and lack of GMP in order to reduce the probability of occurrence of chemical hazards.

### 1.1.5.3 Biological hazards

Biological hazards include food poisoning bacteria such as Salmonella, E. coli and Bacillus cereus, which are hazardous because they can survive inadequate cooking, grow to harmful levels in stored food given the right conditions and spread from raw foods to ‘ready to eat foods’ (cross-contamination) (www.cardiff.gov.uk/ObjView.asp?Object_ID=3968). After World War II, serious food safety incidents occurred in the nascent food processing industry. These typically involved Salmonella contamination of dried egg or dairy products, Campylobacter spp. in canned meat or Clostridium botulinum growth or presence in canned foods. The most pressing food safety issues in the food industry nowadays are due to the presence of E. coli O157:H7 and salmonellae in raw meat and poultry products and in produce (Sperber, 2005). E. coli O157:H7 is usually transferred to foods like beef through contact with intestines of slaughtered animals. Apples used for juice from orchards where cattle or deer graze are also suspected (McSwane et al., 2000). Pathogens come from:

- low quality of raw materials
- poor personal hygiene

- environment (air, water and equipment)
- inadequate cooking
- improper storage/holding temperature
- improper reheating
- cross-contamination – improper segregation of raw and cooked foods

An annual consumer survey carried out by the Food Marketing Institute (FMI) from 1993 through 1997 showed that the number of people who said they were ‘very concerned’ about chemical contaminants such as pesticides declined from 79% to 66%. The FMI survey first included questions on microbial contamination in 1993. From 1995 to 1997, microbial contamination topped the list of consumer concerns. By contrast, consumers ranking themselves as very concerned about foods produced using biotechnology have hovered around 15% for the same 3 years (FMI, 2000). Foodborne infections are caused when micro-organisms are ingested and these can multiply in the human body. Infections result when microbial or naturally occurring toxins are consumed in contaminated foods. Micro-organisms or toxins may be introduced directly from infected food animals or from workers, other foods, or the environment during the preparation or processing of food. Poisonous substances may also be produced by the growth of bacteria and moulds in food (Rooney and Wall, 2003).

The numbers and types of bacteria vary from one food or animal species to another, from one geographic region to another, and with production and slaughter or harvesting methods. During production, processing packaging, transportation, preparation, storage and service any food may be exposed to bacterial contamination. The most common biological hazards in meat and poultry are microbiological, although biological hazards may also be due to parasites or zoonotic disease processes (USDA, 1997). Six conditions are required for bacterial growth. They need a nutrient (e.g. meat, poultry, seafood, dairy products, cooked rice, beans, potatoes), a mildly acid environment (pH = 4.6–7.0), a temperature between 5 and 60°C time (approximately 4 hours to grow to high enough numbers to cause illness), different oxygen requiring environments (aerobic, anaerobic and facultative microorganisms), and enough moisture (water activity >0.95 for disease-causing bacteria; Marrero, 1997; McSwane et al., 2000). Microbial cells have a growth cycle of five phases: lag phase (adaptation period), logarithmic growth phase (bacteria multiplication), stationary growth phase (slowdown of growth), accelerated
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Fig. 1.3 Types of contamination (McSwane et al., 2000; http://www.healthandwelfare.idaho.gov/Rainbow/Documents/Health/Food%20Safety%20%20Sanitation%20Manual.pdf).

- Data: McSwane et al., 2000

death phase (rapid death of microbial cells) and reduced death phase (slowdown of death rate; Marriott, 1997). Examples of biological hazards are disease-causing bacteria, viruses, parasites, moulds, yeasts and naturally occurring toxins (Fig. 1.3). Biological hazards cause the most foodborne illness outbreaks and are of the greatest concern to food service managers and health inspectors (http://www.sfdph.org/eh/pubs/foodsafetyfacts/food_hazards.pdf).

Quantitative scientific assessments of the risks from microorganisms in foods and water on the basis of dose–response relationships and exposure assessment, customarily carried out for chemical contaminants, have been developed for some pathogens, especially in drinking water. Two particular difficulties have to be mentioned for the quantification of microbiological hazards associated with the consumption of foods: the determination of the minimal effective dose and the complicated kinetics of bacterial survival, growth and death in foods which necessitate greater care in the monitoring of bacterial contaminations (Untermann, 1998).

1.1.6 The seven principles of HACCP

The application of HACCP is compatible with the implementation of quality management systems such as the ISO 9000 series and is the system of choice in the management of food safety within such systems (Anon, 2000). One of the benefits of the HACCP system is that it focuses attention on areas where problems potentially may occur, and requires that food service facilities be prepared to deal with problems immediately if they occur (Puckett and Schneider, 1997). The HACCP system consists of seven principles (Fig. 1.4). These principles make up the Codex standard, which has become the reference for international food safety and identified as the baseline for consumer protection under the Agreement on Sanitary and Phytosanitary Measures agreed at the General Agreement on Tariffs and Trade (GATT) negotiations in 1995 (Slatter, 2003).

Principle 1 Conduct a hazard analysis. A hazard analysis is the identification of any hazardous biological, chemical or physical properties in raw materials and processing steps, and an assessment of their likely occurrence and potential to cause food to be unsuitable for consumption (USDA, 1997). The HACCP team conducts a hazard analysis and identifies appropriate control measures (Corlett, 1998).

Hazard analysis is accomplished in two stages: (a) hazard identification based on a review of the origins of possible hazards and (b) hazard evaluation within the frame of the potential significance of each hazard is assessed by considering its severity (referring to health consequences) and its like-
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1. Identify hazards, assess risk and list controls
2. Identify critical control points (CCPs) in the process. CCPs are steps at which control can be applied and a food safety hazard can be prevented, eliminated or reduced to acceptable levels (Rushing and Ward, 1999). The HACCP team should identify the steps in the production process which are essential for the elimination or significant reduction of the identified hazards from Principle 1. These CCPs are identified through the use of the decision tree (Fig. 1.5). A CCP should be a quantifiable procedure in order for measurable limits and monitoring to be achievable in Principles 3 and 4 (Forsythe and Hayes, 1998). It is not possible to find CCPs for all types of products and hazards. Especially in low-processed products such as fresh meat, there is almost no site at which microbial hazards can be eliminated. Thus, only hygiene concepts using the basic HACCP methodology can be developed (Upmann and Jacob, 2004). Some common points where control can be applied in a process include:
   1. chilling to temperatures that minimise microbial growth
   2. testing ingredients for chemical residues
   3. cooking to specific temperatures for exact times in order to destroy microbial pathogens
   4. product formulation control, such as the addition of cultures or adjustment of pH or water activity
   5. testing product for metal contaminants
   6. processing procedures such as filling and sealing cans
   7. slaughter procedures such as evisceration or antimicrobial interventions (Corlett, 1998; USDA, 1999).
3. Establish critical limit(s) for preventive measures associated with each identified CCP. Once the CCPs have been determined, a critical limit or the amount of acceptable deviation has to be established for each CCP. Critical limits for CCPs are expressed as numbers or specific parameters on visual observation, such as time/temperature, humidity, water activity, pH, salt concentration and chlorine level (Corlett, 1998; USDA, 1997). There are two types of critical limits. A critical limit can be an upper limit where a set amount or level cannot be exceeded. A critical limit can also be a lower limit where a minimum amount is required to produce the safe effect (USDA, 1999). Critical limits are set for product safety and not product quality.
Fig. 1.5 Process step CCP decision tree. (Adapted from Conlett, 1998; Efstratiadis and Arvanitoyannis, 2000; Horchner et al., 2008; http://www.jphpk.gov.my/Agronomi/KAV/SHACCP1.pdf.)
For example, the critical limit for frozen raw poultry storage and shipping would require the product be held below 5°C, which does not constitute frozen but prevents bacterial growth. In a cooked product, an example of a critical limit would be that an internal temperature of the product reaches at least 71°C (http://www.qsae.org/web_en/pdf/HACCPImpGuide.pdf).

**Principle 4** Establish CCP monitoring requirements and procedures for using monitoring results to adjust processes and maintain control. Monitoring consists of observations or measurements taken to assess whether a CCP is under control. Monitoring is used to determine when a deviation occurs at a CCP and, if it is not continuous, needs to be conducted at a frequency sufficient to ensure that the CCP is under control (Hubeck and Schlosser, 2002). Continuous monitoring is always preferred when it is feasible. When it is not possible, then the HACCP team will need to decide what will be their non-continuous monitoring procedures and how frequently they will be performed. There are several issues to consider when deciding the frequency of non-continuous monitoring checks; the most important is that the procedures should be performed sufficiently often to accurately reflect that the process is under control (USDA, 1999). The most important steps in food production to monitor are:

1. cooking
2. cooling
3. reheating
4. hot holding

(Ropkins and Beck, 2000).

The three basic requirements for developing monitoring procedures for the HACCP plan are:

1. defining the monitoring procedure
2. determining the frequency for monitoring
3. determining who will do the monitoring

(Collett, 1998).

The following forms are representative of those needed for monitoring the HACCP system in most food plants:

1. raw material evaluation sheet
2. supplier’s guarantee
3. cooker log
4. pack room inspection report
5. cooking process validation letter
6. cooking equipment validation letter
7. equipment calibration log
8. corrective action report
9. employee training report

(Collett, 1998).

**Principle 5** Establish corrective actions to be taken when monitoring indicates that a particular CCP is not under control. The regulation defines corrective action as ‘Procedures to be followed when a deviation occurs’. A deviation is a failure to meet a critical limit (USDA, 1997).

The purpose of corrective actions is:

1. to adjust the process, such as cooking temperatures or cooling rates to maintain control or prevent a deviation
2. to correct the cause of the deviation
3. to re-establish control over the process and CCP
4. to determine the safety and proper disposition of the food being produced while a defect was occurring
5. to maintain records of corrective actions

(Ropkins and Beck, 2000).

All corrective actions cannot be anticipated. An unlisted corrective action should be incorporated into the corrective action document. The corrective action will consist of the decision regarding disposal of non-complying material, correcting the cause of deviation, demonstrating that CCP is once again in control, and, finally, maintaining records of the corrective action (Doodhar, 1999).

