

AN INTRODUCTION TO ISO 22000 -FOOD SAFETY MANAGEMENT SYSTEMS

FOOD SAFETY: AN OVERWIEW

ISO 22000: "THE MISSING LINK IN THE FOOD SAFETY MANAGEMENT SYSTEM"

ANNEXES



This bulletin provides information about food safety, Food Safety Management Systems and ISO 22000, aiming to help exporters implement such systems.

This bulletin has been prepared, without formal editing, by A. Salvi, ITC Intern, under the guidance of S. K. Gujadhur, Senior Adviser on Standards and Quality Management, and in cooperation with L. Ghizzoni, Associate Expert on Standards and Quality Management, Enterprise Competitiveness Section, Division of Business and Institutional Support, International Trade Centre (ITC). J. Surak, International Consultant on Food Safety Management Systems, reviewed the bulletin.

For more information:

Street address: ITC, 54-56 rue de Montbrillant, CH 1202 Geneva, Switzerland Postal address: ITC, Palais des Nations, 1211 Geneva 10, Switzerland Telephone: +41.22.730.03.96 – Fax +41.22.730.05.76 E-mail: <u>quality@intracen.org</u> - Internet: http://web.intracen.org/eqm

Abbreviations and Acronyms

BRC	British Retail Consortium
CASCO	ISO Committee on conformity assessment
CCPs	Critical Control Points
CDC	Centre for Disease Control and Prevention
CIES	International Committee of Food Retail Chains
Codex	Codex Alimentarius Commission
FAO	Food and Agriculture Organization of the United Nations
FSMS	Food Safety Management System
HACCP	Hazard Analysis and Critical Control Point
IFS	International Food Standards
IPPC	International Plant Protection Convention
ISO	International Organization for Standardization
ITC	International Trade Centre
OIE	World Organization for Animal Health
PRPs	Prerequisite programs
SPS	Sanitary and phytosanitary measures
UNCTAD	United Nations Conference on Trade and Development
UNIDO	United Nations Industrial Development Organization
US	United States
WHO	World Health Organization
WTO	World Trade Organization

Table of contents

1.	FOOD SAFETY: AN OVERVIEW	1
1.1	INTRODUCTION	1
	1.1.1 Food safety: an old issue	1
	1.1.2but a recent challenge	1
	1.1.3 Food safety measures: obstacle to trade or catalyst?	2
1.2	SPS Measures	3
1.3	HACCP: THE FOOD SAFETY BASICS	3
	1.3.1 Principles	3
	1.3.2 HACCP: The Current Definition of a Food Safety System	5
1.4	PRIVATE STANDARDS	5
1.5	FOOD SAFETY MANAGEMENT SYSTEMS	6
2.	ISO 22000: THE "MISSING LINK IN THE FOOD SAFETY MANAGEMENT SYSTEM"	7
2.1	New Approach to Food Safety Management	7
	2.1.1 Weaknesses of the Previous System	7
	2.1.2 ISO 22000 Family: A Worldwide Basis	8
2.2	ISO 22000: A NEW GLOBAL FOOD SAFETY STANDARD	8
	2.2.1 Technical Committee ISO/TC 34 "Food Products"	8
	2.2.2 Who is Concerned	9
	2.2.3 Key elements of ISO 22000	9
2.3	LINK WITH HACCP	11
2.4	A NEW ELEMENT: TRACEABILITY	14
2.5	BENEFITS AND COSTS	14
	2.5.1 Benefits for the food industry	14
	2.5.2 Costs	15
2.6	IMPLEMENTING ISO 22000	16
2.7	CERTIFICATION	19
	2.7.1 Principle	
	2.7.2 ISO/TS 22003	19
	2.7.3 Publicizing the certification	20
2.8	MARKET FEEDBACK ON ISO 22000	21
	2.8.1 Statistics	21
	2.8.2 Cases of Best Practice	22

	2.8.3 ISO 22000 and SMEs	23
2.9	Assistance for a better understanding of ISO 22000	23
2.10	CHALLENGES TO COME FOR THE FOOD INDUSTRY	25

Annexes

ANNEX II: THE ISO 22000 FAMILY OF STANDARDS	.29
ANNEX III : ISO 22000:2005 - CONTENTS	.30
ANNEX IV: EIGHT KEYS TO AN ISO 22000:2005-BASED FSMS	.31
ANNEX V: USEFUL WEBSITE LINKS	.32

1. FOOD SAFETY: AN OVERVIEW

1.1 Introduction

1.1.1 Food safety: an old issue...

In 1983, a group of internationally renowned experts convened jointly by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) concluded that "illness due to contaminated food was perhaps the most widespread health problem in the contemporary world," and "an important cause of reduced economic productivity." In 1992, the FAO/WHO-sponsored International Conference on Nutrition recognized that hundreds of millions of people suffer from communicable diseases caused by contaminated food and drinking water. The Conference declared, "Access to nutritionally adequate and safe food is a right of each individual." In the same year, the United Nations Conference on Environment and Development recognized that food was a major vehicle for the transmission of environmental contaminants—both chemical and biological—to human populations throughout the world and urged countries to take measures to prevent or minimize these threats. In 2000, the World Health Assembly, the supreme governing body of WHO adopted unanimously a resolution recognizing food safety as an essential public health function¹.

1.1.2 ...but a recent challenge

Food is a resource of vital importance and its safety in the whole chain, from producer to consumer, is a worldwide concern. Indeed, as food trade expands throughout the world, food safety has become a shared concern among all consumers. This issue began to be taken seriously at a period where there is a significant increase of illness caused by infected food in both developed and developing countries. Indeed, Bovine spongiform encephalopathy, foot-and-mouth disease, salmonella...highlighted the risk of food contamination.

Unsafe food contains hazardous agents or contaminants that can make people sick, immediately or by increasing their risk of chronic disease. Contaminants can enter food at many different points in the food production process, and can occur naturally or as the result of poor or inadequate production practices².

The example of the United States is relevant. Food safety experts insist that the U.S. food supply is one of the safest in the world³. However, the Centre for Disease Control and Prevention (CDC) estimates that more than 76 million people get sick from food related illnesses in the United States each year. This results in more that 300,000 hospitalizations and 5,000 deaths. Recently, there have been several high profile food recalls in the United States:

- When spinach was contaminated with a pathogenic strain of E. coli, 199 people in 28 states were infected, 141 individuals were hospitalized, 31 individuals developed a type of kidney failure, and three died.

¹ Extract from F.Kaferstein, "*Food Safety as a Public Health Issue for Developing Countries*" in "*Food safety in food security and food trade*" available at H<u>http://www.ifpri.org/2020/focus/focus10/focus10_02.pdf</u>H ² See: L.Unnevehr, "*Overview*" in "*Food Safety in Food Security and Food Trade*", International Food Policy Research Institute, (September 2003) available at

Hhttp://www.ifpri.org/2020/focus/focus10/focus10_01.pdfH

³ Source of this paragraph: John G Surak, "A recipe for Safe Food: ISO 22000 and HACCP", (October 2007) available at H<u>http://www.asq.org/quality-progress/2007/10/iso-9000/recipe-for-safe-food-iso-22000-and-haccp.html</u>H

When tainted peanut butter turned up on store shelves, 425 people were infected with Salmonella, and 71 of them were hospitalized. This contamination produced no known deaths.

