34 ISO 22000 Food Safety

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34.1 INTRODUCTION

Food is essential to life and for this reason people have the right to expect that the food they eat is safe and sensorial and ethically suitable for consumption. If the food is abused or contaminated it can cause illness and even death. There are also other economical and social consequences. Food spoilage is wasteful, costly and can adversely affect trade and consumer confidence. International food trade and tourism are also permanently increasing. However these also contribute to the fast transmission and spreading of illnesses around the globe (Dorny *et al*., 2009; Newell *et al.*, 2010).

Rising incomes, mobility and worldwide incidents involving food and agriculture have given rise to the demands to know how food is produced and to be assured of its safety and quality. Recent food crises in many countries have contributed to a decline in the public's confidence of regulatory agencies to deal with food and agricultural safety issues (Ko, 2010). The increased demand for safer food has resulted in the development and introduction of new food safety standards and regulations to reach a higher level of food safety (Aruoma, 2006). An integrated approach to controlling food safety throughout the entire food supply chain from farm to table has become an important issue. Standards are an integral part of daily life and are designed to ensure desirable characteristics of products and services. They are focused on quality, reliability, efficiency, interchangeability, environmental friendliness and safety – while remaining sensitive to economic issues (Traill and König, 2009). Standards have added an enormous and positive contribution to most aspects of human lives and have made our lives safer, easier, and better. They are also vital tools of industry and commerce, although over-standardization can foreclose the entry of products into the complementary service market (Blankart and Knieps 1995; Hermann, 2009). However, when standards are absent, we soon notice if products are of poor quality, do not fit, are incompatible with equipment that we already have, and are unreliable or even dangerous (ISO, 2009). Respecting power of standardization and harmonization, it is obvious that we should follow the basic rules of standards, which are focused on protection of human beings, animals, property and the environment against hazards of all kinds, ensuring interchangeability and interoperability, facilitating communication and providing a basis for the achievement, assessment and demonstration of

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quality. Finally we have to integrate them with technological practice along the food supply chain.

34.2 HISTORY OF FOOD STANDARDS

Knowledge about how to get enough food and how to get it right is an essential part of all cultures in different time periods throughout history. Food safety rules have a long track record. Food laws can be traced back to the earliest societies. Several instructions on the manner of handling food are even contained in the *Old Testament*. Ancient food regulations are referred to in Egyptian, Chinese, Greek and Roman literature. In the Middle Ages, the trade guilds exerted a powerful influence on the regulation of food trade and the prevention of adulteration of food products. Later on, initiative in food control was taken by the state, municipal or other local authorities. After the eighteenth century food adulterations became dangerous to human health, e.g. vinegar was often adulterated with sulphuric acid; wine with preservatives containing lead salts; green vegetables in vinegar with copper; and confectionery products with colorings containing lead and arsenic (Accum, 1820). Developments in chemistry, biology, physics, and particularly in analytics, contributed essentially to the deterioriation of foodstuffs, which were maltreated and even adulterated. For that reason it is understandable that we detected cases of food adulteration from the eighteenth century onwards. The big changes in food production consisted of industrialization and new distribution chains, which were connected to the rapid growth in urban populations together with a public health problem which resulted in the creation of many food laws during the nineteenth century. After World War II, activity in international standardization started to grow intensively. This phenomenon, connected to the new concept of food trade, was also stimulated and supported in the framework of the International Organization for Standardization (ISO) (Lasztity *et al*., 2004; Raspor *et al*., 1993).

ISO was born from the union of two organizations – the ISA (International Federation of the National Standardizing Associations), established in New York in 1926, and the UNSCC (United Nations Standards Coordinating Committee), established in 1944. In October 1946, delegates from 25 countries, meeting at the Institute of Civil Engineers in London, decided to create a new international organization, of which the objective was to "to facilitate the international coordination and unification of industrial standards." The new organization officially started to work on February 23, 1947 (ISO, 2009).

The International Organization for Standardization (ISO) is a nongovernmental organization that forms a bridge between the public and private sectors. ISO is a worldwide federation of national standards bodies. Between 1947 and the present day, ISO has published more than 17 500 International Standards, ranging from standards for activities such as agriculture and construction, through mechanical engineering, to medical devices, to the newest information technology developments and is the world's largest standards development organization (ISO, 2009).

The aim of ISO standards is to (ISO, 2009):

- make the development, manufacturing and supply of products and services more efficient, safer and cleaner;
- facilitate trade between countries and make it fairer;
- provide governments with a technical base for health, safety and environmental legislation, and conformity assessment;

- share technological advances and good management practice;
- disseminate innovation;
- safeguard consumers, and users in general, of products and services;
- make life simpler by providing rational solutions to common problems.

In recent years, certification has become increasingly relevant for agribusiness. In Europe, substantial parts of the value chain are already being certified by standards. There are recent studies discussing the reliability of third-party certification in the food chain and they see progression from checklists to risk-oriented auditing (Albersmeier *et al*., 2009).

34.3 REVIEW OF EXISTING STANDARDS RELATED TO FOOD

Consumers in industrialized countries demand food products of high and consistent quality in broad assortments throughout the year and for competitive prices. Today's consumer has become increasingly concerned about the quality and safety of food (Trienekens and Zuurbier, 2008). In spite of all foodborne diseases preventive programs in food supply chain and invested efforts the number of foodborne diseases is rising and is responsible for approximately 2.2 million deaths annually (WHO, 2009). Not only are bacterial infections a problem (Raspor and Jevšnik, 2008; Tauxe, 2002), but lately enteric viruses have been increasingly recognized as an important cause of foodborne disease (FAO/WHO 2008; Kovač *et al*., 2009). Consumer concerns related to food safety scandals and globalization of food production have resulted in a global and interconnected system for the production and distribution of food.

Since the 1990s there has been an increase in food standards. Companies around the world are using quality assurance systems to improve their product and production processes. In this development there is a move from the former end-of-line product inspection approach to in-line inspection approach. This new environment of quality assurance, where the latter is required at each step in the food production chain to ensure safe food, and to show compliance with regulatory, retailer and customers' requirements, is considered by some authors to consist of both public and private standards.

In the last two decades many public and private standards on food safety and quality have been established as a result of these developments. Public standards have the ultimate role of protecting consumers, while private standards are designed to protect their own business (Trienekens and Zuurbier, 2008). On national and international levels many government laws and regulations on quality and safety of food have also been established through public standards, which tend to focus primarily on risks due to food hazards (Trienekens and Zuurbier, 2008). Private standards often consider food hazards as well as environmental, ethical, occupational health issues and other social responsibility issues. Private standards are driven by the food industry, retail buyers, buyers' organizations, commodity groups, nongovernmental organizations (NGOs) and others, because the key factors driving private standards are brand protection, the promotion of business improvement and efficiency, and assistance in response to consumers concerns (Fulponi, 2006; Henson and Reardon, 2005; Trienekens and Zuurbier, 2008).

On a global level the Codex Alimetarius Commision, established by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) in the early 1960s, has become the single most important international reference point for developments

associated with foods standards. The *Codex Alimentarius Commission* is committed to protecting the health of consumers, ensuring fair practices in the food trade and facilitating international trade in food (CAC, 2006). *Codex Alimentarius* food standard issues range from specific raw and processed materials characteristics to food hygiene, pesticides residues, contaminants and labeling, to analysis and sampling methods (CAC, 2006).

Since the 1990s many private voluntary food quality and safety standards (i.e. ISO standards, International Food Standards (IFS), British Retail Consortium (BRC) and the Safety Quality Food (SQF) programs have been developed. The major aims of private food standards are to (Vellema and Boselie, 2003):

- improve supplier standards and consistency, and avoid product failure;
- eliminate multiple audit of food suppliers-manufacturers through certification of their processes;
- support consumer and retailer objectives by transferring their demands to parties upstream the chain;
- be able to provide concise information about production processes in case of food incidents.

Demands regarding private food safety standards are best represented by worldwide forum: the Global Food Safety Initiative (GFSI), which is coordinated by the Consumer Goods Forum (GFSI, 2009). This forum is a global food network made up of approximately 400 retailers and manufacturers world-wide. In May 2000 the GFSI was launched to provide convergence between food safety standards and establish a benchmarking process for the different food safety management schemes and achieve common acceptance of GFSI recognized standards. The GFSI vision "once certified, accepted everywhere" is eliminating the time spent involved in duplication of audits. The food safety schemes currently benchmarked by GFSI are ISO 22000, BRC, IFS, Dutch HACCP and SQF (GFSI, 2009).