**Principle 6** Establish procedures for verification to confirm that the HACCP system is working effectively. Verification is the application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan (FAO/WHO, 2001). The verification typically consists of two phases. First, verification that the critical limits established for CCPs will prevent, eliminate or reduce hazards to acceptable limits. Second, verification that the overall HACCP plan is functioning effectively. Once critical limits at each CCP are met, minimal sampling of the final product is needed (McSwane et al., 2000). Basic verification procedures include the following:

1. initiation of appropriate verification inspection schedules
2. review of HACCP plan for completeness
3. confirmation of the accuracy of flow diagram
4. review of CCP records
5. review of records for deviations and corrective actions
6. review of critical limits to verify if they are adequate to control significant hazards
7. validation of the HACCP plan, including on-site review
8. review of the modifications made to the HACCP plan
9. a random sample collection and analysis
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10. visual inspection of food production operations to determine that CCPs are under control
11. a review of departures from critical limits and how they were corrected

(Corlett, 1998; McKwase et al., 2000).

Principle 7 Establish documentation concerning all procedures and records appropriate to these principles and their application. The level of documentation required will depend upon the needs and the complexity of the food business. In a small business, a simple log book or diary may be all that is needed. In a bigger or more complicated business, more detailed or formal documentation will be necessary. Record keeping and documentation systems should meet the needs of the business and be adequate to show that the food safety programme is working (http://www.nzfsa.govt.nz/processed-food-retail-sale/fsp/haccp.pdf).

The HACCP will incorporate documents such as the following:
1. the HACCP plan
2. hazard analysis
3. CCP determinations
4. CCP monitoring sheets
5. corrective actions
6. audit records
7. HACCP team meeting minutes
8. calibration records

(Slatter, 2003).

1.1.7 The 12 stages of the HACCP plan
It is no accident that HACCP evolved at the food processing step of the farm to table supply chain. It is at this step that effective controls, such as cooking, drying, acidification or refining are available to eliminate significant hazards. Two categories of processed food exemplify this fact superbly – pasteurised dairy products and canned foods; note that, with both of these food categories, food safety is assured by process control, not by finished product testing. It is time to stop talking about ‘Farm to Table Food Safety’ (Sperber, 2005).

1.1.7.1 HACCP team formation
The first step is the formation of the HACCP team which should be trained. Training is often provided by people who are not HACCP practitioners – who are instead lecturers, academics, regulators or former hygiene trainers (Mortimore, 2001). The HACCP team is interdisciplinary and its members (their number is 4–6) could be:

- production manager
- head of analytical laboratory
- head of microbiological laboratory
- personnel manager
- technical manager
- logistics manager.

The HACCP team has to provide the production-specific expertise and experience which are necessary for the development of the HACCP plan (Untermann, 1999). The responsibilities of the HACCP team are:

- organising and documenting HACCP study
- reviewing deviation from critical limits
- internal auditing of HACCP plans
- communicating, educating and training employees in the operation of HACCP system
- understanding the stages of the process the team will be monitoring (http://www.ipbpm.gov.my/Agronomi/KAV/SHACCP1.pdf).

1.1.7.2 Describe product
A complete description of the product by providing information about the ingredients, processing methods, retail, packaging and storage conditions should aim at identifying any possible hazards occurring to the product and that which the product may cause (Arvanitoyannis and Hadjicostas, 2001). The following questions should be answered for the product description:

1. What is the common name of the product?
2. How is the product to be used?
3. What type of packaging encloses the product?
4. What is the length of shelf life of the product, at what temperature?
5. Where will the product be sold? *Who is the intended consumer and what is the intended use? (Regulatory requirement)
6. What labelling instructions are needed?

1.1.7.3 Identify intended use
Describe the normal expected use of the food. The intended use consists of information on whether the
product has to be prepared prior to consumption, e.g. by heating or whether it can be consumed directly. With regard to a possible acceptable risk level for a food safety hazard it has to be stated for which group of the population the food is intended (Untermann, 1999). The intended consumers may be the general public or a particular segment of the population (e.g. infants, immunocompromised individuals, the elderly etc.) (NACMCF, 1997).

1.1.7.4 Construct flow diagram

The flow diagram should be constructed by the HACCP team which should be fully familiar with the process. The flow diagram should cover all steps in the operation. When applying HACCP to a given operation, consideration should be given to steps preceding and following the specified operation (FAO/WHO, 2001). A correct flow diagram that identifies all the steps involved in the process should be drawn. The flow diagram may also include steps prior to and after the processing that takes place in the establishment (Fig. 1.6; Arvanitoyannis and Hadjicostas, 2001).

1.1.7.5 On-site confirmation of flow diagram

It is important to check that the flow diagram is accurate by physically checking it against activities and that it includes exceptional items such as breakdowns, rework and cleaning. The team should also check that the flow diagram is correct for any shift pattern (Slatter, 2003). The on-site assessment will normally involve an initial meeting with relevant personnel to explain the nature and extent of the review and to promote cooperation during the assessment. At this stage, any additional documentation required for an on-site review could also be requested and examined (Motarjemi, 2000).

1.1.7.6 On-site verification of flow diagram

The HACCP team should confirm the processing operation against the flow diagram during all stages and hours of operation and amend the flow diagram where appropriate (FAO, 1998). Modifications should be made to the flow diagram as necessary and documented. After these five preliminary tasks have been completed, the seven principles of HACCP are applied (Gorlett, 1999).

List all potential hazards associated with each step, conduct a hazard analysis and consider any measures to control identified hazards (see Principle 1)

Determine CCPs (see Principle 2)

Establish critical limits for each CCP (see Principle 3)

Establish a monitoring system for each CCP (see Principle 4)
1.1.8 HACCP failure

The paradox between the increase in foodborne diseases and the implementation of the HACCP system originates from a misunderstanding of what HACCP is, its role in public health and what can be achieved by its application. The HACCP system *per se* does not make food safe, but it is its ‘correct application’ that can make a difference. Neither is the HACCP system the magic wand which can turn unsafe food into safe food. The HACCP system should not be a tool for politicians to gain the confidence of consumers (Motarjemi and Kasperstein, 1999). Like any other system, HACCP has some vulnerable points, and these may be the major drawbacks for its non-international application during recent years (Arvanitoyannis and Traikou, 2005). A list, by no means complete, of some of the most common problems reported when reviewing HACCP plans:

- Only some of the principles are applied (mainly failure to apply Principles 4 and 5).
- The principles have not been applied appropriately (not identifying hazards properly).
- The HACCP plan is a ‘paper exercise’ and is not implemented in practice.
- The HACCP plan is over-complicated.
- Critical limits that are not adequate and not supported by scientific studies.
- Corrective actions do not address the product involved in a deviation.
- Lack of coordination among responsible authorities, public and private sectors.
- Lack of understanding and staff training.
- Lack of commitment by management.

The question that still remains is ‘When HACCP appears to fail, is it the fault of the HACCP system itself or does the real failure lie with the people who are trying to implement it?’ (Mitchell, 1998).

1.1.9 Prerequisite programmes

The HACCP system will incorporate other existing management systems into its procedures. Typical areas are personal hygiene, GMP, supplier quality assurance and maintenance schedules. These are termed ‘Prerequisite Programmes’ (PRPs) and are normally in place before the HACCP plan is developed. Prerequisites are systems in their own right and will support the HACCP by taking the control of general hygiene and GMP out of the HACCP plan (Slatter, 2003). PRPs to HACCP, including training, should be well established, fully operational and verified in order to facilitate the successful application and implementation of the HACCP system (FAO/WHO, 2006a). A HACCP system can be effective only if it is based on sound good manufacturing and hygienic practices (GMP/GHP). Consequently, it is the responsibility of the government agencies to ensure that these PRPs are properly implemented before assessing HACCP implementation (Ababouch, 2000).

Food safety is not synonymous with HACCP. Food safety plus PRPs (Sperber, 2005).

1.1.9.1 Training of personnel

Training is crucial to any food safety system. Poor staff training in food hygiene is a real threat to the safety of food. Staff should understand how food safety knowledge is applied in the food safety programme. Any staff member without commitment to food safety threatens the entire programme (http://www.nzfsa.govt.nz/processed-food-retail-safety/rsp/haccp.pdf). It is important to recognise that employees should first understand what HACCP is and then learn the skills necessary to make it function properly. Specific training activities should include working instructions and procedures that outline the tasks of employees monitoring each CCP. Management should provide adequate time for thorough education and training. Personnel should be given the materials and equipment necessary to perform these tasks. Effective training is an important prerequisite to successful implementation of a HACCP plan (NACMCF, 1997). Staff should have an understanding of:

1. what hazards are and their importance in food safety
2. CCPs and their role in the assurance of product safety
3. critical limits which should be met
4. corrective actions and responsibilities
5. record-keeping requirements
6. the objective of verification procedures (Slatter, 2003).
The first step in training is usually motivation – explaining that everybody could be a vital link in a chain of events leading either to food poisoning or to product safety. It is important to link ‘hygiene conscience’ with ‘product safety’ from the very beginning (Engel, 1998). The trainer most often achieves the best results by keeping the talk short and by working through a set sequence of discrete steps as follows:

1. show the trainees the actual skill they are to acquire
2. demonstrate and explain the operations involved
3. have trainees imitate the necessary actions
4. have trainees practise performing the operations
5. devote at least 50% of the session to trainee practice time (FAO, 1998).

There are many benefits to proper employee training including:

1. improved customer satisfaction – a well-trained staff provides the service and the quality that customers expect
2. lower turnover – money savings to the organisation, better life quality for the employees, higher client satisfaction
3. lower costs – fewer mistakes by well-trained employees
4. fewer accidents due to experience and good training of employees
5. better quality of products (McSwane et al., 2000).

1.1.9.2 Sanitation
Sanitation is broadly defined by ‘all precautions and measures, which are necessary in the production, processing, storage and distribution, in order to assure an unobjectionable, sound and palatable product which is fit for human consumption’ (Bakka, 1997). Sanitation is not sterilisation (McSwane et al., 2000). The first step of sanitisation is the pre-wash, with the objective of removing gross dirt, followed by alkaline and acid washing (to remove proteins, carbohydrates, lipids and minerals, respectively) (da Cruz et al., 2006). This dirt usually contains micro-organisms and nutrients that allow the microbes to grow (Marriott, 1997).