The tainted pet food recall involved a long list of both stores and major brands containing melamine in product imported from China. The exact number of pet deaths is unknown, but it has been estimated to be more than 20.

The cost of a food safety recall is high and accidents can be serious for human health. This has brought claims from customers for more inspectors and more inspections. Yet, because increasing inspections would be costly and because some new pathogens are not even identifiable, more inspections do not seem to be a good option. It is the effectiveness of inspections that needs to be improved so as to ensure food quality at every stage of the chain.

The increasing public concern about food safety resulted in a High-Level International Forum on Food Safety with the theme "Enhancing Food Safety in a Global Community", held in Beijing on 26 and 27 November 2007⁴. The forum was cosponsored by WHO, in collaboration with the Chinese Ministry of Health (MOH) and the State Administration for Quality and Safety Inspection and Quarantine (AQSIS). The forum brought together senior officials from more than 50 countries and international organizations to review the major issues related to food safety. At the conclusion of the forum, the meeting participants adopted the Beijing Declaration on Food Safety⁵. This declaration demonstrates the high-level political commitment of Member States to resolving food safety problems through positive collaboration rather than erecting inefficient barriers to trade. It urges all countries to develop comprehensive programmes to improve consumer protection from production to consumption, from routine to emergency, and from domestic to international.

1.1.3 Food safety measures: obstacle to trade or catalyst?

Indeed, international competitiveness nowadays depends more on guality and safety concerns than on prices. Governments and local authorities intervene in the market place in setting technical regulations; and sanitary and phytosanitary measures⁶. Exported products should satisfy these measures as well as additional requirements demanded by buyers, such as private standards.

The issue about whether or not these measures are barriers to trade arise. Compliance to harmonized international standards is difficult for countries with weak food safety and quality management capacities. Undoubtedly, as these countries lack the administrative, technical and scientific capacities to comply with the dynamic and increasingly strict food safety standards, this represents potentially insurmountable barriers to their development of international market opportunities.

There are also accusations that safety measures could be used as protectionist tools, providing 'scientific' justifications for prohibiting imports of agricultural and food products, or discriminating against imports by applying higher and/or more rigorous regulatory enforced standards than those applied on domestic suppliers.

⁴ Source: H<u>http://www.who.int/foodsafety/fs_management/meetings/forum07/en/index.html</u>H ⁵ See ANNEX 1

⁶ Information related to these concepts is available at "Export Quality Management – An answer book for *small and medium-sized exporters*", (2001) International Trade Centre (ITC), p.4 to 7⁷ Information in this paragraph is taken from Spencer Henson and Steven Jaffee, "A Strategic Perspective

on the Impact of Food Safety Standards on Developing Countries", (August 2006) available at Hhttp://ageconsearch.umn.edu/bitstream/25456/1/ip06he13.pdfH

However, food safety standards may provide a 'common language' through increasingly global supply chains in a manner that diminishes reducing transaction costs. It also promotes consumer confidence in food product safety, without which the market for these products cannot be maintained and/or enhanced⁸.

International standards related to sanitary and phytosanitary measures (SPS) are established by three international bodies (see below).

1.2 SPS Measures⁹

When the safequard of human, animal or plant life and health is invoked, a country can set a standard. This rule is provided by the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)¹⁰. This Agreement includes all the requirements directly related to food safety and animal and plant health. Sanitary measures deal with human or animal health, and phytosanitary measures are related to plant health.

The SPS Agreement recognizes three main international standard-setting bodies, which are the official entities for developing health-related standards, guidelines and recommendations. These are:

The Codex Alimentarius Commission (Codex)¹¹, which is the key international standard-setting body for food safety:

The International Plant Protection Convention (IPPC)¹², which secures action to prevent the spread and introduction of pests of plants and plant products, and to promote appropriate measures for their control;

The World Organization for Animal Health (OIE)¹³, whose purpose is to assure the sanitary safety of international trade in terrestrial and aquatic animals and their products, and on biological standards.

Moreover, the Food and Agriculture Organization of the United Nations (FAO), in association with Codex, the IPPC Secretariat and OIE, developed the International Portal on Food Safety, Animal and Plant Health¹⁴ to provide reliable means of accessing official information on food safety, animal and plant health relevant to the SPS Agreement.

1.3 **HACCP:** The Food Safety Basics

1.3.1 Principles

Hazard Analysis and Critical Control Point (HACCP) was first developed in the late 1950s by the Pillsbury Company to provide safe food for the manned space programs.

⁸ See: John G. Surak, "A recipe for Safe Food: ISO 22000 and HACCP", (October 2007) available at Hhttp://www.asg.org/quality-progress/2007/10/iso-9000/recipe-for-safe-food-iso-22000-and-haccp.html

For more information on SPS measures, see "Information Retrieval on Sanitary and Phytosanitary Measures", (April 2008) ITC Bulletin No.81, available at Hhttp://www.intracen.org/egm/BulletinsH & Handbooks

Available at Hhttp://www.wto.org/english/docs_e/legal_e/15-sps.docH

¹¹ H<u>http://www.codexalimentarius.netH</u>

¹² H<u>http://www.ippc.int</u>

¹³ Hhttp://www.oie.int

¹⁴ Hhttp://www.ipfsaph.org

Codex adopted the HACCP system and guidelines in 1993. HACCP defines system requirements for ensuring the safety of food from production through manufacturing, storage and distribution of a food product. This makes it synonymous with food safety. Indeed, the system gives confidence that food safety is being managed effectively.

It consists in:

- Identifying a *hazard*, which is 'a biological, chemical or physical agent in, or condition of food, with the potential to cause an adverse health effect'¹⁵.
- Implementing controls to ensure that the product will not cause harm to the consumer. A *critical control point* (CCP) is 'a step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level'.

HACCP is much more a tool of prevention than a tool of inspection. It is based on the principle that food safety hazards can be eliminated or minimized during production rather than at the end of the production chain. Thus the hazards are prevented at the earliest possible point in the food chain¹⁶.

In order to strengthen the food safety system, HACCP has evolved over the years. Currently, the HACCP system consists of five preliminary steps and seven principles. A HACCP based food safety system must be supported by basic prerequisite areas (Table 1)¹⁷.

Functional area	Contents of the functional area
	Preliminary step 1 Assemble the HACCP team
HACCP	Preliminary step 2 Describe the product and its distribution
Preliminary Steps	Preliminary step 3 Describe the intended use and the users of the product
	Preliminary step 4 Develop the process flow diagram
	Preliminary step 5 Verify the process flow diagram
	Principle 1 Conduct a hazard analysis
	Principle 2 Determine the Critical Control Points (CCPs)
	Principle 3 Establish Critical Limits (CLs)
Seven Principles	Principle 4 Establish monitoring procedures
of HACCP	Principle 5 Establish corrective action
	Principle 6 Establish verification plan
	Principle 7 Establish record keeping and documentation procedures
	Training
	Personnel practices
	Premises, equipment and facilities
Prerequisite areas for	Good Manufacturing Practices
HACCP	Cleaning, sanitation and pest control
	Receiving, transportation and storage
	Traceability and recall
	Supplier control
	Hazardous material handling

Table 1: Components of a HACCP programme and a prerequisite programme for HACCP

¹⁵ "HACCP and guidelines for its application". Annex in "Recommended International Code of Practice of General Principles of Food Hygiene", CAC/RCP 1-1969, Rev.3 (1997)

¹⁶ These definitions are taken from "*Export Quality Management – An answer book for small and medium-sized exporters*", (2001) International Trade Centre (ITC), p.173

For more information about HACCP, also see "*An Introduction to HACCP*", (December 2002) ITC Bulletin No.71, available at H<u>http://www.intracen.org/eqm/Bulletins & Handbooks</u>

¹⁷ Source: John G. Surak, "HACCP and ISO Development of a food safety management standard", (2003) available at Hhttp://www.asq.org/qic/display-item/index.pl?item=19364H

1.3.2 HACCP: The Current Definition of a Food Safety System¹⁸

HACCP is particularly important for small and medium-sized enterprises (SMEs). On the first hand, as HACCP reduces the risks of producing an unsafe product, it generates greater consumer confidence. The system brings internal benefits by being able to export to countries that adopt HACCP as a regulatory requirement and/or customer requirement.