The Safety Quality Food (SQF) program was designed to meet the needs of suppliers and buyers, to ensure their compliance with food safety regulations in both domestics and global markets at all stages of the supply chain. It comprises SQF 1000, which is based on the principles of HACCP and SQF 2000, and is a complete HACCP system (GFSI, 2009).

The British Retail Consortium (BRC) Global Standard for Food Safety is one of the operational tools most frequently used for due diligence and supplier approval. It helps companies to select and qualify their suppliers. The system reduces the overall costs of the supply chain management and increases the level of safety for customers, suppliers and consumers (GFSI, 2009).

The International Food Standard (IFS) is a common food safety standard with a uniform evaluation system used to qualify and select suppliers. It helps retailers ensure the food safety of their products and monitors the quality level of producers of retail branded products (GFSI, 2009).

A group of experts on food safety representing all parties in the Dutch food chain developed as a standard the Requirements for a HACCP based Food Safety System, also known as Dutch HACCP for food safety management. The Dutch HACCP is a worldwide recognized system for the processing of safe foods and is based on the *Codex Alinorm*, which contains the HACCP principles and steps in detailed requirements suitable for small as well as large-sized food business organizations. Other major aspects of this standard are continuous participation of all parties concerned in food safety in the maintenance of the

certification scheme and a high-level set of requirements of a certification scheme. Today most major world retailers have agreed to accept specific benchmarked schemes (SCV, 2009). These standards are also related to the generic quality assurance systems in the food sector. This is because private standards incorporate the key elements of generic quality assurance systems, such as HACCP and Good Agricultural Practices (GAPs) (Trienekens and Zuurbier, 2008).

34.4 CONCEPTUAL PRINCIPLES FOR STANDARD DEVELOPMENT

According to the definition, standardization is the activity of establishing provisions for common and repeated use, aimed at the achievement of the optimum degree of order in a given context (SIST EN 45020). In particular, the activity consists of the processes of formulating, issuing and implementing standards. Important benefits of standardization are improvement of the suitability of products, processes and services for their intended purposes, prevention of barriers to trade and facilitation of technological cooperation. In the standardization process, involvement is open to all interests through the relevant technical bodies, which are set up in a balanced manner by the representatives of manufacturers, legislators, laboratories, research and education institutes, and consumers.

ISO committees are made up of ISO member bodies. They chose to be participating members or observer members, and the committees are also open to ISO correspondent members. In the case of participating members, the member body facilitates the process of negotiation and consensus building across stakeholders in national mirror committees and contributes to the international negotiation and consensus building process. At meetings of ISO committees, members are represented by delegations drawn from the national mirror committees. National representatives are expected to present their members' views in the overall work of a committee and participate in reviews of the committee's work. ISO's deliverables are developed through a sequence of project stages (ISO, 2007).

A project in ISO, also called work item, is any work leading to the development, revision or amendment of a standard or any other deliverable produced by an ISO committee. Activities follow a planned approach using specifically allocated resources. Each discrete project has a defined beginning and end, intermediate milestones and normally involves a working group. Project management is a discipline of defining and achieving project targets, while optimizing the use of available or allocated resources during the project and involves the participation of the ISO system technical committee (TC) and subcommittee (SC) secretaries. The TC is responsible for the overall management of that committee, including any subcommittees and working group (ISO, 2007).

ISO's deliverables are developed through a sequence of project stages. Each stage has its name, but very often the stages are identified by using the acronyms associated with the product name at each stage (Table 34.1). The preliminary stage is used to advise committee members of future work items, such as further parts of the standard. The proposal stage starts with the submission of a proposal for a new project. This stage is an assessment phase that all proposals for new projects must pass through to ensure that only projects for which there is a confirmed need or appropriate resources are available will be added to the work programme. The preparatory stage comprises the preparation and consideration of one or more working drafts until a consensus has been reached in a working group. The committee stage is the principal stage at which comments from national members are taken into consideration with a view to reaching consensus on the technical content of the

Table 34.1 ISO's project stages.

Stage name	Product name (document)	Acronym
Preliminary stage	Preliminary work item (project)	PWI
Proposal stage	New proposal for a work item	NP
Preparatory stage	Working draft(s)	WD
Committee stage	Committee draft(s)	CD
Enquiry stage	Draft International Standard	DIS
Approval stage	Final Draft International Standard	FDIS
Publication stage	International Standard	IS

Source: ISO (2007).

Table 34.2 Standards that reinforce ISO 22000 family implementation.

Technical specification	Publishing date	Scope
ISO 22000:2005 **Food safety management systems – Requirements for any organization in the food chain**	September 2005	The aim of this standard is to ensure that there are no weak links in food supply chains
ISO/TS 22002-1:2009 **Prerequisite programmes on food safety – Part 1: Food manufacturing**	December 2009	This technical specification specifies requirements for establishing, implementing and maintaining prerequisite programs (PRP) to assist in controlling food safety hazards
ISO/TS 22003:2007 **Food safety management systems – Requirements for bodies providing audit and certification of food safety management systems**	February 2007	This technical specification offers harmonized guidance for the accreditation of certification bodies and defines the applicable rules for the audit of a food safety management system compliant with ISO 22000
ISO/TS 22004:2005 **Food safety management systems – Guidance on the application of ISO 22000:2005**	September 2005	This technical specification provides guidelines on implementing ISO 22000, with particular emphasis on good examples
ISO 2005:2007 **Traceability in the feed and food chain – General principles and basic requirements for system design and implementation**	July 2007	This standard gives the principles and specifies the basic requirements for the design and implementation of a feed and food traceability system

committee draft. In the enquiry stage the document is made available to all member bodies for voting. This is the first full review outside its parent committee. Agreement to publish is achieved in approval stage and in the publication stage the standard is launched. Publication as an international standard requires approval by at least 75% of the member bodies casting a vote (ISO, 2007).

ISO 22000 family was developed by the ISO technical committee for food products (ISO/TC 34) and subcommittee for management systems for food safety (TC 34/SC 17). In September 2005 the new standards of ISO 22000 family was launched. ISO 22000 family is supported by a complete set of standards (Table 34.2) that reinforce its implementation in a professional and trustworthy manner (ISO, 2009).

34.5 ISO 22000

Standards include technical specifications and other precise measures which are often applied as rules, instructions, test procedures or definitions of individual characteristics (Raspor, 1993). Standards are developed primarily with the aim of making the materials, products, procedures and services fit for purpose (ISO 22000:2005, 2005).

34.5.1 Purpose

Food safety is related to the presence of foodborne hazards in food at the point of consumption (Jevšnik *et al*., 2008a, 2008b). As the introduction of food safety hazards can occur at any stage of the food chain, adequate control throughout the food chain is essential (Jevšnik *et al*., 2007, 2008c). Food safety is ensured only then through combined efforts, when all the parties are participating in the food chain (ISO 22000:2005, 2005).

The food chain consists of an entire sequence of stages and operations involved in the creation and consumption of food products. This includes every step from initial production to final consumption. The food chain also includes organizations that do not directly handle food. These include organizations making feed for animals that produce food and for animals that will be used as food. It also includes organizations making materials that will eventually come into contact with food or food ingredients, such as equipment and package materials and cleaning agents (ISO 22000:2005, 2005).

Since the ISO 22000 is a generic food safety management system (FSMS), it can be used by any organization directly or indirectly involved in the food chain. ISO 22000 can help ensure the safety of its products, because it applies to all organizations in the food chain and it does not matter how complex the organization is or what size it is (ISO 22000:2005, 2005).

ISO 22000 defines the requirements for a FSMS that combines the following generally recognized key elements to ensure food safety along the food chain from production to consumption (ISO 22000:2005, 2005):

- interactive communication;
- system management;
- prerequisite programs;
- HACCP principles.

This standard allows each food organization to implement an externally developed combination of control measures. To facilitate the application of this standard, ISO 22000 has been developed as an auditable standard. However individual organizations are free to choose the necessary methods and approaches to fulfil the requirements of these standards (ISO 22000:2005, 2005).

The aim of this standard is to harmonize on a global level the requirements for food safety management for businesses within the food chain and to provide a practical approach to ensure the reduction and elimination of food safety hazards as a means to protect consumers. This standard requires an organization to meet any applicable food safety related statutory and regulatory requirements through its food safety management system (ISO 22000:2005, 2005).