Micro-organisms die at a relatively constant rate in the accelerated death phase. Some things can change the death rate, such as lethal agent or a mixed population of sensitive and resistant cells. Heat, chemicals and radiation can all destroy microbes (Marriott, 1997). Micro-organisms vary in their degree of susceptibility to disinfectants. In general, Gram-positive bacteria are more susceptible to chemical disinfectants while mycobacteria or bacterial endospores are more resistant. The hydrophilic, non-enveloped viruses (adenoviruses, picornaviruses, reoviruses, rotavirus) are more resistant to disinfection than lipophilic, enveloped viruses (coronaviruses, herpesviruses, orthomyxoviruses, paramyxoviruses, retroviruses; Dvorak, 2005).

Commonly used sanitisers in food establishments are presented below. Sanitisers destroy disease-causing organisms which may be present on equipment and utensils even after cleaning (McSwane et al., 2000).

Heat
Heat is the most common method of killing spoilage and pathogenic bacteria in foods (Marriott, 1997). Heat in the form of pressurised steam is the most effective method of sterilisation; moist heat kills micro-organisms at relatively low temperatures by denaturation of protein but proteins are far more stable in dry conditions so that far higher temperatures and/or longer times are necessary to effect a kill using hot air. Most heat is a favoured disinfesting or sterilising agent because it is non-corrosive, economical, has excellent penetration powers, leaves no residue and is active against the majority of micro-organisms (Forsythe and Hayes, 1998). Bacterial populations killed by heat or chemicals tend to die at constant rates – for example, 50% every 10 minutes (http://webhome.broward.edu/~dweber/MCR2010/Study%20Guides/Ch07_MicrofeStudyGuide.pdf).

Chemicals
Many chemical compounds that destroy micro-organisms should not be used to kill bacteria in or on food. Food processors use chemicals to sanitise equipment and utensils that can cross-contaminate food. These chemicals are rinsed off, so they cannot contaminate food. Sanitising, using heat, has become more expensive, so the food industry uses chemical sanitisers more often (Marriott, 1997). Lactic acid, acetic acid and citric acid also are lethal to many micro-organisms. Several other weak acids (e.g. benzoic acid, sorbic acid, sulphur dioxide etc.) are used as preservatives (Harrigan and Park, 1991). The basic characteristics of the ideal chemical agent are:

1. capacity to kill all microbes
2. soluble in water
3. stable on standing
4. not lose activity over time
5. non-toxic to humans and animals
6. low persistence/OM binding.

Radiation
The process involves exposing the food, either packaged or in bulk, to carefully controlled amounts of ionising radiation for a specific time to achieve certain desirable objectives. When microbes present in the food are irradiated, the energy from the radiation breaks the bonds in the DNA molecules, causing defects in the genetic instructions. Unless this damage can be repaired, the organism will die or will be unable to reproduce. Many different kinds of irradiated food were tested over the years such as fruits (bananas, strawberries, mangoes); vegetables (onions, potatoes, peas, carrots, cabbage); grains (wheat flour); meat (fish, chicken, beef); beans (cocoa beans, coffee beans) and various combinations of these and other foods (Hammond et al., 1996). Efficiency of irradiation is affected by a variety of factors such as temperature, protein content of the suspended medium, water activity, presence of oxygen etc. The greater the dose of irradiation the more extensive is the change in organoleptic quality of the food. One of the anxieties surrounding the introduction of irradiation of foods is that the process may be used to treat food that would otherwise be detectable as unacceptable, in which possibly toxins had already accumulated, for example (Harrigan and Park, 1991).

Filtration
Filtration can act as a consistent and effective barrier for microbial pathogens and may in some cases be the only treatment barrier (e.g. for removing Cryptosporidium oocysts by direct filtration when chlorine is used as the sole disinfectant) (http://www.who.int/water_sanitation_health/dwq/wsp170805chap6.pdf). Bacteria and larger micro-organisms can be removed from otherwise clear liquids by filtration through membranes which have holes with a mean pore size of 0.2 µm (Harrigan and Park, 1991). The membrane processes most commonly used to remove microbes from drinking water are microfiltration (MF), ultrafiltration (UF), nanofiltration (NF) and reverse osmosis (RO). There are very few contaminants that cannot be removed by membrane processes (http://www.who.int/water_sanitation_health/dwq/wsp170805chap6.pdf).

1.1.9.3 Good manufacturing practices
Within the food factory, there should be management procedures aimed at the application of codes of Good Manufacturing Practices (GMPs; Harrigan and Park, 1991). GMPs provide general rules for the manufacture, handling and preparation of various kinds of food products. It aims at safeguarding good hygienic and sensory quality traits and may be regarded as an obligation to bestow great care upon production. GMP principles have been developed over a number of years and are now regarded as the foundation on which the production of safe food is based (Upmann and Jacob, 2004). In July 2002, Food and Drug Administration (FDA) formed a Food GMP Modernization Working Group to examine the effectiveness of current food GMPs given the many changes that have occurred in the food industry since 1986. The Working Group has been researching the impact of food GMPs on food safety, as well as the impact (including economic consequences) of revised regulations. Part of the group’s current effort, as of June 2004, is to find out which elements of the food GMPs are critical to retain and which should be improved. FDA is now holding public meetings to obtain the public’s comments to assist in this effort (U.S. Food and Drug Administration, 2004). In the UK, the Institute of Food Science and Technology publishes guides to GMP (GMP 5, 2007). Industries that have adopted the GMPs have the following results amongst others:

2. Better, more agreeable, cleaner and safer working environment.
3. Greater employee motivation and productivity and improved psychological conditions (da Cruz et al., 2006).

The plant management is expected to take all reasonable measures and precautions to ensure the following:

**Personnel**
- disease control
- adequate personal cleanliness
- washing hands thoroughly before starting work, and after using the toilet, handling money, handling anything dirty
- use of gloves
- wear protective clothing, suitable footwear, hair coverings
• avoid smoking, eating, chewing, spitting, sneezing or coughing in the production area
• removing all unsecured jewelry and other objects that might fall into food (Corlett, 1998; FAO, 1998; Forsythe and Hayes, 1998; Marriott, 1997).

Buildings and facilities
• located away from environmentally polluted areas, areas subject to flooding, areas prone to infestations of pests and areas where wastes cannot be removed effectively
• adequate supply of potable water, natural gas, electricity, fuel and other utilities
• adequate drainage and waste disposal systems, ventilation system to minimise odours and vapours, air conditioning and dust control
• walls should be smooth, waterproof, with no ledges and overhangs
• floors made of materials that are impervious, durable, resistant to grease, cleaning agents and to biochemical and microbial attack, free from cracks, crevices, non-slip-surface, easy to clean
• doors should generally be either opened automatically, or provided with heavy-duty plastic strips which permit easy access by personnel and essential traffic (e.g. fork-lift trucks)
• roofing is normally flat or slightly pitched and is supported by trusses or beams, can be a source of natural light, opening windows not recommended
• adequate lighting in hand-washing areas, dressing and locker rooms, toilet and rooms where food is examined, processed or stored
• pest control (insects, flies, cockroaches, moths and beetles, rodents) (Corlett, 1998; FAO, 1998; Forsythe and Hayes, 1998; Jarvis, 1999; Marriott, 1997; McSwane et al., 2000).

Equipment
• all surfaces in contact with food should be smooth, not porous, inert, visible for inspection, accessible for manual cleaning, made of non-toxic material, corrosion-resistant, designed to resist the extended use, cleaning compounds and sanitising agents
• equipment should be readily disassembled for inspection and manual cleaning, designed to protect the contents from external contamination, sanitised with approved sanitizer and rinsed with potable water if required, equipped with rounded corners and edges (Corlett, 1998; Forsythe and Hayes, 1998; McSwane et al., 2000; http://www.hi-tm.com/RFA/Mfg.ppdm/3-prereq-5-06.pdf).

Production and process controls
• no raw material or ingredient should be accepted if it is known to contain parasites, undesirable micro-organisms, pesticides, veterinary drugs or toxic, decomposed or extraneous substances
• checking of raw materials that come into the plant by collecting samples to decide if they should accept or reject deliveries
• raw material should be washed or cleaned (if necessary) to remove soil or other contaminants
• inspection of the overall condition of the trucks used to transport low-moisture raw materials, for areas where food and dust collect, for insect activity (frozen raw materials and other ingredients should be kept frozen)
• the storage rooms used for food materials should be clean, provide adequate space for inspection, good air circulation, correct temperature and humidity. Food materials should not be placed directly on the floor
• equipment should be sited so that it can be easily operated, cleaned, inspected and maintained, not close to walls, ceilings or other equipment
• packaging materials should be hygienic, odourless, not reacting with either the contained food or the surrounding atmosphere
• waste food materials should be disposed of in an appropriate manner
• cleaning materials should not be left in processing areas
• finished products should be labelled and isolated pending checks for conformity with the product specification
• defective products should remain isolated pending a decision on reworking, recovery or disposal
• final products approved for release should be removed into the relevant warehouse area (Corlett, 1998; FAO, 1998; Forsythe and Hayes, 1998; Jarvis, 1999; Marriott, 1997).

1.1.10 Control measures
Control measures are grouped into three groups as follows:
• PRPs that manage the basic conditions and activities
• operational PRPs that manage control measures that the hazard analysis identifies as necessary to control identified hazards to acceptable levels
HACCP and ISO 22000 – A Comparison of the Two Systems

• a HACCP plan to manage control measures that the hazard analysis identifies as necessary to ensure control of identified hazards to acceptable levels (CCPs; ISO 22000:2005b).

After biological, chemical and physical hazards identification for each processing step and each ingredient, it is time to identify measures needed to prevent hazards from compromising the safety of the final product (FAO, 1997).

The following are examples of control measures for physical hazards:
1. Specifications for raw materials and ingredients and vendor certification that unacceptable physical hazards or levels are not present.
2. Use of magnets, metal detectors, sifter screens, de-stoners, clarifiers and air tumblers.
3. Ensuring that GMPs are followed and that no physical contamination occurs to the food through the building facilities, work surfaces or equipment (FAO, 1998).

Some of the measures you can use to prevent chemical hazards are:
1. Use only approved chemicals
2. Have detailed product specifications for chemicals entering the plant
3. Maintain letters of guarantee from suppliers
4. Inspect trucks used to ship final product
5. Proper labelling and storage of chemicals
6. Proper training of employees who handle chemicals (Corlett, 1998).