Indeed, compliance with HACCP is a requirement to export to some markets, e.g. the European Union regulations require that all food is produce under HACCP. In the United States HACCP is required in companies that produce red meat, poultry, fruit and vegetable juices and seafood. However, many US customers go beyond the food regulations and require that their suppliers implement HACCP as part of contractual agreements. HACCP can also be required in certain areas of food safety, for instance, in response to outbreaks of food contamination,. Some countries require in their legislation that HACCP must be applied in defined companies like food suppliers for schools.

HACCP is a well-recognized system and an international standard; however, it is not a substitute for good hygiene practices and other prerequisites for food safety, which are also necessary.

The private sector has established food safety standards that incorporate the principles of HACCP and prerequisite programs. Internationally, retailers and supermarkets require more and more compliance with private standards.

1.4 Private standards¹⁹

Compliance with private standards is not required by law. Officially they are voluntary, however, the standards are mandatory if a food processor wants to sell its products in some markets. When this is done, the private standards become the industry norm. Where a small number of food retailers account for a high proportion of food sales, the options for suppliers who do not participate in either an individual or collective retailer standard scheme can be considerably reduced.

According to the United Nations Conference on Trade and Development (UNCTAD), there are more than 400 such private schemes, and this number is expanding. This is due to several factors related to food safety, including:

- High profile food safety concerns and problems of confidence in regulatory agencies;
- Legal requirements on companies to demonstrate "due diligence" in the prevention of food safety risks;
- Growing attention to "corporate social responsibility" and a drive by companies to minimize alleged risks;
- "Globalisation" of supply chains and a trend towards vertical integration through the use of direct contracts between suppliers and retailers;
- Expansion of supermarkets in food retailing both nationally and internationally;

¹⁸ Source: "Export Quality Management – An answer book for small and medium-sized exporters", (2001) International Trade Centre (ITC), p.177-178, available at H<u>http://www.intracen.org/eqm/BulletinsH &</u> Handbooks
¹⁹ The information related to this section is taken from M/TO Desument C/ODC/OTN/742 sucjustrates

¹⁹ The information related to this section is taken from WTO Document G/SPS/GEN746 available at H<u>http://docsonline.wto.org</u>H

Global expansion of food service companies. There are different categories of private standards:

Individual firm schemes	Collective national schemes	Collective international schemes
Tesco Nature's Choice Carrefour Filière Qualité	Assured Food Standards British Retail Consortium (BRC) Global Standard - Food QS Qualitat Sicherheit Label Rouge Food and Drink Federation/British Retail Consortium Technical Standard for the Supply of Identity Preserved Non- Genetically Modified Food Ingredients and Product	EurepGAP (now GLOBALGAP) International Food Standard Global Food Safety Initiative ISO 22000: Food safety management systems Safe Quality Food (SQF) 1000 and 2000 ISO 22005: Traceability in the feed and food chain

1.5 Food safety management systems

A food safety management system is defined as a set of interrelated or interacting elements to establish policy and objectives and to achieve those objectives used to direct and control an organization with regard to food safety²⁰.

In 1987, the International Organization for Standardization's (ISO) Technical Committee 176 "Quality Management and Quality Assurance" (ISO/TC 176) established requirements for a quality management system in the ISO 9000 series of standards. Management systems were extended to the specific area of the environment. In 1996, ISO Technical Committee 207 "Environmental Management" (ISO/TC 207) established the requirements for an environmental management system in ISO 14001. In 2005, the Technical Committee 34, "Food Products" (ISO/TC 34), developed the requirements for a food safety management system in ISO 22000.

Indeed, because of globalisation and international trade, customers demand safe food products. That encouraged food processing companies around the world to implement food safety management systems (FSMS) to ensure the production and distribution of safe foods.

During the 1990s²¹, countries, including Denmark, the Netherlands, Germany, Ireland, Australia, and the United States, developed national standards that incorporated various concepts of a food safety management system. In addition, various non-governmental agencies such as the CIES-Business Forum²², British Retail Consortium, the Food Safety Initiative, and the National Food Processors Association (now Grocery

²⁰ Definition from "ISO 22000, Food safety management system – An easy-to-use checklist for small business – Are you ready?", (2007) ISO/ITC ²¹ Source: John G.Surak, "ISO 22000:Requirements for food safety management systems", (2005) available

at H<u>http://www.asq.org/qic/display-item/index.pl?item=20317</u>H²² Comité International d'Entreprises à Succursales – International Committee of Food Retail Chains

Manufacturers Association) developed programmes to certify various parts of a food safety system.

Because of the proliferation of national and private standards that described the requirements of a food safety management system and the marketplace pressures, Danish Standards proposed the development of an ISO standard that defines the requirements of a food safety management system which contained the following characteristics:

- Focuses only on a food safety management system. (The quality management system would be addressed by ISO 9001);
- Usable by all organizations in the food chain;
- Combines recognized food safety elements including: HACCP principles as defined by Codex, prerequisite programs, systems approach, communications along the food chain, and prerequisite programs (PRPs);
- Harmonizes national food safety standards;
- Provides an auditable standard that could be used as part of third-party certification.
- Addresses customer and regulator food safety concerns and requirements;
- Allows food safety control to be achieved through either the HACCP plan or operational PRPs;
- Ensures that the process to control food safety is validated, verified, implemented, monitored, and managed.

ISO 22000 has been developed with a structure similar to ISO 9001 and ISO 14001. Thus, ISO 22000 can be utilized with other ISO management system standards.

Consequently , ISO 22000:2005, Food safety management system - Requirements for any organization in the food chain, is the latest step in the evolution of food safety systems beyond HACCP. It goes beyond regulatory compliance by assuring that the customer's food safety requirements are met. ISO 22000 aims to answer to the needs of food businesses, which have increasingly been required to implement a clearly understood Food Safety Management System.

2. ISO 22000: THE "MISSING LINK IN THE FOOD SAFETY MANAGEMENT SYSTEM"

2.1 New Approach to Food Safety Management

2.1.1 Weaknesses of the Previous System

As one looks at the "plethora" of food safety standards, one sees that these standards are similar but not necessary equivalent. This may generate the risk of uneven levels of food safety, confusion over requirements, increased costs and concern on what standard must a company implement in order to meet customer requirements. In addition, many proprietary standards are outside the scrutiny of users and customers. Moreover, developing countries were unable to participate effectively in the international

institutions that have evolved to establish the global food standards and provide rules for the implementation of national measures²³.