34.5.2 Principles

34.5.2.1 *The Quality Management System (QMS)*

Food quality and safety are important drivers for the organization and management of food production systems in agribusiness and the food industry. In the last decades consumers have become very critical about food quality and food safety as a result of several incidents of contaminated food, such as mad cow disease (BSE), foot and mouth disease (FMD), product recalls linked to pathogen-related foodborne illnesses (*Listeriosis*) and dioxin poisoning. In order to build and maintain the trust of consumers in food quality and food safety, quality management systems (QMS) are used to control the quality and safety of products.

Severe food legislation requirements, in combination with changes in food supply chains, health and demographic situations, lifestyle, social situations and environmental conditions, have led to significant efforts in the development of quality management systems in agribusiness and food industry worldwide. Nowadays in the food industry quality assurance systems, such as GMP, HACCP, ISO and BRC standards, are applied for assuring food quality (Van der Spiegel *et al.*, 2003). Because quality systems differ in several aspects, they are combined or integrated to assure more aspects of food quality. Quality is divided into aspects of product safety, products quality and total quality, which embrace products safety and quality (Raspor and Jevšnik, 2008). Each quality assurance system is focused on a particular aspect. For example, GMP and HACCP are especially developed to assure food safety (Hoogland *et al*., 1998; Raspor, 2004). Like HACCP, BRC deals with food safety and product quality but also evaluates management aspects like ISO and facility conditions like GMP. Additionally ISO and TQM focus more on management aspects, whereas GMP and HACCP focus on technology aspects (Hoogland *et al*., 1998). Food manufacturers have to decide which quality assurance is most suitable to their situation and how this system should be implemented. Over the last few years, a large number of companies have implemented quality assurance systems and TQM systems in order to introduce effective quality systems and consequently produce and distribute high quality products (Raspor, 2008).

In the food industry, quality is the requirement for consumer acceptance. Historically, commercial organizations in economically advanced nations have focused on preventing defective goods and services from entering the market. Total Quality Management (TQM) is the theory of management based on principles of quality assurance. TQM is not a quality assurance system but a management view that covers the complete quality system.

Quality assurance is a modern term describing the control, evaluation and audit of a food processing system. It consists of the integration of all functions and processes within an organization in order to achieve continuous improvement of the quality of goods and services (Vasconcellos, 2004). The application provides the best possible care by products and services to continuously meet or possibly exceed the needs and expectations of the customer. Established techniques and processes are commonly used to assist the manager in continuously evaluating quality trends and to identify improvement opportunities. To achieve the required standards, quality management throughout all stages of the agro-food chain is very important. The policy of food companies will increasingly be directed toward food safety, ensured by effective quality management (Barendsz, 1998; Raspor, 2006).

The food industry places increasing emphasis on product innovation as a mechanism to sustain consumer interest and develop market growth and market share. As part of any TQM activity, priority must be given to the structure and improvement of communication,

especially in the food sector, where internationalization and globalization are increasingly important topics. TQM techniques such as, employee training and empowerment, data-based team decision-making processes, benchmarking operations against the best competitor companies and partnership have demonstrated an ability to maximize productivity while minimizing costs (Barendsz, 1998).

New challenges in reducing incidence of food safety hazards due to typical changes in food supply chains (e.g. longer chains, booming food service establishments), health and demographic situations (e.g. more vulnerable groups, rapid urbanization), social situations (e.g. increased consumption of ready-to-eat foods, increased travel and exposure to unsafe foods) and environmental conditions (e.g. increased pollution) underpin the need for effective food safety management system (Crerar, 2000; Motarjemi and Käferstein, 1999; Raspor, 2003a; Van der Spiegel *et al*., 2003; Woteki and Kineman, 2003). Food safety management systems commonly consist in essence of safety control, which is aimed at realizing food safety and assurance and is focused on providing confidence in meeting safety requirements (Luning *et al*., 2002, 2006; Luning and Marcelis, 2007). Both activities contribute to the overall performance of a food safety management system (Raspor, 2008).

The term "food safety management system" (FSMS) is composed of two concepts: "food safety" and "management system." "Food safety" is defined according to *Codex Alimentarius* (CAC, 2003) as the assurance that food will not harm the consumer when it is prepared and/or eaten according to its intended use, which in reality is not always the case (Jevšnik *et al*., 2008c). "Quality management system" refers to all activities that organizations use to direct, control, and coordinate quality, including formulating a quality policy, setting quality objectives, quality planning, control, assurance and improvement (ISO 9000:2000, 2000). A food safety management system involves that part of the QMS specially focused on food safety.

The most effective food safety systems are established, operated and updated within the framework of a structured management system and incorporated into the overall management activities of the organization. This provides maximum benefit for the organization and interested parties. This international standard has been aligned with ISO 9001 in order to enhance the compatibility of the two standards (ISO 22000:2005, 2005).

ISO 22000 can be applied independently of other management system standards. It contains traditional quality assurance preventive measures plus preventive food safety measures. Its implementation can be aligned or integrated with existing related management system requirements, while organizations may utilize existing management systems to establish a food safety management system that complies with the requirements of this standard (ISO 22000:2005, 2005).

34.5.2.2 *Communication*

Communication is one of the most important behavioral aspects of humans. The business strategy guides the policies and practices for external and internal communication, which when successfully implemented is helping to achieve management goals (Large, 2005; Miller, 2006). Food reaches consumers via supply chains that link many different types of organization and they stretch across multiple borders. One weak link can result in unsafe food that is dangerous to health. Confidence in the safety and integrity of the food supply is an important requirement for consumers as well as for food handlers (Wentholt *et al*., 2009).

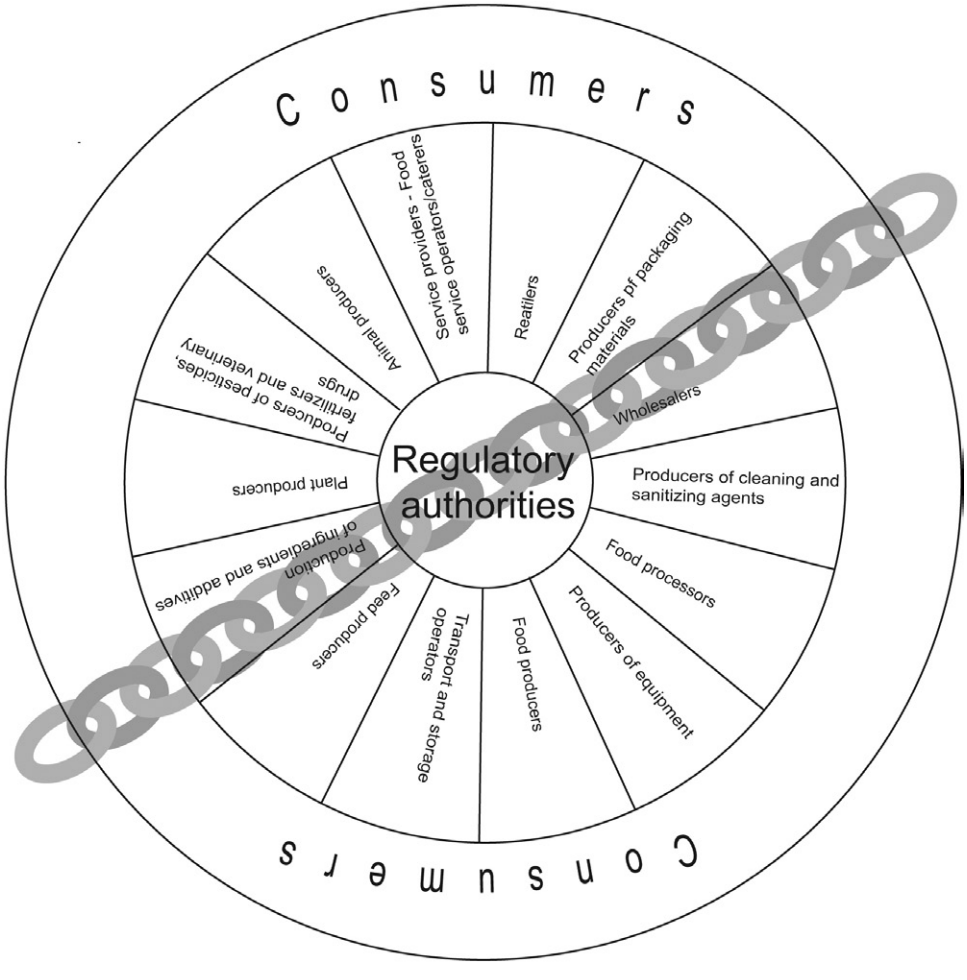

Fig. 34.1 The routes of communication and interaction within the food supply chain.