Control measures taken to prevent biological hazards are:

Bacterial hazards
1. Time/temperature control (refrigeration, storage time)
2. Heating and cooking processes to eliminate or reduce micro-organisms
3. Cooling and freezing
4. Fermentation and/or pH control
5. Addition of salt or other preservatives which may inhibit micro-organism growth
6. Drying which may use heat to kill or remove micro-organisms
7. Source control (examination of raw materials and ingredients from suppliers).

Viral hazards
1. Cooking processes (heating, cooking, steaming, frying, baking) which may destroy viruses

Parasite hazards
1. Dietary control
2. Inactivation (heating, drying, freezing)

1.1.11 Advantages of HACCP
Food companies that have had effective sanitation and HACCP programmes have a number of positive operating characteristics that distinguish them from companies that do not have these programmes (Corlett, 1998).

• Application of HACCP system throughout the food chain from the primary producer to the consumer.
• More effective use of resources, savings and more timely response to food safety problems.
• Internationally recognised.
• The application of HACCP systems can promote international trade by increasing confidence in food safety.
• The HACCP system allows for the identification of conceivable, reasonably expected hazards, even where failures have not previously been experienced. It is therefore particularly useful for new operations.
• Staff and business owners gain confidence and are better equipped for informed discussion on food safety measures with food inspectors, third-party auditors, consultants, trading partners, consumers and others.
• The development of a HACCP system can lead to improved education and awareness of staff working in SLDBs and staff members are empowered when their input is sought and valued.
• The HACCP system has strengthened the regulatory approach to food safety by providing food control authorities with an opportunity to revisit their method of food inspection and the training provided to food inspectors.
• More focused control on processes critical to food safety, with the flexibility to accommodate additional changes in production, quality or other specific measures, e.g., control of allergens or emerging pathogens.
1.2.1 Introduction to ISO 22000

ISO 22000 is the new international generic FSMS standard for food safety management systems. It defines a set of general food safety requirements that apply to all organisations in the food chain. These requirements are listed in sections 4, 5, 6, 7 and 8 of ISO 22000 (see Section 2.8). Recognised worldwide, this universal standard harmonises key requirements and overcomes the difficulties of various food safety standards by region, country, activity, organisation and food-type (http://www.foodsafety.uk.sgs.com/westbury_dairies_case_study-4.pdf).

If an organisation is part of the food chain, ISO 22000 requires the establishment of a food safety management system (FSMS) and usage of this system to ensure that food products do not cause adverse human health effects (http://www.praxiom.com/iso-22000-intro.html). The requirements of ISO 22000 may apply to all types of organisations within the food chain ranging from feed producers, primary producers, food manufacturers, transport and storage operators, sub-contractors to retail and food service outlets, together with inter-related organisations such as producers of equipment, packaging materials, cleaning agents, additives and ingredients (http://www.nsa.ie/IR/index.cfm/area/page/information/ISO 22000).

1.2.1.2 Disadvantages of HACCP

- Resource-intensive during development, unless supported by extensive structure of trade associations or other industry groupings.
- Needs to be validated for effectiveness.
- Difficult to anticipate all hazards introduced by subtle variations on seemingly standard processes thus needs constant vigilance and updating.
- Element of technical knowledge required to adopt them.
- Perceived complexity and bureaucracy – many smaller businesses regard HACCP as complicated and bureaucratic.
- Lack of knowledge and adequate training – many small businesses remain unaware of HACCP or lack sufficient in-house knowledge and training about the risks associated with their procedures to put in place or maintain effective HACCP-based controls.
- The costs of ongoing training against a backdrop of high staff turnover, typical in the industry, can also be prohibitive for many smaller food businesses (FAO/WHO, 2006a; FSA, 2001).

Organisations are cognisant of the need to demonstrate and provide evidence of their ability to provide safe food (http://www.nsa.ie/IR/index.cfm/area/page/information/ISO 22000). ISO 22000 will help these organisations to establish an FSMS and implement it in the food plant with proper improvement and update of the FSMS system. This standard promotes conformity of products and services to international standards by providing assurance about quality, safety and reliability (Tajkarimi, 2007).

The ISO 22000 standard intends to define the food safety management requirements that companies need to meet and exceed in order to comply with food safety regulations all over the world. It is intended to be one standard that encompasses all the consumer and market needs. It speeds and simplifies processes without compromising other quality or safety management systems (http://www.foodsafety.sgs.com/what-is_iso_22000). ISO 22000 uses generally recognised methods of food safety management such as interactive communication across the food chain, system management, control of food safety hazards through PRPs and HACCP plans, and continual improvement as well as periodic updating of the management system (http://www.degrandison.ie/274-FSMS.htm). Furthermore, the requirement of Emergency preparedness and response plan (see 5.7) of ISO 22000 is also a basic requirement of ISO 14001 which is the worldwide Environmental Management System (EMS; Culley, 1998). This standard has many elements in common with ISO 9001, it has its roots in BS 7750 (Quality Standard), and it is also related to Eco-Management and Audit Regulation (EMAR). One of the strengths of ISO 14001 is that it is not a performance standard. It does not specify how the requirements of any section should be satisfied, nor does it specify levels of environmental performance that an organisation should achieve (Ritchie and Hayes, 1998).

The standard has become necessary because of the significant increase of illnesses caused by infected food in both developed and developing countries. In addition to the health hazards, foodborne illnesses can give rise to considerable economic costs including medical treatment, absence from work, insurance payments and legal compensation. As a result, a number of countries have developed national standards for the supply of safe food and individual companies and groupings in the food sector have developed their own standards or programmes for auditing their suppliers (http://www.ios.org/iso/en/commitment/repress releas/ archives2005/Re1959.html).

While ISO 22000 can be implemented on its own, it is designed to be fully compatible with ISO 9001:2000 and companies already certified to ISO 9001 will find...
it is easy to extend this to certification to ISO 22000 (Fig. 1.7) [http://www.iso.org/iso/en/commcentre/pressreleases/archives/2005/Ref959.html], ISO 9001:2000 on quality management does not deal specifically with food safety. As a result, many countries, such as Denmark, the Netherlands, Ireland and Australia amongst others developed voluntary national standards and other documents specifying auditable requirements for FSMS (Faergemand and Jespersen, 2004).

1.2.2 An introduction of ISO 22000

The challenge for ISO 22000 is that it should be recognised by all segments in the food chain. It seems certain that the HACCP standards will be replaced with ISO 22000. What is not yet certain is whether the retailer will accept it. One factor in favour of ISO 22000 is that its intent is global. Thus, produce is increasingly sourced globally, confidence can be gained from one single universally accepted ISO standard (http://www.bvqi.com/webapp/servlet/FileServlet?mode=download&...Magazine.pdf).

The standard has three parts:

- ISO/TS 22003, Food safety management system – Condition for organisations which make certification and inspection of food safety management system, defines the rules applicable for the audit and certification of a food safety management system (FSMS) complying with the requirements given in ISO 22000 (or other sets of specified FSMS requirements), and provides the necessary information and confidence to customers about the way certification has been wanted to their suppliers. Published in the first quarter of 2006.

The standard has the following objectives:

- to enhance food safety
- to ensure consumer protection
- to strengthen consumer confidence
HACCP and ISO 22000 – Application to Foods of Animal Origin

- to improve cost efficiency throughout the food supply chain
- to comply with the Codex HACCP principles
- to harmonise the voluntary international standards
- to provide an auditable standard that can be used either for internal audits, self-certification or third-party certification
- the structure to align with ISO 9001:2000 and ISO 22000:2005
- to provide communication of HACCP concepts internationally

Table 1.2. Timetable for the development of ISO 22000.

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
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<tbody>
<tr>
<td>2001</td>
<td>Development of the standard</td>
</tr>
<tr>
<td>3 June 2004</td>
<td>Draft International Standard</td>
</tr>
<tr>
<td>3 November 2004</td>
<td>Deadline for comments on the draft</td>
</tr>
<tr>
<td>5 July 2005</td>
<td>Final draft of the International Standard</td>
</tr>
</tbody>
</table>

1.2.3 History of ISO 22000

In 2001, ISO started the development of an auditable standard, which further defines HACCP's role in FSMS and culminated in the newly formed ISO 22000 (http://www.foodsafety.sgs.com/what_is_iso_22000.html). The publication of ISO 22000 was complemented by an ISO Technical Specification (ISO/TS 22004) giving guidance on the implementation of the standard, with a particular emphasis on small- and medium-sized enterprises. Working Group 8 (WG 8) on FSMS prepared ISO 22000 and ISO/TS 22004, which were both published in 2005 (FAO/WHO, 2007). Another Technical Specification (ISO/TS 22003) was also published explaining certification requirements applicable when third-party certification is used (Frost, 2005). The Draft International Standard ISO/DIS 22000 was issued on 3 June 2004. The deadline for comments was 3 November 2004. ISO 22000 was expected to be available as an International Standard in 2005 (Faergemand and Jespersen, 2004). ISO circulated the final draft of the standard to the national standard bodies that make up its membership for a 2-month voting period, ending on 5 July 2005. The standard can be applied on its own, or in combination with other management system standards such as ISO 9001:2000, with or without independent (third party) certification of conformity (Frost, 2005). The working group that developed ISO 22000 has representatives from 14 countries and input from 13 others representing all continents. In the working group, there are also representatives from organisations such as the Codex Alimentarius, the Global Food Safety Initiative (GFSI) and the Confederation of Food and Drink Industries of the EU (CIAA) (http://www.haccp.com.au/bulletins/bulletin3_1.pdf; http://www.lrqa.co.uk/products/otherproducts/ISO-22000/). The timetable for the development of ISO 22000 is given in Table 1.2.

1.2.4 Relationship of ISO 22000 to HACCP

The design and implementation of an organisation's food safety management system are influenced by varying factors, in particular food safety hazards, the products provided, the processes employed and the size and structure of the organisation. This Technical Specification provides guidance on the use of ISO 22000, which is based on the principles of HACCP as described by the Codex Alimentarius Commission and is designed to be applied together with relevant standards published by that organisation (ISO 22000:2005). ISO 22000 will dynamically combine the HACCP principles and application steps with PRPs, using the hazard analysis to determine the strategy to be used to ensure hazard control by combining the PRPs and the HACCP plan (Table 1.3; Faergemand and Jespersen, 2004).