2.1.2 ISO 22000 Family: A Worldwide Basis

The impetus behind the development of the ISO 22000 family of standards²⁴ was to establish a non-proprietary, international set of food safety management system standards that are applicable to the entire supply chain from input suppliers through primary production, processing, marketing and retailing, and encompassing all the steps from transportation to distribution²⁵. Indeed, food safety is strengthened by the harmonization of working procedures. If everyone uses the same methods and language, the system's effectiveness improves, increasing food safety, reducing the risk of critical errors and misunderstandings, and maximising the use of resources²⁶.

ISO standards are developed though a transparent consensual process that encourages the international participation of all potential stakeholders. Through this process, the ISO 22000 system specifies requirements to ensure the production of safe food for any organisation in the food chain. This offers a unique solution for good practices on a worldwide basis. Progressively, ISO 22000 is becoming better known and more widely accepted and recognized than any other national standard.

Copies of the ISO 22000 family of standards can be obtained from the ISO Central Secretariat in Geneva (<u>www.iso.org</u>) and the ISO National Member Institutes (<u>http://www.wssn.net</u>).

2.2 ISO 22000: A New Global Food Safety Standard

2.2.1 Technical Committee ISO/TC 34 "Food Products" 27

The Technical Committee 34 "*Food products*" developed ISO 22000. Its scope is standardization in the field of human and animal foodstuffs as well as animal and vegetable propagation materials, in particular terminology, sampling, testing methods and analysis, product specifications and requirements for packaging, storage and transportation.

ISO/TC 34 includes working groups on Food Safety Management Systems, Genetically Modified Organisms (GMO), Traceability Systems and Food Irradiation, and Subcommittees on Seeds, Fruits and Vegetables, Cereals, Milk, Meat and Poultry, Spices, Tea, Microbiology, Animal Feeding Stuffs, Fats and Oils, Sensory Analysis, and Coffee.

The Committee published 724 standards related to TC 34 and its Subcommittees. There are 53 participating countries and 54 observer countries to TC 34. TC 34 is in active liaison with the Codex Alimentarius Commission.

²³ See: S.Henson, "Food safety Issues in International Trade" in "Food Safety in Food Security and Food Trade", International Food Policy Research Institute, (September 2003) available at <u>Hhttp://www.ifpri.org/2020/focus/focus10_focus10_05.pdf</u>H

²⁴ See Annex II

²⁵ Source: A. Chambers, "Survey incomplete but reveals ISO 22000 implementation in 72 countries", ISO Management System, (May-June 2008) p.8

²⁶ See J.Faergemand, "Is your food safe?", ISO Focus, (September 2007) p.29

²⁷ More information about ISO/TC 34 at H<u>http://www.iso.org/iso/iso_technical_committee?commid=47858</u>H

ISO 22000:2005 (first edition) was published on 1 September 2005 and is the first standard of the ISO 22000 family of standards (Annex II). Annex III lists the major elements of the Standard.

2.2.2 Who is Concerned

ISO 22000:2005 Food Safety Management System - Requirements for any Organization in the Food Chain aims to ensure that there are no weak links in the food supply chain. This is done by preventing or eliminating food safety hazards.

A food safety hazard may be introduced at any stage of the pr oduction chain. To provide adequate control, ISO 22000 can be applied to all types of organizations within the food chain, from feed producers, primary producers, food manufacturers, transport and storage operators and subcontractors to retail and food service outlets, together with inter-related organizations such as producers of equipment, packaging material, cleaning agents, additives and ingredients.

2.2.3 Key elements of ISO 22000

ISO 22000 is composed of three major parts²⁸:

- Requirements for HACCP;
- Requirements for prerequisite programs (PRPs);
- Requirements for implementing and maintaining the food safety management system.

These requirements can be defined as the proverbial three-legged stool (Figure 1). All three components are required for a food safety management system. If one part is missing or lacking, the stool becomes unstable, or the food safety management system becomes ineffective in preventing food safety incidents.



Figure 1: The ISO 22000 model for a food safety management system

The ISO 22000 Food Safety Management System includes the following:

- Uses a systems and a process approach to define a food safety management system;
- Clarifies management's responsibility to manage the food safety management system;
- Develops a quality policy with measurable objectives;
- Ensures management review of the food safety management system;
- Increases the responsibility for the food safety team leader;

²⁸ Source (including figure 1): John G.Surak, "*Moving from HACCP to ISO 22000*", (2007) available at H<u>http://www.asq.org/qic/display-item/index.pl?item=21078</u>H

- Increases the requirements for internal and external communication of food safety issues;
- Clarifies prerequisite programs;
- Develops a system to manage prerequisite programs;
- Clarifies documentation requirements;
- Separates verification activities from validation activities;
- Allows for the development of a food safety management system without a CCP.

It has been noted that the system works because it enables transparency, independence from any particular stakeholder group, self-sustainability (it is up to the company to qualify for it and maintain the conditions to keep it) and flexibility.

Experience shows that a system is effective because of several factors:²⁹

- The company is involved in the food safety objectives. Indeed, a system that is developed by the food manufacturers themselves within the objectives specified by the authorities and customers, is more firmly grounded in the organisation and therefore, more effective than pre-defined systems implemented by directives. When employees understand the meaning of the system, implementation is smoother and costs lower:
- There is common methodology and terminology. When there is one system to serve various corporate branches and crossing international borders, this strengthens food safety by harmonizing food procedures within the company.
- The common vocabulary avoids costly and risky misunderstandings.
- ISO 22000 has the ability to effectively link to other ISO standards, especially ISO 9001 (quality management) and ISO 14001 (environmental management).
- ISO 22000 is not meant to be hidden away in a laboratory or on a book shelf after implementation.
- The standards strongly focus on communication (Figure 2)³⁰: that creates confidence among clients, authorities and suppliers. With effective communication, the major food safety challenges are understood where they are most important, that is at the production floor.

²⁹ Source: Jacob Faergemand, "Market feedback on ISO 22000", ISO Management System, (May-June 2008) p. 32-34

³⁰ Taken from R.Frost, "*ISO 22000 is first in family of food safety management system standards*", ISO Management System, (November-December 2005) p.17

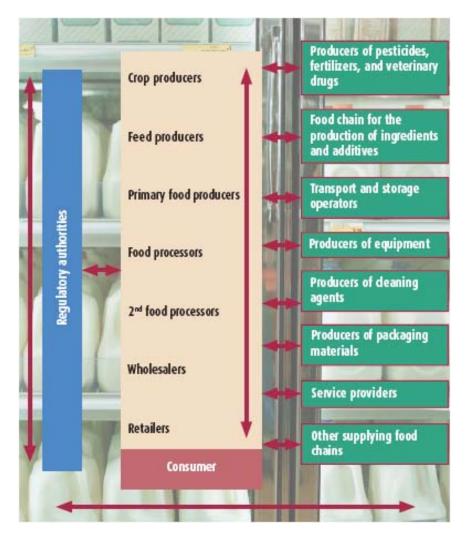


Figure 2: Example of communication within the food chain

2.3 Link with HACCP

ISO 22000:2005 is a natural evolution of the HACCP process. It goes beyond the food safety recommendations as revised in 2003 by the Codex Alimentarius Commission.

ISO 22000 is the first standard that endorses the Codex recommendations and also fills in the gaps and inconsistencies held by years of accumulated experience with HACCP. Table 2 lists and interprets the new key elements, which mainly relate to the interpretation, consistency and thoroughness of the HACCP method of controlling food safety hazards³¹.