As food safety hazards can enter the food chain at any stage, adequate control and communication (Fig. 34.1) throughout is essential. This implies communication between organization both upstream and downstream in the food chain. Food safety is a joint responsibility of all actors in the food chain and requires their combined efforts and that is why communication with customers and suppliers about identified hazards and control measures will assist in clarifying customer and supplier requirements. The majority of microbial foodborne illnesses are thought to be preventable if food safety principles are understood and practiced throughout the entire food supply chain from production to consumption (Jacob *et al*., 2009; Smole-Možina and Uzunović-Kamberović, 2005).

Recognition of the organization's role and position within the food chain is essential to ensure effective interactive communication throughout the chain in order to deliver

safe food products to the final consumer. Despite the efforts of food safety information campaigns and educational efforts, food remains a prevalent vehicle of disease (Jevsnik *et al*., 2008c; Redmond and Griffith, 2003).

34.5.2.3 *Prerequisite programs (PRPs)*

Prerequisite programs are clearly an essential element in the task of developing simple, effective HACCP systems. Prior to application of HACCP to any sector of the food chain, that sector should have in place prerequisite programs (CAC, 2003) such as good hygienic practices, the appropriate codes of practice, and appropriate food safety requirements (Raspor, 2000, 2002, 2004).

HACCP must be supported by a strong foundation of prerequisite programs (Raspor, 2008). Prerequisite programs or even better pre-requirements to HACCP may include (Sperber, 1998):

- specifications for raw materials, finished products, and labeling;
- supplier approval and/or certification; chemical control programs;
- audits and inspections;
- product identification and retrieval procedures;
- training;
- water and air control;
- good manufacturing practices.

These prerequisite programs to HACCP should be well established, fully operational and verified in order to facilitate the successful application and implementation of the HACCP system. Raspor (2008) described in his work Good Agriculture Practice (GAP), Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), Good Hygiene Practice (GHP), Good Transport Practice (GTP), Good Storage Practice (GSP), Good Retail Practice (GRP), Good Catering Practice (GCP) and Good Housekeeping Practice (GHP) as nine basic good practices. Which prerequisite program (PRP) is needed depends on the segment of the food chain in which the organization operates and the type of organization.

ISO 22000 defines prerequisite programs as basic conditions and activities, which are necessary to maintain a hygienic environment throughout the food chain suitable for the production, handling and provision of safe end-products and safe food for human consumption. With regard to the standard examples of equivalent term of PRPs are also Good Agricultural Practice (GAP), Good Veterinarian Practice (GVP), Good Manufacture Practice (GMP), Good Hygienic Practice (GHP), Good Production Practice (GPP), Good Distribution Practice (GDP) and Good Trading Practice (GTP) (ISO 22000:2005, 2005).

34.5.2.4 *The HACCP plan*

The Hazard Analysis Critical Control Point (HACCP) concept is now well-known internationally and is being implemented in many countries throughout Europe, the United States and beyond. In the late 1960s, the HACCP concept was developed. The concept of HACCP is the result of joint effort of the Pillsbury Co., the National Aeronautics and Space

Administration, and the US Army Natick Laboratories to attempt to apply a zero-defects program to the production of food (Bauman, 1974).

The HACCP system, which is science based and systematic, identifies specific hazards and measures for their control to ensure the safety of food. HACCP is a tool to assess hazards and establish control systems that focus on prevention rather than relying mainly on end-product testing (Raspor 2002). In food safety program we should be able to identify all hazards, analyze them, assess the likelihood of their occurrence and identify measures for their control. Hazard is a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect (CAC, 2003).

The HACCP system consists of the following seven basic principles (CAC, 2003):

1. conduct a hazard analysis;
2. determine the Critical Control Points (CCPs);
3. establish critical limit(s);
4. establish a system to monitor control of the CCP;
5. establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control;
6. establish procedures for verification to confirm that the HACCP system is working effectively;
7. establish documentation concerning all procedures and records appropriate to these principles and their application.

The successful application of the HACCP system requires the full commitment and involvement of management and the workforce. For all types of food business, management awareness and commitment is necessary for implementation of an effective HACCP system. The effectiveness will also rely upon management and employees having the appropriate HACCP knowledge and skills. The HACCP system also requires a multidisciplinary approach, which should include individuals who have specific knowledge in the food field and expertise appropriate to the location, such as expertise in agronomy, veterinary health, production, microbiology, medicine, public health, food technology, environmental health, chemistry and engineering (Raspor, 2002). The application of the HACCP system is also compatible with the implementation of quality management systems, such as the ISO 9000 series (Hoyle, 2009).

During hazard identification, evaluation, and subsequent operations in designing and applying HACCP systems, attention must be given to the impact of raw materials, ingredients, food manufacturing practices, role of manufacturing processes to control hazards, likely end-use of the product, categories of consumers of concern, and epidemiological evidence relative to food safety.

ISO 22000 combines the Codex Alimentarius HACCP system principles and application steps, developed by Codex Alimentarius with prerequisite programs. It uses the hazard analysis to determine the strategy for hazard control. This standard requires that all hazards that may be reasonably expected to occur in the food chain, including hazards that may be associated with the type of process and facilities used, are identified and assessed. Like this it provides the means to determine and document why certain identified hazards need to be controlled by a particular organization and why others need not (Köenig 2009). During hazard analysis, the organization determines the strategy to be used to ensure hazard control by combining the PRPs, operational PRPs and the HACCP plan.

34.6 APPLICATION OF ISO 22000 IN PRACTICE

ISO 22000 is a generic food safety management system standard. It defines a set of general food safety requirements (Table 34.3) for a food safety management system, where an organization in the food chain needs to demonstrate its ability to control food safety hazards. These requirements are listed in Sections 1 (Scope), 2 (Normative references),

Table 34.3 The requirements of ISO 22000:2005.

			7.10 Control of nonconformity	
			7.9 Traceability system	
	5.8 Management review		7.8 Verification planning	
	5.7 Emergency preparedness and response		7.7 Updating of preliminary information and documents specifying PRPs and the HACCP plan	
	5.6 Communication		7.6 Establishing the HACCP plan	
	5.5 Food safety team leader		7.5 Establishing the operational prerequisite programs (PRPs)	8.5 Improvement
	5.4 Responsibility and authority	6.4 Work environment	7.4 Hazard analysis	8.4 FSMS verification
	5.3 FSMS planning	6.3 Infrastructure	7.3 Preliminary steps to enable hazard analysis	8.3 Control of monitoring and measuring
4.2 Documentation requirements	5.2 Food safety policy	6.2 Human resources	7.2 Prerequisite programs (PRPs)	8.2 Validation of control measure combinations
4.1 General requirements	5.1 Management commitment	6.1 Provision of resources	7.1 General	8.1 General
4 **Food safety management system**	**5** **Management responsibility**	**6** **Resource management**	**7** **Planning and realization of safe products**	**8** **Verification, validation and improvement**

3 (Terms and definitions), 4 (Food safety management system), 5 (Management responsibility), 6 (Resource management), 7 (Planning and realization of safe products) and 8 (Validation, verification and improvement of the FSMS).

ISO 22000 is intended to enable an organization to (ISO 22000:2005, 2005):

- embed and improve the internal processes, which is needed to provide consistently safe food for the consumer;
- provide confidence to the organization and the management team that the organization's practices and procedures are in place and they are effective;
- provide confidence to the customers and other stakeholders that the organization has the ability to control food safety hazards and provide safe products;
- provide means of continual improvement to ensure that the food safety management system is reviewed and updated so that all activities related to food safety are continually optimized and effective;
- ensure adequate control at all stages of the food supply chain to prevent the introduction of food safety hazards;
- ensure that the organization conforms to its stated food safety policy;
- demonstrate such conformity to relevant interested parties;
- seek certification or registration of its food safety management system by an external organization, or make a self-assessment or self-declaration of conformity to this standard;
- effectively communicate food safety issues to their suppliers, customers, and relevant interested parties in the food chain.

All requirements of this standard are intended to be applicable to all organizations, which are involved in any aspect of the food chain regardless of the size and complexity. This includes organizations directly or indirectly involved in one or more steps of the food chain. Organizations that are directly involved can be feed producers, harvesters, farmers, producers of ingredients, food manufacturers, retailers, food services, catering services, organizations providing cleaning and sanitation services and transportation, storage and distribution services. Indirectly involved can be suppliers or producers of equipment, cleaning and sanitizing agents, packaging material and other elements which contact with food. For the application of ISO 22000 the ISO 9000:2000 *Quality Management Systems – Fundamentals and Vocabulary* is indispensible (ISO 22000:2005, 2005).