1.2.5 Application of ISO 22000

ISO 22000:2005 applies to all organisations, regardless of their size, that impact the food chain (http://www.cciaa.org/newswire/press_release.asp?p_ad=11944; http://www.msi.ie/IR/index.cfm/area/page/information/ISO 22000). The standard was drafted to serve the needs of not just food producers and manufacturers, but also virtually every other organisation that participates in the food supply chain. ISO 22000 is written with a structure compatible to other management system standards in the light of ISO 9001:2000 (applying ISO 15161 as guideline) while combining HACCP and Codex HACCP (http://www.bulletcow.com/English/Site/ISO9000/Introduction/English/HACCP,English/ISO_22000/iso_22000.html). Direct or indirect organisations which can be certified with ISO 22000 standard are the following:

(a) Direct organisations
- farmers
- harvesters
- bar producers
- food component producers
HACCP and ISO 22000 – A Comparison of the Two Systems

Table 1.3 Cross-references between the HACCP principles and application steps and clauses of ISO 22000:2005 (ISO 22000:2005a, Surak, 2003b).

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- food producers
- food sellers
- food services
- ready made food companies
- organisations which service cleaning, sanitising
- (b) Indirect organisations
- producers of equipment
- package materials
- ingredients and additives
- organisations etc. producing other elements which contact with food
- incorporation of legal and regulatory requirements relating to food safety including HACCP systems
- a uniformly auditable standard
- a drive for continuous improvement
- improved internal and external communications
- improved documentation
- improved compliance with hygiene regulations
- improved food safety hazard control
- easy to understand, apply and recognise
- facilitates traceability and clear communication across the supply chain
- clear responsibilities and authorities agreed for all staff
- resource optimisation (internally and along the food chain)
- valid basis for taking decisions
- provides a framework for third-party certification
- can be applied independently
- allow small and/or less developed organisations to implement an externally developed system
- speeds and simplifies processes, increases efficiency and reduces costs without compromising existing or other quality or management systems
- applicable to all organisations in the global food supply chain
- the structure aligns with the management system clauses of ISO 9001 and ISO 14001
- all control measures are subjected to hazard analysis
- better planning – less post-process verification

1.2.6 Benefits of ISO 22000

Adopting the ISO 22000 standard provides the company with competitive efficiencies worldwide. With registration to ISO 22000, the ensuing advantages are:

- incorporation of legal and regulatory requirements relating to food safety including HACCP systems
- a uniformly auditable standard
- a drive for continuous improvement
- improved internal and external communications
- improved documentation
- improved compliance with hygiene regulations
- improved food safety hazard control
- easy to understand, apply and recognise
- facilitates traceability and clear communication across the supply chain
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- food producers
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- incorporation of legal and regulatory requirements relating to food safety including HACCP systems
HACCP and ISO 22000 – Application to Foods of Animal Origin

- systematic management of PRPs
- a systematic and proactive approach to identification of food safety hazards and development and implementation of control measures
- enables streamlined communication and collaboration for quicker, more informed decision making about hazards with supply chain partners
- increased international acceptance of food products
- reduces risk of product/service liability claims
- ensures safety of food products
- greater health protection
- job productivity and satisfaction of employees are increased
- employees become conscious about hygiene and food safety
- can be applied by all manufacturers and participants in the entire food chain supply
- food wastes (food decaying etc.) fees decrease to minimum
- work environment gets better
- it is a trusted system which was confirmed by FAO/WHO

1.2.7 ISO 22000 standard clauses

1 Scope

The scope focuses on control measures to be implemented to ensure that processes are in place to meet customer and regulatory food safety requirements. The types of organisations in the food chain to which this standard can be applied are the ones that are directly or indirectly involved in one or more steps of the food chain, regardless of the size or complicatedness of the organisation (Pillay and Muliyil, 2005).

2 Normative references

Normative reference deals with reference materials that can be used to determine definition associated with terms and vocabulary used in the ISO standard document (Pillay and Muliyil, 2005). Standards are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies (Arvanitoyannis and Hadjicostas, 2001). Codex normative texts fall into three groups (FAO/WHO, 2005):

- the standards, usually related to product characteristics
- the code of practices, defining the production, processing, manufacturing, transport and storage practices that are essential to ensure the safety of food for consumption
- the guidelines, which can be principles that set out policy in certain key areas, or interpretative guidelines for the understanding of these principles or for the interpretation of the provisions of the Codex general standards (FAO, 2006).

3 Terms and definitions

In an attempt to maintain consistency and encourage the use of common terminology, the ISO 22000 standard terms and definitions section makes reference to the use of 82 definitions occurring in ISO 9000:2000 and lists definitions that are specific to this application. The rationale behind the definition section is to provide clarity of terminology and promote the use of a common language (Pillay and Muliyil, 2005).

3.1 Food safety

The basic food safety concept is this: food will not harm the consumer so long as intended use guidelines are followed when it is prepared or eaten. Conversely, food is potentially harmful whenever it has been exposed to hazardous agents and intended use guidelines have not been followed (http://www.praxiom.com/iso-22000-definitions.htm).

3.2 Food chain

Sequence of the steps and operations involved in the production, processing, distribution, storage and handling of a food and its ingredients, from primary production to consumption (ISO 22000:2005a).

3.3 Food safety hazard

Any biological, chemical or physical property that may cause a food to be unsafe for human consumption (http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/cfr2003/pdf/9CFR417.1.pdf).
3.4 Food safety policy
A food safety policy statement formally defines an organisation’s commitment to food safety (see 3.1). It expresses, in general terms, what top management intends to do about food safety and describes the direction the organisation wishes to take. More precisely, a food safety policy statement should express an organisation’s commitment to the implementation and ongoing maintenance of its FSMS. The food safety policy should drive the establishment of the FSMS and should also encourage people to update and improve its overall effectiveness (http://www.praxiom.com/iso-22000-definitions.htm).

3.5 End product
Product that will undergo no further processing or transformation by the organisation (ISO 22000:2005a).

3.6 Flow diagram
A diagram which identifies process steps, inputs and outputs (materials), sequential relationships (consecutive, feedback) and food safety controls (http://www.nzfsa.govt.nz/processed-food-retail-sale/fsp/haccp.pdf).

3.7 Control measure
Any action or activity that can be used to prevent or eliminate a food safety hazard (see 3.3) or reduce it to an acceptable level (http://www.codexalimentarius.net/download/standards/10087/CXC0572004e.pdf).

3.8 Prerequisite programme (PRP)
Describes all those activities other than specific HACCP plans, which affect food safety. Universal steps or procedures that control the operational activities within a food establishment allowing production of safe end food products (see 3.5). Managed and documented (Griffith, 2006).

3.9 Operational PRP
Operational prerequisite programmes (OPRPs) are prerequisite programmes (PRPs; see 3.8) that are essential. They are essential because a hazard analysis has shown that they are necessary in order to control specific food safety hazards (see 3.3). OPRPs are used to reduce the likelihood that products will be exposed to hazards, that they will be contaminated, and that hazards will proliferate. OPRPs are also used to reduce the likelihood that the processing environment will be exposed to hazards, that it will be contaminated, and that hazards will proliferate in that environment (http://www.praxiom.com/iso-22000-definitions.htm).

3.10 Critical control point (CCP)
A point in a step or procedure at which a control is to be applied to prevent or eliminate a hazard or reduce it to an acceptable level (PAHO, 2005).

3.11 Critical limit
The maximum or minimum value to which a physical, biological or chemical hazard should be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of the identified food safety hazard (http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/CH_2003/pdf/9CFR417.1.pdf).

3.12 Monitoring
Observations or measurements to assess whether control measures (see 3.7) at a critical point are being effectively implemented (http://www.qsae.org/web_en/pdf/HACCPImplGuides.pdf).

3.13 Correction
Action to eliminate a detected non-conformity (ISO 22000:2005a).

3.14 Corrective action
Remedial procedure to be followed when a deviation occurs. Action to be taken when the results of monitoring indicate a loss of control (http://www.nzfsa.govt.nz/processed-food-retail-sale/fsp/haccp.pdf).

3.15 Validation
Validation is the initial phase in which the plan is tested and reviewed. The choices made while working through the preliminary steps and HACCP principles should be repeatedly tested and shown to prevent or control identified hazards in the ‘real world’. In this phase, microbial or residue testing can be effectively used to verify that the process is in control and is producing acceptable product. Such testing provides clear evidence that the techniques and methods adopted by the plant to control hazards are not just effective in theory but will work in this specific plant (USDA, 1999).

3.16 Verification
Application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan (PAHO, 2005).

3.17 Updating
Immediate and/or planned activity to ensure application of the most recent information (ISO 22000:2005a).
4.2 Control of documents

Documents required by the FSMS are controlled by documented procedures, which provide for the:

- approval of documents for adequacy prior to issue
- review and update as necessary and re-approval of documents
- assurance that occurring changes and the current version status of documents are identified
- assurance that relevant versions of applicable documents are available at points of use
- assurance that documents remain legible and readily identifiable
- assurance that relevant documents of external origin are identified and their distribution controlled and
- prevention of the unintended use of obsolete documents and apply suitable identification to them if they are retained for any purpose (ISO 22000:2005a; http://www.qualitycouncil.com/samples/iso.pdf).

4.2.3 Control of records

Records should be established and maintained to provide evidence of conformity to requirements and of effective operation of the FSMS. Records should remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the necessary controls for the identification, storage, protection, retrieval, retention time and disposition of records (Arvanitoyannis and Hadjicostas, 2001).

5 Management responsibility

5.1 Management commitment

Management responsibility outlines the commitment of top management to the implementation and maintenance of the FSMS (Fig. 1.8). Assigning a food safety system manager and team, setting clear policies, goals, emergency contingency plans and responsibilities, along with establishment of effective communication mechanisms within the organisation and with suppliers or customers are key elements of this clause. Regularly scheduled management reviews ensure that top management is made aware of the status of the system and that actions are authorised to correct non-conformities and continually improve the FSMS (Pillay and Muliyil, 2005).