³¹ Extract of the article written by D. Blanc (including table 2), "*ISO 22000 From intent to implementation*", ISO Management Systems, (May-June 2006) p.7

Clause in the standard	New elements
5.2 Food Safety Policy	There shall be a food safety policy that is supported by measurable objectives
5.5 Food safety team leader	The responsibilities of the food safety team leader go beyond those of the HACCP leader. The food safety team leader is responsible for: organizing the team's training and work; ensuring the implementation and updating of the system; reporting to management; communicating.
5.6 Communication	External communication relating to food safety hazards throughout the food chain (upstream and downstream); Internal communication relating to ensure that the HACCP team is informed in real time of all changes likely to affect the system.
5.7 Emergency preparedness and response	Emergencies go beyond the recall or withdrawal of a product. Procedures need to be established to manage potential emergency situations that can impact food safety.
6.2 Human resources	The requirements of competence of the HACCP team members and the staff having an impact on food safety.
7.2 Prerequisite programmes	The company should itself select and implement appropriate good hygiene practices.
7.4.2 Hazard identification and determination of acceptable levels	Taking into account the various stages in the food chain (primary production, processing, distribution) where hazards can occur; Determination of acceptable levels in the finished product.
7.4.4 Selection and assessment of control measures	Selection of control measures associated with hazards assessed as requiring control; Assessment of the effectiveness of control measures; Method for assigning these control measures either to the HACCP plan ("conventional" CCP) or to operational PRPs (new concept).
7.5 Establishing the operational prerequisite programmes (PRPs)	Establishment of a monitoring system (procedures, responsibilities, corrective actions) for the control measures assigned to the operational PRPs.
7.7 Updating of preliminary information and documents specifying the PRPs and HACCP plan	After the completion of the 12 steps of Codex HACCP, the food safety team must update the HACCP plan to ensure the plan is effective
8.2 Validation of control measure combinations	Prior validation of the effectiveness of the control measures to ensure observance of the predefined acceptable level for the relevant hazard.
8.4.2 Evaluation of individual verification results 8.4.3	Systematic review of individual results of the plan and verification (e.g implementation of operational PRPs and CCPs, compliance with acceptable levels, and analysis of products and services, etc.). Analysis and overall review of the implementation, operation and
Analysis of result of verification activities	efficiency of the system and of the trends in terms of hazard control, with management reporting.

Table 2: Key innovations of ISO 22000

Figure 3³² sets out the steps of the ISO 22000 approach to hazard analysis. It links these to the twelve steps outlined by Codex and identifies where the process has been improved. ISO 22000 provides a detailed description of these steps and the expected outcome of each, in terms of management system.

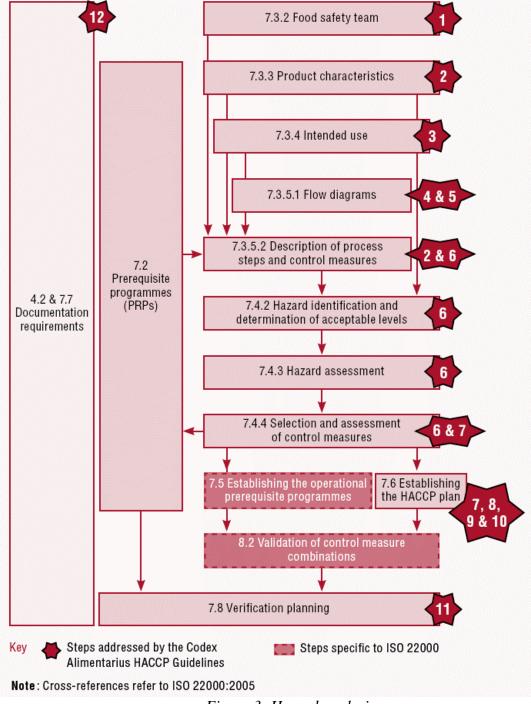


Figure 3: Hazard analysis

³² "ISO 22000 Food safety Management Systems, An easy-to-use checklist for small business, Are you ready?", (2007) ISO/ITC p.54

2.4 A New Element: Traceability

Cases of food poisoning, outbreaks and other food hazards have shown the need for food-related standards that protect public health and reduce the negative social and economic impact of these crises.

In ISO 22000, traceability was mentioned very briefly as an important component of food safety. In June 2007, a new standard was published on this issue: ISO 22005:2007, *Traceability in the feed and food chain – General principles and basic requirements for system design and implementation.* It has been developed by ISO /TC 34, *Food products.*

A traceability system is a safety for public health: it allows documenting, locating a product from primary production to consumption. In case of nonconformity of a product, it is easy to identify its cause. It also provides security from a social and economic point of view: in offering a unique solution for good practice on a worldwide basis, it avoids possible confusion over requirements, costs and complication for suppliers otherwise obliged to conform to multiple programmes. As a consequence, it contributes to lowering trade barriers.

This standard allows organizations that operate at any step of the food chain to³³:

- Trace the flow of materials (feed, food, their ingredients and packaging);
- Identify necessary documentation and tracking for each stage of production;
- Ensure adequate coordination between the different actors involved;
- Require that each party be informed of at least his direct suppliers and clients, and more;
- Improve the appropriate use and reliability of information, effectiveness and productivity of the organization.

2.5 Benefits and costs

2.5.1 Benefits for the food industry³⁴

ISO 22000 creates maximum trust for retailers. Organizations implementing the standard will benefit from:

- Organized and targeted communication among trade partners;
- Optimization of resources (internally and along the food chain);
- Improved documentation;
- Better planning, less post-process verification;
- More efficient and dynamic control of food safety hazards;
- All control measures subjected to hazard analysis;
- Systematic management of prerequisite programmes;
- Wide application because it is focused on end results;
- Valid basis for taking decisions;
- Increased due diligence;
- Control focused on what is necessary;
- Saving resources by reducing overlapping system audits.

³³ Source: M. Lazarte, "New ISO standard to facilitate traceability in food supply chains", ISO Management System, (September-October 2007) p.36-37

⁴ Source: Jacob Faergemand, "Is your food safe?", ISO Focus, (September 2007) p.30-31

Other stakeholders will benefit from:

• Confidence that the organizations implementing ISO 22000 have the ability to identify and control food safety hazards.

The standard adds value because it:

- Is an auditable standard with clear requirements;
- Is internationally accepted;
- Integrates and harmonizes various existing national and industry-based certification schemes;
- Addresses a desire for harmonization from the food processing industries concerning food safety;
- Is aligned with ISO 9001:2000, Quality management systems Requirements, and ISO 14001:2004, Environmental management systems – Requirements with guidance for use, and the Occupational Health and Safety Assessment Series (OHSAS) and can also incorporate retailers' standards;
- Contributes to a better understanding and further development of HACCP.

2.5.2 Costs

Implementing a Food Safety Management System can be expensive, especially for SMEs. Companies that wish to have ISO 22000 certification will have to incur direct and indirect costs.

- Direct or implementation costs include:
 - Awareness building courses and training for employees;
 - Acquiring additional equipment and instruments, and making infrastructural changes to comply with prerequisite programmes;
 - Acquiring relevant international standards of the ISO 22000 family and other publications;
 - Hiring consultants or external trainers, if required.