34.6.1 Food Safety Management System (FSMS)

The FSMS requires that the operator is obligated to establish, document, implement and maintain an effective FSMS, which should be update as necessary (see Fig. 34.2). One of the most emerging challenges is still to assess the performance of a present FSMS and to satisfy its needs regarding microorganisms in food (Jacxsens *et al.*, 2009).

The organization is obligated to (ISO 22000:2005, 2005):

- ensure that food safety hazards that may be reasonably expected to occur are identified, evaluated and controlled;
- communicate appropriate information throughout the food chain;

Fig. 34.2 ISO 22000:2005 requirements for food safety management system.

- communicate information concerning development, implementation and updating FSMS;
- evaluate periodically and update the FSMS.

Established and controlled documentation system is a part of effective ISO 22000. Traceable documentation reflects and represents actual situation of technological process control in production and preparing of food or in food trade, for assurance of healthy and safe food. A documented procedure has to be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records. The FSMS documentation should include (ISO 22000:2005, 2005):

- documented statements of the food safety policy and related objectives;
- documented procedures and records; and
- documents to ensure the effective development, implementation and updating of the FSMS.

Responsibility for safety is based upon documented personal responsibility of all workers included in the process. The operator has to ensure that all documents, records and data critical to the management of product quality and safety are in place and effectively controlled. All documents has to be legible, readily, identifiable and retrievable. Records are a special type of document, which are established and maintained to provide evidence of conformity to requirements and of the effective operation of the FSMS. All documents should be approved, signed and dated by appropriate authorized persons and kept up-to-date (ISO 22000:2005, 2005).

34.6.2 Management responsibility

The key to *management responsibility* (Fig. 34.3) is that management responsibility outlines the commitment of top management to the development, implementation and maintenance of FSMS, when changes to the food safety management system are planned and implemented (Luning *et al.*, 2002). Responsibilities and authorities of the FSMS are defined by top management and personnel of organization have to be acquainted with them to ensure the effective operation and maintenance of the FSMS. All personnel have responsibility to report problems with FSMS to designated persons, who should have defined responsibility and authority to initiate and record actions. Top management is also responsible for the appointment of a food safety team leader, who has the knowledge and expertise appropriate to (ISO 22000:2005, 2005):

- manage a food safety team and organize its work;
- ensure relevant training and education of the food safety team members;

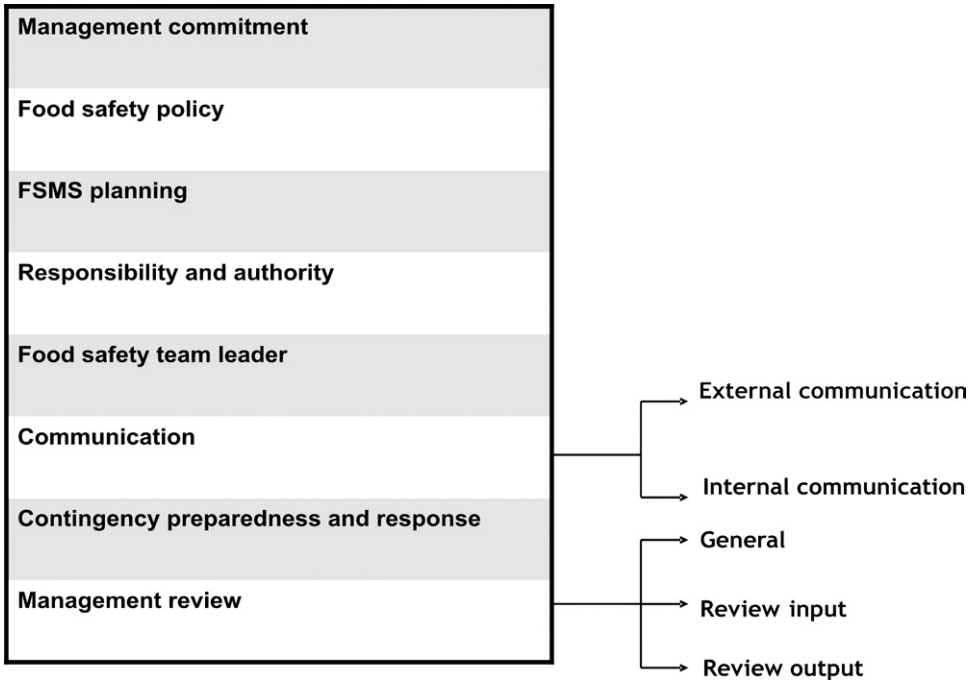

Fig. 34.3 ISO 22000:2005 requirements for management responsibility.

- ensure that the FSMS is established, implemented, maintained and updated; and
- report to the organization's top management on the effectiveness and suitability of the FSMS.

The food safety intentions of top management need to be documented throughout the business objectives of the organization and communicated through the organization. The organization has to assure continual improvement by communicating the importance of meeting statutory, regulatory and customer requirements, establishing the food safety policy, conducting management reviews and ensuring the availability of resources (ISO 22000:2005, 2005).

The standard defines food safety policy as overall intentions and directions of an organization related to food safety as formally expressed by top management. The food safety policy has to be consistent with the purpose of the organization in the food chain, both statutory and regulatory requirements and agreed food safety requirements for the customers. Beside that it has to be communicated, implemented and maintained at all levels of the organization, reviewed for further suitability and supported by measurable objectives (ISO 22000:2005, 2005).

Clear internal and external communication (Fig. 34.3) along the food chain is essential to ensure that food safety hazards are identified and adequately controlled. To ensure that sufficient information on issues concerning food safety is available throughout the food chain, the organization should establish, implement and maintain effective arrangements for communicating with (ISO 22000:2005, 2005):

- supplier and contractors;
- customers or consumers;
- regulatory and statutory authorities;
- media;
- stakeholders.

Such communication provides information on food safety aspects of the organization's products that may be relevant to other organizations in the food chain. This also applies to food safety hazards that need to be controlled by other organizations in the food chains. Only designated personnel shall have defined responsibilities and authority to communicate externally any information concerning food safety (ISO 22000:2005, 2005).

The organization shall establish, implement and maintain effective arrangements for communicating with personnel on issues having an impact on good safety. The food safety team should be immediately informed about (ISO 22000:2005, 2005):

- products or new products;
- raw materials, ingredients, services;
- production systems and equipment;
- production premises, location of equipment, surrounding environment;
- cleaning and sanitation programs;
- packaging, storage, and distribution system;
- personnel qualification levels and/or allocation of responsibilities and authorizations;
- statutory and regulatory requirements;
- knowledge regarding food safety hazards and control;
- customer, sector and other requirements that the organization considers necessary;
- relevant enquiries from external interested parties;
- complaints indicating food safety hazards associated with the products;
- other conditions that have an impact on food safety.

Information obtained through external and internal communication should be included as input to system updating and management review.

Top management shall review the organization's FSMS at defined intervals to ensure its continuing suitability and effectiveness and records of management reviews have to be maintained. The input to management review (Fig. 34.3) should include current performance and improvement opportunities related to the follow-up actions from previous management reviews; analysis of results of verification activities, changing circumstances that can affect food safety, emergency situations, accidents and withdrawals, reviewing results of system-updating activities, review of communication activities and external audits or inspections. The output from the management review (Fig. 34.3) should include decisions and actions related to assurance of food safety, improvement of effectiveness of FSMS, resource needs and revisions of the organization's food safety policy and related objectives. Top management should establish, implement and maintain procedures to manage potential emergency situations and accidents that can impact food safety as well (ISO 22000:2005, 2005).

34.6.3 Resource management

An effectively implemented FSMS requires that top management provides adequate resources, budgets, and personnel to effectively run the system (Fig. 34.4). The food safety

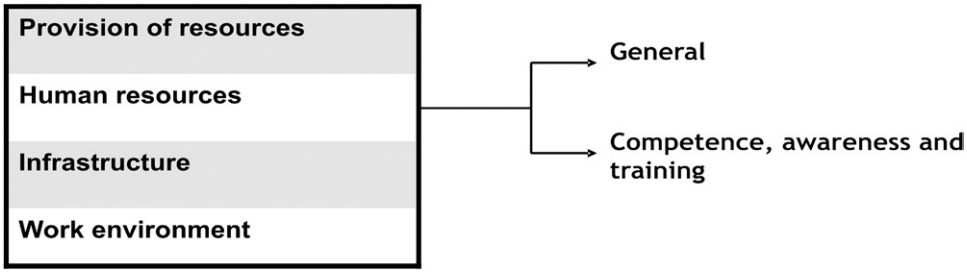

Fig. 34.4 ISO 22000:2005 requirements for resource management.

team and other personnel carrying out activities having an impact on food safety should be competent, and have appropriate education, training, skills and experience (Seaman, 2010). Where the assistance of external experts is required, records of agreement or contracts, defining the responsibility and authority should be available too (ISO 22000:2005, 2005).