Management should demonstrate their commitment to developing and improving their FSMS by:

- conducting regular management reviews
- establishing organisational objectives and food safety policies
- ensuring the availability of necessary resources and
ensuring that everyone is aware of the importance of meeting customer, regulatory and legal requirements (Tricker, 2001). Food safety management systems ensure that all food producers:
- comply with the requirements of relevant legislation
- identify all hazards and controls relating to their food business, e.g. temperature control, microbiological, chemical or physical contamination
- identify points in the food process that are critical to food safety and
- put in place control and monitoring procedures at these points (University of Sussex, 2006).

5.2 Establish food safety policy
The food safety intentions of top management need to be documented and communicated throughout the organisation. The requirement for the policy to be supported by measurable objectives should provide audit evidence of the effectiveness of the policy (IRCA, 2005). Top management should ensure that the food safety policy:
- is appropriate for the purpose of the organisation in the food chain
- conforms with statutory and regulatory requirements, and with agreed food safety requirements for the customers
- is communicated, implemented and maintained at all levels of organisation
- is reviewed for continuing suitability (see 5.8)
- addresses communication (see 5.6) and
- is supported by measurable objectives (ISO 22000:2005a).
5.3 Planning of FSMS
Top management should ensure that:

- planning of the FSMS is carried out towards meeting requirements explained in 4.1 as well as the objectives of the organisation that support food safety and the integrity of the FSMS is maintained when changes to the food safety management system are planned and implemented (http://www.bsi-americas.com/FSM_Update/BackIssues/December2006.xalter).

5.4 Clarify your FSMS responsibilities and authorities
Top management should ensure that responsibilities and authorities are defined and communicated within the organisation to ensure the effective operation and maintenance of the FSMS. All personnel should have responsibility to report problems with the FSMS to designated person(s). Designated personnel should have defined responsibility and authority to initiate and record actions (ISO 22000:2005a).

5.5 Appoint a food safety team leader
A food safety team leader performs a similar role in an FSMS to that provided by the management representative in a Quality Management System (QMS) although the establishment of a food safety team of two or more people is also required. The team leader’s role should be known throughout the organisation (IRCA, 2005). Top management appoints a food safety team leader who shall have the responsibility and authority:

- to manage a food safety team (see 7.3.2) and organise its work
- to ensure relevant training and education of the food safety team members (see 6.2.1)
- to ensure that the food safety management system is established, implemented, maintained and updated and to report to the organisation’s top management on the effectiveness and suitability of the FSMS (http://www.bsi-americas.com/FSM_Update/BackIssues/February2007.xalter).

5.6 Establish your communication
The organisation should establish, implement and maintain effective arrangements for communicating with:

- suppliers and vendors
- customers
- regulatory agencies

5.6.2 Internal communication
It is the responsibility of top management to facilitate the communication processes within the organisation (Fig. 1.9; Arvanitoyannis and Hadjicostas, 2001). Internal communication should be from the ‘top down’ – from the highest manager within the organisation down to the production worker who is at the heart of making the product (Calley, 1998). The food safety team should be informed including the following:

- 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 authorisations
- statutory and regulatory requirements
- knowledge regarding food safety hazards and control
- customer, sector and other requirements that the organisation considers necessary
- relevant enquiries from external interested parties
- complaints indicating food safety hazards associated with the product and other conditions that have an impact on food safety and quality (ISO 22000:2005a; http://bis.org.in/sf/fad/FAD15(1681).pdf).

5.7 Emergency preparedness and response
A risk management approach will be normally adopted when implementing this clause, based on the risk of compromising food safety during emergency incidents. Auditors should be familiar with the concepts used to determine risk levels, taking into account such factors as incident severity, duration, likelihood of occurrence and the degree of control already in place. In addition to the identified risk levels, auditors should focus on the process for identifying risks and determining any necessary responses from a food safety standpoint (IRCA, 2005). Emergency situations may include, for example, fire, flooding, food contamination, poisoning, bio-terrorism, sabotage, energy failure, vehicle accidents and contamination of the environment (http://bis.org.in/sf/fad/FAD15(1681).pdf).
This requirement is also found in ISO 14001. The preparation for accidents or emergencies can be managed through:

- orientation of classes for new employees
- hazard evaluations
- emergency system evaluations and surveys
- training of the appropriate personnel
- staff or department meetings to keep personnel aware of their responsibilities and roles and
- emergency scenarios and the implementation of practice drills (Culley, 1998).
Response actions include all those activities that occur from the initial report of the incident through the decontamination and equipment clean-up phases of the incident. The focus of response actions is to stabilise, confine, contain and control the release of hazardous materials, transfer and recover materials, prevent unnecessary damage and stabilise the situation for the final clean-up operations (Ritchie and Hayes, 1998).

5.8 Review of management
5.8.1 General
Management shall review, at defined intervals, the continuing suitability and effectiveness of quality and safety management systems. This review shall include assessing opportunities for improvement and the need for changes to the quality and safety management systems (PAHO, 2005). Records from management reviews should be maintained (see 4.2.3) (Arvanitoyannis and Hadjicostas, 2001).

5.8.2 Review input
The input to management review should include current performance and improvement opportunities related to the following:

- results of external audits or inspections
- customer feedback (see 5.6.1)
- emergency situations, accidents (see 5.7) and withdrawals (see 7.10.4)
- analysis of results of verification activities (see 8.4.3)
- follow-up actions from previous management reviews
- changes possibly affecting the FSMS (see 5.6.2) and
- reviewing results of system updating activities (see 8.5.2) (ISO 22000:2005a; Tricker, 2001).

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

- assurance of the food safety (see 4.1)
- improvement of FSMS effectiveness (see 8.5)
- resource needs (see 8.1) and
- revisions of the organisation’s food safety policy and related objectives (see 5.2; ISO 22000:2005a).

6 Resources management
6.1 Providing of adequate resources
An effectively implemented FSMS requires that top management provide adequate resources, budgets and personnel to effectively run the system (Fig. 1.10).

6.2 Provide adequate human resources
6.2.1 General
The food safety team and other personnel carrying out activities having an impact on food safety should be competent and have appropriate education, training, skills and experience. Where the assistance of external experts is required for the development, implementation, operation or assessment of the FSMS, records of agreement or contracts defining the responsibility and authority of experts should be available (ISO 22000:2005a).

6.2.2 Competence, awareness and training
The organisation is responsible for ensuring that all personnel are trained and experienced to the extent necessary to undertake their assigned activities and responsibilities effectively. Thus, whenever training needs have been identified, top management should endeavour to make the relevant training available and full records should be maintained of all training undertaken by employees (Tricker, 2001).

The organisation should:

- determine the necessary competencies for personnel performing work affecting food safety
- provide training
- assess the effectiveness of the actions taken
- make sure its personnel are aware of their activities and its importance for the achievement of the food safety objectives
- keep appropriate records of training, skills and experience (Arvanitoyannis and Hadjicostas, 2001).

6.3 Provide adequate infrastructure
The organisation shall determine, provide and maintain the required infrastructure for:

- workplace and associated facilities
- process equipment (both software and hardware) and supporting services (such as transport or communication; Arvanitoyannis and Hadjicostas, 2001; http://www.qualitycouncil.com/samples/iso.pdf).

6.4 Provide adequate work environment
The organisation identifies and manages the human factors (e.g. work methodologies, achievement and
involvement opportunities, safety rules and guidance, ergonomics etc.) and physical factors (e.g. light, hygiene, vibration, noise, humidity, pollution, heat, cleanliness and air flow) of the work environment needed to achieve conformity of the product (http://www.qualitycouncil.com/samples/iso.pdf; Tricker, 2001).

7 Planning and realisation of safe product

7.1 General

Planning and realisation of safe products incorporate the elements of GMP and HACCP, including any regulatory requirements applicable to the organisation and processes. Adequate prerequisite programmes (e.g. training, sanitation, maintenance, traceability, supplier review, control of non-conforming product and recall procedures) are required that address general requirements to provide a foundation for the production of safe food (Fig. 1.12; Pillay and Muliyil, 2005).

7.2 Establish prerequisite programmes (PRPs)

Basic prerequisite programmes should be in place to:

- protect products from contamination by biological, chemical and physical food safety hazards
- control bacterial growth that can result from temperature abuse and
- maintain equipment (FDA, 2006).

The existence and effectiveness of prerequisite programmes should be assessed during the design and implementation of each HACCP plan. All prerequisite programmes should be documented and regularly
Audited. Prerequisite programmes are established and managed separately from the HACCP plan (FDA/USDA/NACMCF, 1997). A tree diagram of prerequisite programmes according to ISO 22000 is presented in Fig. 1.13. PRPs should:

- be appropriate to organisation’s needs with regard to food safety
- be appropriate to the size and type of the operation, and the nature of products being manufactured and/or handled
- be implemented to the entire production system and
- be approved by the food safety team (ISO 22000:2005a).

7.3 Primary levels of hazard analysis materialisation

7.3.1 General

The origin of the raw materials, ingredients and product contact materials should be taken into account when they might impact on the evaluation of the occurrence of hazards and the levels of these hazards. The information to be taken into account may be different from the original information required to maintain traceability (ISO 22000:2005b).

7.3.2 Food safety team

In addition to the final resources needed to fund a team of competent managers and specialists, it may prove difficult to find appropriate training and recruit experts. Nevertheless, an organisation can find a solution such as:

- exchanging or sharing HACCP team members
- integrating supplier or client experts into the team and
- using e-learning when the required vocational training is not available in appropriate timeframes, locations or quality (Blanc, 2006).

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 as appropriate:

- biological, chemical and physical characteristics
- composition of formulated ingredients, including additives and processing aids.
Fig. 1.12 Planning and realisation of safe product (Arvanitoyannis and Hadjicostas, 2001; Tricker, 2001).

- origin
- method of production
- packaging and delivery methods
- storage conditions and shelf life
- preparation and/or handling before use or processing
- food safety-related acceptance criteria or specifications of purchased materials and ingredients appropriate
Fig. 1.13 Tree diagram for determination of prerequisite programmes according to ISO 22000.

7.3.3.2 Characteristics of end products
Characteristics of end products should be described including the following information:

• product name or similar identification
• composition
• biological, chemical and physical hazard specification
• intended shelf life and storage conditions
• packaging labelling relating to food safety and/or instructions for handling, preparation and usage and
• methods of distribution (ISO 22000:2005a).