The cost of establishing and implementing a FSMS will vary from company to company depending upon the scope, work and in-house competency available.

- Indirect costs also occur:
 - Time spent by the management and other staff in developing the FSMS;
 - Costs related to the implementation and maintenance of the FSMS; the internal auditing; documentation and taking corrective actions.
- Certification costs:

If you wish to obtain third-party certification, you will have to pay a certification fee to the certification body selected for the purpose. It is advisable to obtain quotations of the fee involved from several accredited certification bodies before deciding on a particular certification body. The fee depends upon the size of your organization, the number of locations, the number of employees, etc.

To take an example: in India, the fee charged by accredited certification bodies varies from USD 3 500 (for a small company employing up to 50 persons with a maximum of two product lines) to USD 5 000 (for a medium-size company employing up to 100 persons with a maximum of two product lines). All these estimated fees include five surveillance audits by the certification body. Bear in mind that you will need to add the cost of travel, boarding and lodging of the auditors to the basic fee³⁵.

2.6 Implementing ISO 22000³⁶

To implement ISO 22000:2005, the best means is to adopt a step-by-step approach. The logic is the same for ISO 22000 as that for ISO 9001 and ISO 14001: it is to establish a series of actions to be implemented prior to building the system.

These actions are the direct responsibility of management, and include:

- An initial analysis of customer needs, expectations and requirements;
- Identification (or confirmation) of regulatory requirements;
- Definition of a policy supported by measurable objectives;
- Determination of gaps in the current quality system as compared to ISO 22000 requirements;
- Planning of actions and resources needed to meet the objectives and close the gaps with the requirements of the standard.

Once these steps have been accomplished, management should define how it will control FSMS improvement. This is the "management system" phase, including:

- Analysis of the individual results obtained;
- Evaluation of combined results;
- Formulation of recommendations for improvement.

On the basis of these findings, a method based on eight points has been proposed (see Annex IV):

<u>Step 1</u> - Meet basic food safety requirements

The purpose is to identify all the basic conditions and activities necessary to maintain, on a permanent basis, a hygienic environment during the production, handling, storage and provision of safe food or end products for human consumption.

Basic entry data to help develop these PRPs can include:

- Basic Text on Food Hygiene by the Codex Alimentarius Commission;
- Applicable and statutory requirements for both the home nation and potential export nations;
- Good hygiene practice guides;
- Contractual requirements with customers;
- Trade practices and customs.

The organization must identify the PRPs to be observed, implement PRPs effectively, and ensure the permanent implementation of its PRPs. This also includes the

³⁵ Source: S C Arora, Principal Consultant, Federation of Indian Chambers of Commerce and Industry (FICCI) Quality Forum

³⁶ Extract from O.Boutou, "*Eight keys to successful ISO 22000 implementation*", ISO Management Systems, (May-June 2008) p.35-39

identification of methods that will be used to verify the effectiveness of each individual PRP program.

<u>Step 2</u> - Evaluate the safety of the product

The organization should first address the steps preceding hazard analysis by:

- Assembling a HACCP team with multidisciplinary skills;
- Producing a product description including description of raw ingredients, and characteristics of end products;
- Defining the consumers and the intended product use;
- Defining any existing processing steps and control measures;
- Drawing a process flow diagram and on-site confirmation.

Then, the organization can proceed with the following steps:

- Hazard identification and assessment (biological, physical or chemical);
- Selection and assessment of control measures to be aligned with CCPs (Critical Control Points) and/or operational PRPs.
- Establishing and managing a HACCP plan and/or operational PRPs.

System maintenance and improvement are addressed throughout the planning, validation, monitoring, verification and updating cycles. The purpose is to enable the organization to efficiently implement and/or review its HACCP plan by incorporating the new ISO 22000:2005 concepts.

Step 3 - Steps to ensure product safety

The establishment of a safety policy requires the full commitment of all and a management committed to mobilizing personnel, encouraging the achievement of objectives, creating favourable conditions for team work and communicating to personnel the importance of its ISO 22000:2005 based project, and raising awareness of food safety.

ISO 22000:2005 requires that an organization analyses its position in the food chain and to assess the degree of upstream and downstream control of potential food safety hazards.

Management should analyse:

- Its main customer/regulatory and statutory requirements;
- Its main organizational weaknesses regarding food safety;
- The main supplier organizational weaknesses regarding food safety;
- The changes in the organization, or the supply chain, that are necessary to meet the customer and regulatory food safety requirements.

Management should be able to develop, formalize and communicate its food safety policy to all interested stakeholders, based on this analysis. In addition, management should develop measurable food safety objectives and both strategic and operational plans that will ensure the production of safe food products. The food safety policy and food safety objectives need to be periodically reviewed and adjusted accordingly.

Step 4 - Planning the FSMS

To achieve the objectives and ensure end product safety, the process of system planning will require responses to the following questions:

- What do we need to do and how? In what order? Within what deadlines?
- Who is responsible? Who are the authorities?
- How should we build the documentation system?
- What physical and human resources should be deployed?
- How should we measure the implementation of the FSMS?

It is particularly important to structure the various actions and resources in accordance with a schedule. Good forward planning enables the organisation to anticipate and handle any eventualities, while controlling impacts on food safety.

<u>Step 5</u> - Needs for effective FSMS implementation

At this stage, the HACCP plan should be well established. The means and activities that will make it function properly should be identified and implemented. Such food safety processes can include regulatory provisions (food traceability for example), and consensus-based or voluntary provision (control of non-conformities, calibration of measuring equipment...). Each manufacturer is free to add any other means or activities it deems necessary or appropriate to those that have already been determined.

The purpose of this step is to address the implementation of an effective traceability system, supplemented by measuring, calibration, and monitoring equipment to ensure that nonconformities do not occur.

<u>Step 6</u> - What has to be done in the event of the production of potentially non-conforming product

Organisations must have a system in place to respond to emergency situations, such as food safety alerts, outbreaks of food poisoning, process malfunctions, equipment failures, product withdrawals and recalls.

Step 7 - Ensure effective implementation and maintenance of the FSMS

Top management (Element 5.1) must demonstrate its commitment for the development, implementation and maintenance of the FSMS. In addition, the food safety team leader (Element 5.5) is responsible for the day-to-day implementation and management activities of the FSMS which include developing a verification plan. It requires the verification activities to be planned to ensure that the actions taken have been implemented and are effective.

As a result, the organisation must provide evidence of FSMS effectiveness in terms of the level to which planned activities have been realised, and the extent to which expected results have been achieved.

Step 8 - Build on experience to improve the FSMS

Improvement of the FSMS is possible only after the analysis of data. The organisation should take account of the results of verification activities before making decisions during the management review. This review should enable the organisation to identify

new resource needs, generate improvement actions and decide on the appropriateness of the organisation's policy.

The purpose is to achieve optimal food quality and safety in adopting a continual improvement approach.

2.7 Certification

2.7.1 Principle

The certification process consists of two levels. First there is the Accreditation Body. The Accreditation Body is to oversee the activities of the Certification Bodies. They do this by ensuring that the Certification Bodies are operating in compliance with ISO/TS 22003:2007, and ISO 17021:2006. This is done to ensure that the ISO 22000 certification is recognizable in the international market. Examples of national accreditation bodies include ANAB, RvA, JAB, JAS-ANS, and UKAS.³⁷ Second there are the Certification Bodies. These companies conduct the certification audits and issue the certificates to companies that demonstrate that their food safety management system complies with ISO 22000.