Meta-analysis of barriers during HACCP implementation has shown that among 21 elements we can allocate seven elements (training, human resources, planning, knowledge and competence, management commitment) representing almost 50% (47.8%) of all identified barriers. The influence of each element on HACCP efficiency was ranked according to frequency of their citation in analyzed studies (Jevšnik *et al*., 2006; Raspor, 2008).

The organization is responsible for ensuring that all personnel are trained and experienced to the extent necessary to undertake their assigned activities and responsibilities effectively. The organization is obligated to (ISO 22000:2005, 2005):

- determine the necessary competencies for personnel performing work affecting food safety;
- provide training to ensure personnel having the necessary competencies;
- assess the effectiveness of the action taken;
- ensure that 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;
- provide the resources for the establishment, management and maintenance of the infrastructure and work environment needed to implement the standards.

Practical experience and a review of food safety literature performed by Taylor and Kane (2005) indicates that success in developing, installing, monitoring and verifying a successful HACCP system depends on overcoming a complex mix of managerial, organizational and technical hurdles. Even the largest and most well-equipped food companies with significant resources of money, technical expertise and management skills face a difficult challenge; whilst the SMEs often feel that the difficulties of HACCP are potentially insurmountable (Taylor and Kane, 2005). The fact that a person is and will be responsible for HACCP implementation and further control calls for an in-depth analysis and understanding of individual's reaction to received information (Jevšnik *et al*., 2006).

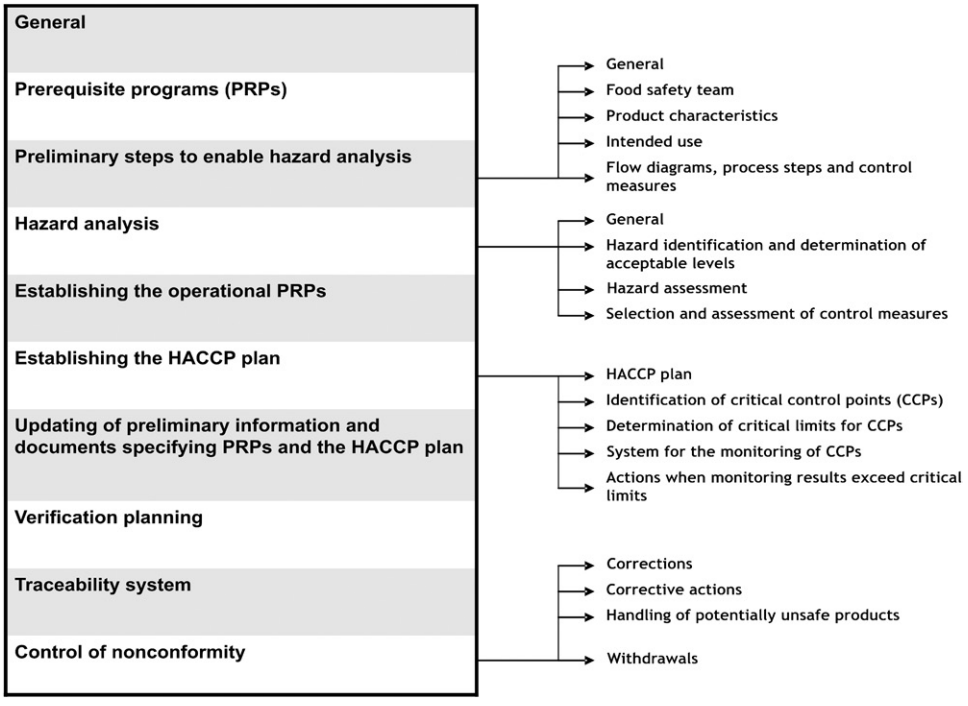

Fig. 34.5 ISO 22000:2005 requirements for planning and realization of safe products.

34.6.4 Planning and realization of safe products

With regard to the standard, the organization is obligated to plan and develop the processes needed for the realization of safe products (Fig. 34.5). Beside that, the organization also has to implement, operate and ensure the effectiveness of the planned activities with PRPs, operational PRPs and/or the HACCP plan (ISO 22000:2005, 2005).

This standard requires that the organization establishes, implements and maintains PRPs to assist in controlling (ISO 22000:2005, 2005):

- the likelihood of introducing food safety hazards to the product through the work environment;
- biological, chemical and physical contamination of the products;
- cross-contamination between products;
- food safety levels in the product and product processing environment.

The organization needs to identify statutory and regulatory requirements related to the PRPs, which need to be appropriate to (ISO 22000:2005, 2005):

- the organization needs with regard to food safety;
- the size and type of the operation;
- the nature of the products being manufactured and/or handled;
- implementation across the entire production system;
- approval by the food safety team.

When selecting and/or establishing PRPs, the organization shall consider and utilize appropriate information, such as statutory and regulatory requirements, customer requirements, recognized guidelines, *Codex Alimentarius Commission* principles and codes of practices, national, international or sector standards. The organization shall consider construction and layout of buildings, associated utilities, premises, supplies of air, water energy, cleaning and sanitizing, personnel hygiene, pest control and other aspects as appropriate. Verification of PRPs shall be planned and modified as necessary. Records of verification and modifications shall be maintained (ISO 22000:2005, 2005).

In *preliminary steps to enable hazard analysis* (Fig. 34.5) the standard interprets requirements for food safety team, product characteristics, intended use, flow diagrams, process steps and control measures. All relevant information needed to conduct the hazard analysis has to be collected, maintained updated and documented (ISO 22000:2005, 2005).

The food safety team has to be composed of competent managers, and specialists need to have a combination of multidisciplinary knowledge and experience, which should also be supported by records. The records have to demonstrate that the food safety team has the required knowledge and experience (ISO 22000:2005, 2005).

Product description is a very important part of hazard analysis. Product description has to be done by the whole food safety team, because the product needs to be handled from different aspects. The descriptions have to be kept up-to-date. Only in that way can we foresee all potential risks. The characteristics of end-products should be described in documents required to conduct hazard analysis, including (ISO 22000:2005, 2005):

- product name or similar identification;
- composition;
- biological, chemical and physical characteristics relevant for food safety;
- intended shelf-life and storage conditions;
- packaging;
- labeling;
- method of distribution.

All raw materials, ingredients and product-contact materials have to be described in documents to the extent needed to conduct the hazard analysis, including (ISO 22000:2005, 2005):

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

The standard requires description of intended use, reasonably expected handling and any unintended but reasonably expected mishandling and misuse of the end-product (ISO 22000:2005, 2005).

The standard defines flow diagrams as schematic and systematic presentation of the sequence and interactions of steps. Flow diagrams are a basis for evaluating the possible

occurrence, increase or introduction of food safety hazards and have to be clear, accurate and sufficiently detailed. They should include 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 and where end-products, intermediate products, by-products and waste are released or removed. The food safety team has to verify the accuracy of the flow diagrams by on-site checking. In the flow diagram there should also be description of the existing control measures, process parameters and/or the rigorousness with which they are applied, or the procedures that may influence food safety (ISO 22000:2005, 2005).

In *hazard analysis* (Fig. 34.5) the standard interprets requirements for hazard identification and determination of acceptable levels, hazard assessment, selection and assessment of control measures. The food safety team is responsible for conducting a hazard analysis to determine which hazards need to be controlled, the degree of control required to ensure food safety and which combination of control measures is required. Food safety hazards identification should be based on the preliminary information and collected data, experience, external information including to the extent possible, 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. The acceptable level in the end-product should be determined through statutory and regulatory requirements, customer food safety requirements and the intended use (ISO 22000:2005, 2005).

Hazard assessment serves to determine which of the potential hazards identified requires specific control measures. In conducting the hazard assessment the following should be taken into consideration (ISO 22000:2005, 2005):

- sources of the hazard;
- probability of the hazard;
- nature of the hazard;
- severity of the adverse health effects that can be caused by the hazard.