7.3.4 Intended use
Intended use should indicate whether the product is to be sold at retail, to food service or as an ingredient for another food item (Harris, 1999). The HACCP team should specify where the product will be sold, as well as the target group, especially if it happens to be a sensitive portion of the population (i.e. elderly, immune-suppressed, pregnant women, and infants; FAO, 1998).

7.3.5 Flow diagrams, process steps and control measures
7.3.5.1 Flow diagrams
Flow diagrams should be clear, accurate and sufficiently detailed. Flow diagrams should include the following:

• the sequence and interaction of all steps in the operation
• any outsourced processes and subcontracted work
• where raw materials, ingredients and intermediate products enter the flow
• where reworking and recycling take place by products
• where end products, intermediate products and waste are released or removed and

7.3.5.2 Description of process steps and control measures
The existing control measures should 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 should also be described. The requirements should be described (ISO 22000:2005a).

7.4 Carry out hazard analysis
7.4.1 General
The hazard analysis for a specific food consists of a systematic evaluation of all raw materials, ingredients and production steps; identification of hazards that are likely to occur; and consideration of control or preventive measures for hazards (Corlett, 1998).

7.4.2 Hazard identification and determination of acceptable levels
Food safety hazards identification should be based on:

• preliminary information and data collected (see 7.3)
• experience
• external information (epidemiological and other historical data) and
• 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 (ISO 22000:2005a).

The acceptable level in the end product should be determined through:

• objectives, targets or end product criteria established by statutory and regulatory authorities
• specifications or other information communicated by the organisation representing the subsequent step in the food chain and
• the maximum levels found by the food safety team taking into account acceptable levels agreed on with the customer and/or according to law, scientific literature and professional experience (ISO 22000:2005b).

7.4.3 Hazard assessment
Hazard assessment serves to determine which of the potential hazards identified require specific control measures. To ensure such control, the standard requires the selection of (or combination of) control measures (see 7.4.4; Blanc, 2006). In conducting the hazard assessment, the following should be taken into consideration:

• the sources of the hazard
• the probability of occurrence of the hazard
• the nature of the hazard and
• the severity of the adverse health effects that can be caused by the hazard (ISO 22000:2005b).
7.4.4 Selection and assessment of control measures

The selection and categorisation of control measures should be carried out according to:

- the effect on identified food safety hazards
- the feasibility for monitoring
- the place within the system relative to other control measures
- the likelihood of failure or significant processing variability
- the severity of the consequences in case of failure
- whether the control measure is established and applied to eliminate or reduce hazards and

The following may guide the organisation in the categorisation process:

- the impact of a control measure on the hazard level (the higher impact there is, the more likely the control measure belongs to the HACCP plan)
- the severity on consumer health of a hazard that the measure is selected to control (the more severe it is, the more likely it belongs to the HACCP plan) and
- the need for monitoring (the more pressing the need, the more likely it belongs to the HACCP plan) (ISO 22000:2005b).

7.5 Establish operational prerequisite programmes

One of the outputs of the hazard analysis is the determination of operational PRPs. This sets up prevention and control measures which deal with food safety risk levels somewhat below those which need to be included in the HACCP plan. Auditors should examine the decision-making process at the hazard analysis stage as well as how the necessary control and monitoring activities for operational PRPs are determined (IRCA, 2005). The operational PRPs should include the following information for each programme:

- food safety hazards to be controlled (see 7.4.4)
- control measures (see 7.4.4)
- monitoring procedures that demonstrate that operational PRPs are not in control (see 7.4.4) and

7.6 Establish HACCP plan

7.6.1 HACCP plan

The initial focus of the HACCP coordinator and the team is the development of the HACCP plan or plans for specific food products (Corlett, 1998). On the identification of the highest risks to food safety within the hazard analysis, the HACCP plan becomes the blueprint for their control in the production/service processes being audited. The auditor does not need to be a HACCP expert but can evaluate the process from decision making in the hazard analysis through the determination of control parameters including identification of critical control points (CCPs). Given the importance of this methodology to the FSMS, the auditor should allocate a good proportion of the audit duration to its evaluation (IRCA, 2005). The HACCP plan should include the following information for each identified CCP:

- food safety hazards to be controlled at CCP (see 7.4.4)
- control measures (see 7.6.1)
- critical limits (CLs; see 7.6.3)
- monitoring procedures (see 7.6.4)
- corrections and corrective actions if critical limits are not in control (see 7.6.5)
- responsibilities and authorities and

7.6.2 Identification of CCPs

CCPs may be located at any point in the food production and manufacturing system for a food product where hazards need to be either prevented, eliminated or reduced to acceptable levels (Corlett, 1998). The identification of CCPs has two consequences for the HACCP team which should then:

- ensure that appropriate control measures are effectively designed and implemented. In particular, if a hazard has been identified at a step where control is necessary for product safety and no control measure exists at that step, then the product or process should be modified at that step or at an earlier or later stage, to include a control measure, and
- establish and implement a monitoring system per critical point (Commission of the European Communities, 2005). CCPS should be carefully identified and documented. They should be used only for purposes of product safety or where use should be justified by the critical nature of the CCP. CCPs should not be confused with control points that do not control safety but refer to quality issues (Corlett, 1998).
7.6.3 Determination of critical limits for CCPs
The establishment of critical limits succeeds the identification of all factors associated with CCPs. Scientifically determined critical limits levels are established for all the identified factors and components causing an unacceptable consumer health risk (Arvanitoyannis and Hadjicostas, 2001).

7.6.4 System for monitoring results exceed critical limits
Most monitoring procedures for CCPs should provide real-time information related to on-line processes. Furthermore, monitoring should provide this information in time to make adjustments to ensure control of the process to prevent violating the critical limits. Therefore, there may not be time for lengthy analytical testing. Physical and chemical measurements that give information about the degree of microbiological control are often preferred to microbiological testing because they can be done rapidly (ISO 22000:2005b). The monitoring system should consist of procedures, instructions and records that cover:

- measurements or observations
- monitoring devices
- calibration methods (see 8.3)
- monitoring frequency
- responsibility and authority related to monitoring and evaluation of monitoring results and
- record requirements and methods (ISO 22000:2005a).

7.6.5 Action when monitoring results exceed critical limits
The critical limits are set at a point where the products become unsafe. In practice, therefore, it is common to work against limits that give an early warning that a process might become out of control. The organisation may choose whether any actions are going to be taken when exceeding warning limits (ISO 22000:2005b).

7.7 Updating of documents and primary knowledge in determined operational PRPs and HACCP plan
The organisation should update the operational PRPs and HACCP plan, if necessary:

- product characteristics (see 7.3.3)
- intended use (see 7.3.4)
- flow diagrams (see 7.3.5.1)
- process steps (see 7.3.5.2) and
- control measures (see 7.3.5.2) (ISO 22000:2005a).

7.8 Verification planning
This clause sets in place those monitoring arrangements at the process level which are designed to provide assurance that the FSMS is performing effectively on a daily basis. The food safety team is involved in result evaluation (see 8.4.2) and failures are to be dealt with through the potentially unsafe product disposition process (see 7.10.3). As with several other sections of the standard, this clause is best audited as part of a process audit of the verification processes in the FSMS (IRCA, 2005). The verification activities should confirm that:

- PRPs are properly implemented (see 7.2)
- input to the hazard analysis (see 7.3) is continually updated
- operational PRPs (see 7.5) and HACCP plan (see 7.6.1) are implemented and effective
- hazard levels are within the acceptable levels (see 7.4.2) and
- other procedures required by the organisation are implemented and effective (ISO 22000:2005a).

7.9 Establish a product traceability system
A traceability system is mandatory in ISO 22000 but happens to be a common process in the food industry, often as a result of legislation. The auditor should check the batch and/or lot identification in records maintained throughout the process from material receipt to end product dispatch. Note that the organisation needs to define a retention period for traceability records which is related to system assessment and considers the implications for disposition of potentially unsafe products and product withdrawal (IRCA, 2005).

7.10 Non-conformity control
7.10.1 Corrections
The organisation should ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with non-conforming product shall be defined in a documented procedure (ISO 9001:2000). A documented procedure should be established and maintained defining:

- the identification and assessment of affected end products to determine their proper handling (see 7.10.3) and
- a review of corrections carried out (ISO 22000:2005a).

When non-conforming product is corrected, it shall be subject to re-verification to demonstrate conformity
to the requirements. When non-conforming product is detected after delivery or use has started, the organisation shall take action appropriate to the effects, or potential effects, of the non-conformity (ISO 9001:2000).

7.10.2 Corrective actions
Once the non-conformance has been identified, the next step is to initiate the corrective action process (Culley, 1998). A documented procedure shall be established to define requirements for:

- reviewing non-conformities (including customer complaints)
- determining the causes of non-conformities
- evaluating the need for action to ensure that non-conformities do not recur
- implementing corrective action required
- recording results of action taken (see 4.2.4) and
- reviewing corrective action taken (Tricker, 2001).

7.10.3 Handling of potentially unsafe products
7.10.3.1 General
The organisation should deal with non-conforming product by one or more of the following ways:

- by taking action to eliminate the detected non-conformity
- by authorising its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer
- by taking action to preclude its original intended use or application (ISO 9001:2000).

7.10.3.2 Evaluation for release
Each lot of product affected by the non-conformity should be released as safe when:

- there is an evidence that the control measures have been effective
- there is evidence that the combined effect of the control measures for that particular product complies with the performance intended (see 7.4.2) and
- the results of sampling, analysis and/or other verification activities demonstrate that the affected lot of product complies with the acceptable levels for the food safety hazards concerned (ISO 22000:2005a).

7.10.3.3 Disposition of non-conforming products
Following evaluation, if the lot of product is not acceptable for release it shall be handled by one of the following activities:

- reprocessing or further processing within or outside the organisation to ensure that the food safety hazard or parameters not within specified limit, are eliminated or reduced to acceptable levels and
- destruction and/or disposal as waste. Inadvertent use of such material shall be prevented (http://bis.org.in/d/ fdfAD15(1681).pdf).

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

- top management should appoint personnel having the authority to initiate a withdrawal and personnel responsible for executing the withdrawal and
- the organisation should establish and maintain a documented procedure for:
  (a) notification to relevant interested parties (e.g. statutory and regulatory authorities, customers and/or consumers)
  (b) handling of withdrawn products as well as affected lots of the products still in stock and
  (c) the sequence of actions to be taken (http://bis.org.in/ sf/fad/FAD15(1681).pdf; ISO 22000:2005a).