The company that decides to get certified to ISO 22000 should select the Certification Body. It is recommended that the company requests proposals and quotations from at least three certification bodies. After selection of the Certification Body, the company submits an Application of Certification. The Certification Body organizes a suitable Audit Team and holds a Pre-evaluation Inspection of the company's Food Safety Management System. At the Pre-evaluation Inspection the adequacy of the system documents is checked, such as food safety policy and measurable food safety objectives, manuals, HACCP plan, procedures, and working documents, and the relevant implementation throughout the whole company according to the requirements of the ISO 22000:2005 standard. If deficiencies are observed, the company will take corrective actions within a designated time interval.

Once the system documents meet the Standard, the Evaluation Audit takes place and the System in its entirety is assessed for compliance with the Standard. This audit will ensure that all previous corrective actions are completed and effective. If the Evaluation Audit does not record deviations from ISO 22000:2005 requirements, the Certification Body issues the Certificate.

Otherwise, if deviations/non-compliances are recorded, the Certification Body does not issue a certificate until all outstanding corrective actions are completed.³⁸.

2.7.2 ISO/TS 22003

Certification to 22000:2005 is not a requirement of the Standard. It can be implemented solely for the benefits it provides.

However, certification is sometimes required by customers, or regulators, or certification is judged desirable as a marketing differentiator. Though, ISO Technical Committee ISO/TC 34 *"Food products"*, in collaboration with ISO/CASCO, Committee on Conformity Assessment, has created a technical specification in the ISO 22000 series, which harmonizes good food safety audit and certification practices worldwide.

³⁷ See H<u>www.iaf.nu</u>

³⁸ Source: H<u>http://www.eurocert1.com/certificate_uk.asp?certificate_id=61&organization=1</u>H

Indeed, the technical specification ISO/TS 22003³⁹, *Food safety management systems* – *Requirements for bodies providing audit and certification of food safety management systems*, was published in 2007 to increase the acceptance of ISO 22000 and ensure that accredited certification programmes are implemented in a professional and trustworthy manner. It provides the necessary information and confidence on how the certification of an organization's food safety management system has been conducted.

The Technical Standard is to be used with ISO 17021:2006, *Conformity assessment - Requirements for bodies providing audit and certification of management systems.* The two standards place rigorous requirements for competence and impartiality on the certification bodies that offer audits and certification to food safety management systems.

ISO/TS 22003 covers topics such as resource requirements, competence of management and personnel (including auditors and persons involved in decisions related to certification), process requirements and requirements for certification bodies.

Certification of a FSMS demonstrates that the FSMS of the organization:

- Is conforming to specific requirements;
- Is capable of consistently achieving its stated policy and objectives;
- Is effectively implemented.

2.7.3 Publicizing the certification⁴⁰

Companies that are certified to ISO 22000 are encouraged to publicize their certification. However, there are a few rules that must be followed as part of the advertising process. These rules include:

- Don't use ISO's logo, the company can use a logo provided by the certification body. The certification body will determine appropriate use of the logo;
- Don't adapt or modify ISO's logo for your use;
- If your organisation is certified to ISO 22000:2005, use the full designation;
- The terms "certified", "certification", "registered" and "registration" are equivalent and can all be used;
- Don't say your organisation has been "accredited";
- Don't use "ISO certified", or "ISO certification" but "ISO 22000:2005 certified", or "ISO 22000:2005 certification";
- Don't display ISO 22000:2005 certification marks of conformity on products, product labels, or product packaging, or in any way that may be interpreted as denoting product conformity;
- Don't give the impression in any context that ISO 22000:2005 certifications are product certifications or product guarantees;
- When including a reference to ISO 22000:2005 certifications in productrelated information, including advertisements, do not do so in such a way that ISO 22000:2005 certifications may be interpreted as being product certifications or product guarantees;

³⁹ Source: "ISO/TS 22003 aims to build confidence in certification of food safety management systems", ISO (15.02.2007) Ref.:1048 available from H<u>http://www.iso.org/iso/pressrelease.htm?refid=Ref1048</u>H

⁴⁰ Adapted from "*An introduction to ISO 14000 – Environmental Management Systems*", (October 2007) ITC Bulletin No 78 p.21

• Be accurate and precise about the scope (the extent) of your organization's ISO 22000:2005 certification, as far as both the activities and geographical locations covered by the certifications are concerned.

2.8 Market feedback on ISO 22000

2.8.1 Statistics

Since its publication in September 2005, the standard has been well received by the food industry: it has become a global standard. Indeed, three years after the launching of the standard, the questions to know how many countries had adopted ISO 22000:2005 as a national standard arose: an incomplete and informal but useful survey has been realised.

- In early 2007, the survey recorded 357 certifications in 45 countries;
- By the third quarter of 2007, contributors identified 715 companies in 57 countries;
- In March 2008, the most recent survey revealed that ISO 22000 is used by at least 1152 companies in 72 countries.

It is interesting to evaluate the number of certificates by category (Table 3), by country (Table 4) and by region (Table 5) 41 .

Category	# of certificates
Catering	164
Food processor	149
Dairy processor	116
Beverage	90
manufacturer/winery	
Meat/poultry processor	72
Ingredients	66
Packaging	54
Confectionery	51
Fruit and vegetable	46
processor	
Distributors and handlers	45
Feed manufacturer	32
Seafood/fish processor	25
Bakery	25

Table 3: Top 15 categories

Table 4: Top 15 countries

⁴¹ These three tables have been reproduced from A. Chambers, "*Survey incomplete but reveals ISO 22000 implementation in 72 countries*", ISO Management Systems, (May-June 2008) p.10-11

Country	# of certificates
Turkey	200
Japan	60
India	60
Denmark	54
China	52
Australia	44
France	37
Hungary	37
Greece	35
Romania	34
Sweden	32
Taiwan 31	
South Korea 29	
Italy	28
Cyprus	27

 Table 5: Certificates by major regions

Region	# of certificates	% of certificate
Europe	661	57.4
Far East	232	20.1
Africa/West Asia	161	14.0
Australia/New Zealand	44	3.8
Central/South America	32	2.8
North America	22	1.9
Total	1152	100.0

2.8.2 Cases of Best Practice

(a) <u>Danone</u>⁴²

Danone, which is one of the world's largest providers of dairy products, already had a food safety management system prior to ISO 22000. However, Dominique Berget, Danone's Corporate Food Safety Director, pointed out the relevance of an ISO standard that would be recognized all over the world. About 30 Danone sites are now ISO 22000 certified, and Danone said it was planning to certify all of its production sites to ISO 22000 in two years.

⁴² Source: S. Tranchard, special report "*World food giant Danone one of the earliest adopters of ISO 22000*", ISO Management Systems, (May-June 2008) p.12-15

(b) Kraft Foods⁴³

Kraft Foods, one of the largest food and beverage companies, pointed the lack of a food safety specificity of ISO 9001. It sees ISO 22000 as the best vehicle for winning acceptance from its stakeholders worldwide for a single food safety management system standard, and has initiated pilot projects in Europe and the Asia/Pacific region.

(c) <u>VanDrie Group⁴⁴</u>

The VanDrie Group is the largest integrated veal producer in the world. Respect for man, animal and quality has been part of the group for generations. Their system was already based on the HACCP system and the ISO 9001 standard; ISO 22000 was a natural step. It plans to certify all of its Dutch companies before 2009.