Based on the hazard assessment an appropriate combination of control measures that are capable of preventing, eliminating or reducing these food safety hazards to defined acceptable levels has to be selected. The selected control measures have to be categorized as to whether they need to be managed through operational PRP(s) or by the HACCP plan. The selection is carried out with regard to its effect on identified food safety hazards relative to the strictness applied, its feasibility for monitoring, its place within the system relative to other control measures, the likelihood of failure in the functioning of a control measure or significant variability, the severity of the consequence(s) in the case of failure in its functioning, whether the control measure is specifically established and applied to eliminate or significantly reduce the level of hazard(s) and synergistic effects between two or more measures resulting in their combined effect being higher than the sum of their individual effects. The methodology and parameters used for categorization have to be described in documents and the results of the assessment shall be recorded (ISO 22000:2005, 2005).

One of the outputs of the hazard analysis is the determination of operational PRPs, which sets up prevention and control measures which deal with food safety risk levels below those needed for including in the HACCP plan. The operational PRPs should include the following information for each program (ISO 22000:2005, 2005):

- food safety hazards to be controlled;
- control measures;
- monitoring procedures demonstrating that operational PRPs are implemented;
- corrections and corrective actions if operational PRPs are not in control;
- responsibilities and authorities;
- records of monitoring.

In establishing the *HACCP plan* (Fig. 34.5) the standard interprets requirements for the hazard plan, identification of critical control points (CCP), determination of critical limits for critical control points, system for the monitoring of critical control point and actions when monitoring result exceeded critical limits.

The HACCP plan is a documented process and documentation has to include information for each identified critical control point (CCP) such as (ISO 22000:2005, 2005):

- food safety hazard(s) to be controlled at CPP;
- control measure(s);
- critical limit(s);
- monitoring procedure(s);
- corrections and corrective actions to be taken if critical limits are exceeded;
- responsibilities and authorities;
- record(s) of monitoring.

It is important to control all steps that are important for production of safe food. CCP is a step at which control can be applied and is essential to prevent or eliminate food safety hazard or reduce it to an acceptable level and can be located at any point in the food production and manufacturing system. For each hazard that is controlled by the HACCP plan CCPs need to be carefully identified and documented and they should be used only for purposes of product safety (ISO 22000:2005, 2005).

Critical limits, which separate acceptability from unacceptability, need to be determined for the monitoring established for each CCP. Parameters for CCP should be quickly measurable and the rationale for the chosen critical limits needs to be documented. If only subjective measurements are possible, such as visual inspection clear instructions should be provided with education and training. Sources for information for establishing critical limits are regulatory requirements, recommendations, standards, specifications, expertises, literature searches, and own experimental results (ISO 22000:2005, 2005).

A monitoring system shall be established for each CCP to demonstrate that the CCP is in control. Monitoring is activity of conducting a planned sequence of observations or measurements to assess control measures being operated with the intended purpose to assure healthy and safe food. The monitoring system shall consist of relevant procedures, instructions and records that cover (ISO 22000:2005, 2005):

- measurements or observations that provide results within an adequate time-frame;
- monitoring devices used;
- applicable calibration methods;
- monitoring frequency:
- responsibility and authority related to monitoring and evaluation of monitoring results;
- record requirements and methods.

The monitoring methods and frequency shall be capable of determining when the critical limits have been exceeded in time for the product to be isolated before it is used or consumed (ISO 22000:2005, 2005).

Planned corrections and corrective actions when critical limits are exceeded should be specified in the HACCP plan. The critical limits are set at a point where the products become unsafe. The actions shall ensure that the cause of nonconformity is identified, that the parameter(s) controlled at the CCP is (are) brought back under control and that recurrence is prevented. Documented procedures need to be established and maintained for the appropriate handling of potentially unsafe products to ensure that they are not released until they have been evaluated (ISO 22000:2005, 2005).

Updating is immediate and/or planned activity to ensure application of the most recent information. The organization should update the information about product characteristics, intended use, flow diagrams, process steps and control measures. The HACCP plan and the procedures and instructions specifying the PRP(s) need to be amended too, if necessary (ISO 22000:2005, 2005).

Verification 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 verification planning shall define the purpose, methods, frequencies and responsibilities for the verification activities and they shall confirm that (ISO 22000:2005, 2005):

- PRP(s) are properly implemented;
- input to the hazard analysis is continually updated;
- the operational PRP(s) and the elements within the HACCP plan are implemented and effective;
- hazard levels are within identified acceptable levels;
- other procedures required by the organization are implemented and effective.

Verification results shall be recorded and shall be communicated to the food safety team.

The objective of traceability is following the route of the product from producer to consumer and the other way round. The standard demands that the organization shall establish and apply a traceability system that enables the identification of product lots and their relation to batches of raw materials, processing and delivery records. The traceability system should be able to identify incoming material from immediate suppliers and the initial distribution route of the end-product and traceability records need to be maintained for a defined period for system assessment to enable the handling of potentially unsafe products and in the event of product withdrawal. The records shall be in accordance with statutory, regulatory and customer requirements (ISO 22000:2005, 2005).

In establishing the *control of nonconformity* (Fig. 34.5) the standard interprets requirements for the corrections, corrective actions, handling of potentially unsafe products and withdrawals. The organization shall ensure that when critical limits for CCP(s) are exceeded, or there is a loss of control of operational PRP(s), the products affected are identified and controlled with regard to their use and release. A documented procedure shall be established and maintained defining (ISO 22000:2005, 2005):

- the identification and assessment of affected end-products to determine their proper handling; and
- a review of corrections carried out.

All corrections have to be approved by the responsible person(s), and shall be recorded together with information on the nature of the nonconformity, its cause(s) and consequence(s), including information needed for traceability purposes related to the nonconforming lots (ISO 22000:2005, 2005).

Data derived from the monitoring of operational PRP(s) and CCPs need to be evaluated by designated person(s) with sufficient knowledge and authority to initiate corrective actions. Corrective actions should be initiated when critical limits are exceeded or when there is a lack of conformity with operational PRPs. The organization shall establish and maintain documented procedures to define requirements for (ISO 22000:2005, 2005):

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

The organization should deal with nonconforming products by taking actions to prevent the nonconforming product from entering the food chain. All groups of products that may have been affected by a nonconforming situation shall be held under control until they have been evaluated. If products are subsequently determined to be unsafe, the organization has to notify relevant parties and initiate withdrawal (ISO 22000:2005, 2005).

Each group of products affected by the nonconformity should be released as safe only when there is evidence that the control measures have been effective and the combined effect of the control measures for that particular product complies with the performance intended, and the results of sampling, analysis and/or other verification activities demonstrate that the affected group of products complies with the acceptable levels for the food safety hazards concerned. If the group of products is not acceptable for release it shall be handled by reprocessing or further processing, destruction and/or disposal as waste (ISO 22000:2005, 2005).

To enable and facilitate the complete and timely withdrawal of groups of end-products that have been identified as unsafe (ISO 22000:2005, 2005):

- top management should appoint personnel having the authority to initiate a withdrawal and personnel responsible for executing the withdrawal;
- the organization shall establish and maintain a document procedure for notification to relevant interested parties, handling of withdrawn products as well as affected groups of products still in stock and the sequence of action to be taken.

Withdrawn products have to be secured or held under supervision until they are destroyed, used for purposes other than originally intended, determined to be safe for the same intended use or reprocessed in a manner to ensure that they become safe. The cause, extent and result of a withdrawal need to be recorded and reported to the top management as input to the management review. The organization shall verify and record the effectiveness of the withdrawal program (ISO 22000:2005, 2005).

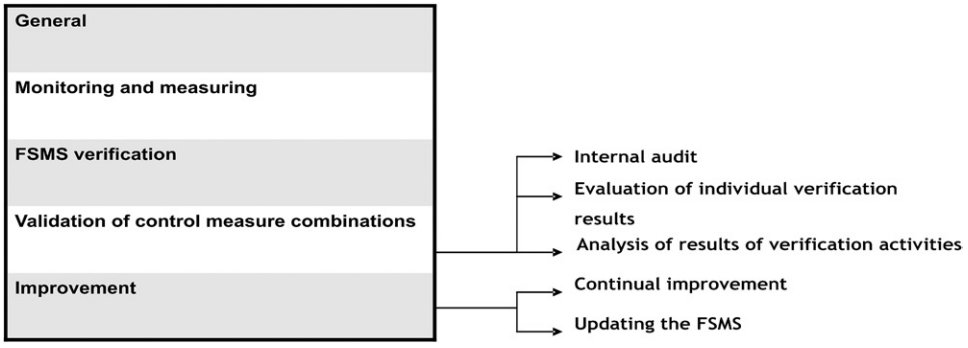

Fig. 34.6 ISO 22000:2005 requirements for validation, verification and improvement of the food safety management system.