8 Validation, verification and improvement of FSMS
8.1 General
In order to maintain and demonstrate the effectiveness of the FSMS, the organisation should validate that all assumptions used within the system are scientifically sound. In addition, the organisation should plan, conduct and document regular verification of all components of the system to evaluate whether or not the system is operating as designed or if modifications are needed. The verification should also form part of a continual improvement process whereby the organisation reviews verification. This section is covered under validation, verification and improvement of the FSMS (Fig. 1.14; Pillay and Muliyil, 2005).

8.2 Validation of food safety control measure combinations
Validation of control measure combinations, basically a new requirement introduced by ISO 22000 that relates to the control measures addressing hazards having been assessed as needing control, control measures that should then be validated before being
implemented (Blanc, 2006). Steps prior to validation include:

- identify the food safety hazards that are intended to be controlled
- identify the food safety outcome required
- identify the necessary control measures and determine which are to be validated
- identify whether the control measure has previously been appropriately validated or whether its performance is so well established for the application and
- if necessary, prioritise control measures to be validated (FAO/WHO, 2006b).

The organisation should validate (see 3.15) that:

- the selected control measures are capable of achieving the intended control of food safety hazards and
- the control measures are effective and capable of ensuring control of the identified food safety hazards to obtain end products that meet the defined acceptable levels (ISO 22000:2005a).

8.3 Control of monitoring and measuring

This clause addresses the need for known accuracy of measuring equipment and aligns with the corresponding requirement in ISO 9001. Note that it applies only to monitoring and measuring of parameters used in the FSMS in relation to food safety. Standards used for calibration should reflect the way the equipment is used (IRCA, 2005). Where necessary to ensure valid results, measuring equipment should be:

- calibrated or verified at specified intervals against international or national measurement standards
- adjusted or re-adjusted
- identified to enable the calibration status to be determined
- safeguarded from adjustments that would impair the measurement and
- properly handled, maintained and stored (Arvanitoyannis and Hadjicostas, 2001).

8.4 Verification of FSMS

8.4.1 Internal audit

The organisation should audit those systems and procedures, which are critical to product safety, legality
and quality, to ensure they are in place, appropriate and complied with (http://www.pasa.doh.gov.uk/food/docs/code_of_practice_2001.pdf). Each procedure is audited separately, products are audited, processes are audited and records are audited. All of these audits are planned out only as far as the next audit – the frequency is varied to suit the level of confidence in the area being audited. Because the audits are small, less trained staff can be used, and this in turn reduces the negative connotations of an internal audit (since now almost anyone can be used as an auditor). Periodically, a full internal audit is carried out to ensure that the overall system still complies with the standard (de Beer, 1993). The schedule for conducting internal audits shall be documented and include planning, reports and improvements. The detailed auditing programme should include as a minimum:

- preparation and issuing of audit plans
- scope of the audits
- frequency of the audits
- methods for conducting the audits
- reporting of findings
- distribution of reports
- implementation of corrective actions and follow-up activities and
- selection and training of competent auditors (PAHO, 2005).

The organisation shall conduct internal audits at planned intervals to determine whether the FSMS:

- complies with the planned arrangements, to the FSMS requirements established by the organisation, and to the requirements of this International Standard and
- is effectively implemented and maintained (Arvanitoyannis and Hadjicostas, 2001).

8.4.2 Evaluation of individual verification results
If verification does not demonstrate conformity with the planned arrangements, the organisation should take action to achieve the required conformity. Such actions should review:

- existing procedures and communication channels (see 5.6 and 7.7)
- conclusions of the food safety hazard analysis (see 7.4), established operational PRPs (see 7.5) and HACCP plan (see 7.6.1)
- PRPs (see 7.2) and
- effectiveness of human resource management and training activities (see 6.2; ISO 22000:2005a).

8.4.3 Analysis of results of verification activities
Verification activities are carried out by individuals within a company, third-party experts and regulatory agencies. It is important that individuals doing verification have appropriate technical expertise to perform this function (http://www.nzfsa.govt.nz/processed-food-retail-sale/fsp/haccp.pdf). The assessor should consider what, how, when and by whom the verification procedures have been undertaken, and whether these are adequate and effective. This may be indicated by an assessment of the validation data, sampling results, internal and external audit documentation as well as the frequency and thoroughness of all verification activities (Motarjemi, 2000). The analysis of results of verification activities should be carried out in order:

- to confirm that the overall performance of the system meets the planned arrangements and FSMS requirements
- to identify the need for updating or improving the FSMS
- to identify trends that indicate a higher incidence of potentially unsafe products
- to establish information for planning of the internal audit and
- to provide evidence that any corrections and corrective actions are effective (ISO 22000:2005a).

8.5 Improvement

8.5.1 Continual improvement
By conducting routine internal audits and monitoring, it will become evident that the policy, objectives, targets and plans will have to be modified. Continual improvement is not really a last step but an integral part of every step in environmental management whether it is mentioned or not (Lee Kuhre, 1995). Actions for improvement include the following:

- analysing and evaluating the existing situation to identify areas for improvement
- establishing the objectives for improvement
- searching for possible solutions to achieve the objectives
- evaluating these solutions and making a selection
- implementing the selected solution
- measuring, verifying, analysing and evaluating results of the implementation to determine that the objectives have been met and
- formalising changes (ISO 9000:2000).

Management should ensure that the organisation continually improves the effectiveness of the FSMS through:
8.5.2 Updating of FSMS

Frequently upgrading the entire system will keep it cost-effective and impacts will be reduced to the max-
imum extent possible (Lee Kuhre, 1995). This clause involves the food safety team in a pre-planned periodic evaluation of the currency of the information used in the FSMS (refer to Definition 3.17). Allied with the lower level updating in Clause 7.7, the results of this evaluation feed into the management review (Clause 5.8.2). Auditors should check whether the scope of this evaluation covers the whole FSMS starting with the issues which trigger an update through to the successful implementation of the change (IRCA, 2005). The evaluation and updating activities should be based on:

- input from management review (see 5.6)
- input from other information concerning the suitability, adequacy and efficiency of the FSMS
- output from the analysis of results of verification activities (see 8.4.3)
- output from management review (see 5.8.3; ISO 22000:2005a).

ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>CCPs</td>
<td>Critical control points</td>
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<tr>
<td>CIAA</td>
<td>Confederation of Food and Drink Industries of the EU</td>
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<td>CLs</td>
<td>Critical limits</td>
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<tr>
<td>EMAR</td>
<td>Eco-Management and Audit Regulation</td>
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<td>EMS</td>
<td>Environmental management system</td>
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<td>FDA</td>
<td>Food and Drug Administration</td>
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<td>FMEA</td>
<td>Failure, mode and effect analysis</td>
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<td>FMI</td>
<td>Food Marketing Institute</td>
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<td>FSIS</td>
<td>Food Safety and Inspection Services</td>
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<td>FSMS</td>
<td>Food safety management system</td>
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<td>GATT</td>
<td>General Agreement on Tariffs and Trade</td>
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<td>GFSI</td>
<td>Global Food Safety Initiative</td>
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<td>GMPs</td>
<td>Good manufacturing practices</td>
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<td>HACCP</td>
<td>Hazard Analysis and Critical Control Points</td>
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<td>ISO/TS</td>
<td>ISO Technical Specification</td>
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<td>NF</td>
<td>Nanofiltration</td>
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<td>OPRPs</td>
<td>Operational prerequisite programmes</td>
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<td>PRPs</td>
<td>Pre-requisite programmes</td>
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<td>QMS</td>
<td>Quality management system</td>
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<tr>
<td>RO</td>
<td>Reverse osmosis</td>
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<tr>
<td>SLDBs</td>
<td>Small and/or less developed businesses</td>
</tr>
<tr>
<td>TBT</td>
<td>Technical Barriers to Trade</td>
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<tr>
<td>TQM</td>
<td>Total quality management</td>
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<tr>
<td>TQS</td>
<td>Total quality system</td>
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<tr>
<td>UF</td>
<td>Ultrafiltration</td>
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<tr>
<td>WTO</td>
<td>World Trade Organisation</td>
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</table>

REFERENCES


Codex Alimentarius Commission (1997) Hazard Analysis and Critical Control Point (HACCP) System and


Food Safety and Inspection Service (1996) Pathogen reduction; hazard analysis and critical control point (HACCP) systems; final rule. Federal Register, 61(44), 38806–38899.

Food Safety and Inspection Service (2000b) Very small plants successfully implement HACCP News release.


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Cooperative. Available at www.ces.ncsu.edu/depts/foodsafety/pdf/haccpcontrol.pdf


Electronic references

http://www.cardiff.ac.uk/ObLyView.asp/Object_ID=398

http://www.webhome.bowdard.edu/~dweber/MCB2010/Study%20Guides/Ch07_MicrobeStudyGuide.pdf
http://www.eere.sciences.utoloe.edu/Faculty/Sighti/ COURSES/Microbial%20Ecology%201Lecture/12%20-%20Controlling%20microbes.pdf
http://muglythb.mit.edu/Course%20Materials/22.01/Fall%202001/fod%20irradiation.pdf
http://www.sfsa.com/publications/haccp/WHAT_IS_HACCP.pdf
http://www.praxiom.com/iso-22000-intro.htm
http://www.nasa.gov/centers/arc/information/ISO22000.html
http://www.degrandison.ac/275-FSMS.htm
http://www.bulthek.com/English_Site/ISO9000_Introduction_English/HACCP/English/ISO_22000/iso_22000.html
http://www.ourfood.com/foodsafety/FoodSafetyAndControlSystem15.pdf
http://www.foodsafety.sgs.com/what_is_22000.pdf
http://www.gmi.com/registration/foodsafety/iso22000/default.asp
HACCP and ISO 22000 – A Comparison of the Two Systems

http://www.bis.org.in/cert/fsms.htm
http://www.praxiom.com/iso-22000-definitions.htm
http://www.codesalimentarius.net/download/standards/10087/CXC_057_2004e.pdf
http://www.qualitycouncil.com/samples/iso.pdf
http://www.bsiamerica.com/HealthUpdate/HaRiskIssues/December2006.xalter