34.6.5 Validation, verification and improvement of the food safety management system

With regard to the validation, verification and improvement of the FSMS (Fig. 34.6) the food safety team shall plan and implement the processes needed to validate control measures and/or control measure combinations and to verify and improve the FSMS (Luning *et al*., 2009; Sperber, 1998). Before implementation of control measures to be included in operational PRP(s) and the HACCP plan and after any change therein, the organization should validate 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 22000:2005, 2005).

The organization has to provide evidence that the specified monitoring and measuring methods and equipment are adequate to ensure performance of the monitoring and measuring procedures (Bernardo *et al.*, 2010). In order to ensure valid results, the measuring equipment and methods used shall be calibrated or verified at specified intervals against international or national measurement standards, adjusted or readjusted as necessary, identified to enable the calibration status to be determined, safeguarded from adjustments that would invalidate the measurement and protected from damage and deterioration. All records about verification and calibration need to be maintained (ISO 22000:2005, 2005).

In *FSMS verification* (Fig. 34.6) the standard interprets requirements for the internal audit, evaluation of individual verification results and analysis of results of verification activities.

The organization shall conduct internal audits at planned intervals to determine whether the FSMS conforms to the planned arrangements, to the requirements established by the organization, and to the requirements of standard, and is effectively implemented and updated. An audit program shall take into consideration the importance of the processes and areas to be audited, as well as any updating actions resulting from previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and the conduct of audits shall ensure the objectivity and impartiality of the audit process (ISO 22000:2005, 2005).

The food safety team has to systematically evaluate the individual results of planned verification. If verification does not demonstrate conformity with the planned arrangements, the organization should take action to achieve the required conformity. Such action should

review existing procedures and communication channels, the conclusions of the hazard analysis, the established operational PRP(s) and the HACCP plan, the PRPR(s) and the effectiveness of human resource management and of training activities (ISO 22000:2005, 2005).

The food safety team shall analyze the results of verification activities, including the results of the internal audits and external audits. The analysis shall be carried out in order to (ISO 22000:2005, 2005):

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

In *improvement* (Fig. 34.6) the standard interprets requirements for continual improvement and updating the food safety management system. Top management has to ensure that the organization continually improves the effectiveness of the food safety system through the use of communication, management review, internal audit, evaluation of individual verification results, analysis of results of verification activities, validation of control measure combinations, corrective actions and FSMS updating. Apart from that, top management has to ensure that the FSMS is continually updated. In order to achieve this, the food safety team shall evaluate the FSMS at planned intervals. The team shall then consider whether it is necessary to review the hazard analysis, the established operational PRP(s) and the HACCP plan. The evaluation and updating activities shall be based on (ISO 22000:2005, 2005):

- input from external and internal communication and from other information concerning the suitability, adequacy and effectiveness of the FSMS;
- output from the analysis of results of verification activities and from management review.

34.7 ADVANTAGES AND DISADVANTAGES OF STANDARDIZATION

Many advantages and disadvantages are often very strongly influenced by the personal views of professionals or scientists in the field. Adopting uniformly auditable standards in the food safety field provides the company with competitive efficiencies worldwide, because employee become conscious about hygiene and food safety and job productivity and satisfaction of employees is ensured. Standardization represents on the one hand a drive for continuous improvement to ensure confidence in the delivery of safe food to consumers and facilitates traceability and clear communication across the food supply chain; on the other hand it can technologically hinder the development and innovativeness of new products. Standardization speeds and simplifies processes, increases inefficiency with wide and easy application, improves documentation, ensures better planning and optimization of resources as well as reducing cost. With registration to one of four GFSI food safety schemes the advantages ensured are safety of food products, greater health protection, increased international acceptance of food products, efficient and dynamic control of food safety hazards.

With registration to ISO 22000 family, which is a systematic and proactive approach to identification of food safety hazards and development and implementation of control measures, the ensuing advantages (Arvanitoyannis and Kassaveti, 2009) are incorporation of legal and regulatory requirements relating to food safety, including with HACCP, clear responsibility and authorities agreed for all staff, improved internal and external communication and resource optimization as well as system management of PRPs. (Raspor, 2000, 2002). Furthermore this standard enables streamlined communication and collaboration for quicker, more informed decision making about hazards with food supply chains partners. Beside that it can be applied by all manufacturers and participants in the entire food supply chain and at the same time allows small and/or less developed organizations to implement an externally developed system, because the standard provides the benefit of saving resources by reducing overlapping system audits.

It is to be pointed out that adequate attention may also have some disadvantages. Currently, there is a proliferation of standards worldwide. Many countries have developed national, voluntary standards, each with their own interpretation and related documents. Unquestionably this situation is still leading to confusion. One effect of proliferation is that, in particular, companies from developing countries and emerging economies have problems in complying with all these standards. Another important obstacle is the increasing cost of certification and accreditation of each standard, which also puts pressure on company profits in industrialized countries. Beside that, it makes it very hard for quality managers to assess the food safety performance of their suppliers. One more problem in the present-day situation is that there are no food safety standards for each actor in food supply chain (Trienekens and Zuurbier, 2008). Currently ISO 22000 possesses characteristics which could satisfy current needs in FSMS. Moreover, the standardized components may have excess functionality since they should satisfy the requirements of all the products in which components are replaced by them. Thus, standardization may increase the volume, weight and cost of the component. Excess functionary of the components may lead to increased lower consumption in the usage phase, resulting in high operational cost.

34.8 FUTURE NEEDS

Nowadays, proliferation of standards is a pressing problem, leading to confusion and obscurity. For this reason we should in the future think about the reduction of standards and extensiveness of their elements. To implement a rational step of freedom to motivate innovativeness and development standards there must be a rationale that is deep, wide and accurate to attract all specific food producers and satisfy their different needs. Technically standards should envisage implementation of sophisticated measurement and data acquisition, which will enable full decision-making without any possible misinterpretation of computer program or human. Novel technical possibilities will encourage new applications in a large variety of areas along the food supply chain (Raspor, 2003b). However, for this we will also need more consistent markers in food supply chain. It is expected that we will realize nutritional markers which will follow the food supply chain in the nutrition chain and will be used in humans as well (Raspor, 2005). All this affects food systems in a changing world and constantly asks for novelties in a diverse field of activities, which is constantly bombarded by novelties that can be implemented in practice (Raspor, 2009a).

One important challenge for the future may also be climate change (Semenza and Menne, 2009), which will bring threats and also new standards to the food supply chain.

This new requirement will be based on novel techniques like electrolyzed oxidizing (EO) water, which has been regarded as a new sanitizer in recent years (Huang *et al*., 2008). We shall start to prepare relevant new microbiological criteria for food safety and performance objectives management (van Schothorst *et al*., 2009) to be analysed with available methods and techniques. However the success of new food processing technologies is also highly dependent on consumers' acceptance of food products produced by means of these novel technologies (Nielsen *et al*., 2009).

It may be expected in future that this type of standard will became obligatory by law, because government legal power is to neutralize market power and to implement current legislation in a harmonized way (Blankart and Knieps, 1995). The consumer at home also needs greater attention and should not be neglected at national, community and international level in the food supply chain, because studies in recent years have highlighted gaps in food safety knowledge and some critical violations regarding food handling at home (Jevšnik *et al*., 2008b; Raspor 2009b).

34.9 CONCLUSIONS

Foodborne diseases have highlighted problems with food safety and increased public anxiety that modern farming systems, food processing and marketing do not provide adequate safeguards for public health. In the future an in-depth investigation will be necessary into the disturbing truth behind the unlabeled, patented, genetically engineered foods that have quietly filled grocery stores' shelves in the past decade. From north to south, from west to east, globalization is stretching its impact on food supply chains, and consumers have suffered negative impacts by this new attitude. Health implications, government policies and the push towards globalization are all part of the game in our food supply. The future of food is going to be an even more complex web of market and political forces that are changing what we eat, as huge multinational corporations seek to control the world's food system. Do we still have potential and courage to explore alternatives and the power to introduce them to large-scale industrial agriculture, placing organic and sustainable agriculture as real solutions to the farm crisis today? The consumers' future food reveals that there is a revolution going on from stable to table, from farm to fork, from spring to drink. On the dinner tables of tomorrow consumers may expect a new food icon, the result of an evolution that is transforming the very nature of the food we eat, to create a new breed of future for healthy and controlled nutrition. To build and maintain trust of consumers in food quality and food safety, quality assurance is of major importance in the food sector. That is why legal requirements as well as quality norms and standards are constantly elaborated. Currently standards are reasonable tools, which help in safe food production, food processing, food distribution and safe consumption out of home. All this will continue in the future with more networked systems, of which quality management systems and food safety management systems will remain an integral part.

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