(d) <u>Arla Foods⁴⁵</u>

This company sees ISO 22000 as the umbrella for food safety standard and hopes that ISO 22000 will replace food retailer standards like British Retail Consortium (BRC) and the International Food Standards (IFS) over time.

2.8.3 ISO 22000 and SMEs

Bramfood Manufacturers and Distributors, a Canadian SME employing 20 people, is the first company in North America to achieve ISO 22000 certification⁴⁶. According to this company, to be ISO 2200:2005 certified is a "remarkable achievement and will help them to flourish". It enables this company to look forward to aiming at international business and hitting the European market. To them, ISO 22000:2005 is a food industry useful trade tool for global business because it cuts down barriers, expands market access and creates a level playing field for all competitors.

They estimate that SMEs should adopt ISO 22000:2005 in order to enhance their food safety management system, increase their product acceptability, grow their business and give tough competition to the bigger companies.

Magro Brothers is Malta's leading food manufacturer and is ISO 22000 certified. The company said that it "did not encounter any great difficulties to customize the standard's generic requirements". ISO 22000's requirements for food safety management systems surpass their previous combination of ISO 9001 and HACCP.

2.9 Assistance for a better understanding of ISO 22000

(a) <u>ISO/TS 22004</u>

ISO/TS 22004, Food safety management systems – Guidance on the application of ISO 22000 was published in 2005. It provides:

⁴³ Source: P.Overbosch, A.L Lozano, S.Mould, special report *"Kraft Foods evaluate ISO 22000 as global standard for ensuring food safety"*, ISO Management Systems, (May-June 2008) p.12-15

 ⁴⁴ Source: H.Swinkel, special report "World's largest veal producer to implement ISO 22000 at all its facilities", ISO Management Systems, (May-June 2008) p.20-22
 ⁴⁵ P.Junedahl, special report "Arla Foods sees ISO 22000 becoming international benchmark for food

⁴⁵ P.Junedahl, special report "Arla Foods sees ISO 22000 becoming international benchmark for food safety", ISO Management Systems, (May-June 2008) p.23-28

⁴⁶ Source: M.Rajah, B.Singh, "*Canadian food sector SME's ISO 22000 scoop*", ISO Management Systems, (January-February 2007) p.5

- Users with explanations that will help in the application of the standard
- Additional information for small and/or less developed organizations on how to implement certain requirements.

The guidance helps to avoid misinterpretation of ISO 22000, to clarify the meanings of its terms and to eliminate confusion.

(b) <u>Guide</u>

In 2007, ISO and the International Trade Centre (ITC) jointly published ISO 22000, *Food safety management system – An easy-to-use checklist for small business – Are you ready?*⁴⁷. The aim of the software-based self-diagnostic tool is to provide help to small and medium sized enterprises to use and implement ISO 22000. It targets especially developing countries and transition economies, in their efforts to improve their market share of food and agricultural products in the global market.

The checklist, in 13 parts, consists of questions covering various aspects of the setting-up, implementation and certification of a food safety management system defined by ISO 22000. Each part provides a brief explanation of the relevant requirements and guidance on how to incorporate it in a food safety management system. By answering "yes" or "no", the user confirms that he understands the issue and has included it in his food safety management system or shows that he is not sure about that aspect. In this case, the Checklist provides the user with additional information and guidance.

It is available from the ISO Central Secretariat (<u>www.iso.org</u>), the ISO National Member Institutes (<u>http://www.wssn.net</u>), and ITC (<u>www.intracen.org</u>).

(c) <u>Distance learning programme⁴⁸</u>

A Swiss distance-learning course was created to help food companies to achieve certification to the new Food Safety Management Standard ISO 22000. For example, thanks to this, Olga Kouassi, a quality management consultant and auditor in the Ivory Coast, is now qualified to help local companies implement the standard and audit their food safety management system.

The course is supported by case studies and discusses all the main elements necessary to implement a food safety management system in conformity with the standard.

Participants receive immediate feedback on their course work, and are provided with models adaptable to their own business situations. They can also interact with online discussion groups for support and answers to questions. (See the detailed description of the course at: <u>www.i3academia.com</u>).

Thanks to the training help that provided a considerable amount of relevant information and documents that could be easily put into practice, a company in the lvory Coast has been led through to its ISO 22000:2005 certification audit. This was a source of major satisfaction for them.

⁴⁷ "ISO 22000, Food safety management system – An easy-to-use checklist for small business – Are you ready?", (2007) ISO/ITC

⁴⁸ Source and more information in: D.Blanc, "*Distance learning programme boosts ISO 22000 in the Ivory Coast*", ISO Management Systems, (May-June 2007) p.43-45

- (d) <u>Training Programme⁴⁹</u>
 - ITC⁵⁰

The International Trade Centre (ITC) is implementing one of the components of the project on "Bangladesh Quality Support Programme". One objective of the project is to improve the competitiveness of exports from selected priority sectors. According to the ITC "Strategy for developing the Agro-Processed Foods sector in Bangladesh"⁵¹ there is a need to improve quality control in food processing and for food inputs to reduce the risk of accidental contamination and to meet compliance requirements for target markets for food, health and safety. The strategy recommends building the capacity of trainers, counsellors and consultants in Bangladesh and to improve linkages between providers so that they can train and advise enterprises, intermediaries and transporters together on the implementation of ISO 22000 and other standards.

The proposed activities on FSMS related to ISO 22000 are the following:

- Organization of two three-day workshops on "Implementing Food Safety Management Systems ISO 22000";
- Hands-on assistance to strengthen six selected Trainers-cum-Counsellors on Food Safety Management Systems (ISO 22000);
- Direct assistance to six agro-processed enterprises to implement Food Safety Management Systems (ISO 22000).
 - UNIDO⁵²

The United Nations Industrial Development Organization (UNIDO) has planned a special project for some countries in the SAARC region (namely Bangladesh, Bhutan, Maldives and Nepal), to strengthen national capacities related to Standards, Metrology, Testing and Quality (SMTQ). One of the important activities of this project is to develop awareness about ISO 22000 FSMS and also develop national capacities for conducting FSMS Audits of the enterprises implementing ISO 22000 FSMS.

The three stages of this training program are:

- Stage 1: Self study of the material provided by the training organization at the duty station of the participant;
- Stage 2: Certified Food Safety Management System Auditor/Lead Auditor Training based on ISO 22000;
- Stage 3: Written examination.

2.10 Challenges to come for the food industry

To enable an efficient development of ISO 22000's implementation, retailers, important food producers and national authorities need to be enlisted, at least in a dialogue.

⁴⁹ The following information gives some examples of training programmes on ISO 22000 by UN agencies such as ITC and UNIDO. The information is an illustrative one and it is far from being exhaustive as other technical cooperation agencies and organisations may provide training programmes on ISO 22000.

⁵⁰ ITC, "Bangladesh Quality Support Programme BGD-75-21-A, Concept Paper on establishing Food Safety Management Systems (ISO 22000) in Bangladesh for the Agro-process sector".

⁵¹ The strategy has been produced by the stakeholders of the sector in collaboration with the Ministry of Commerce and ITC, July 2007.

⁵² UNIDO, "ISO 22000 Food Safety Management System Awareness Seminar and Food Safety Management System Auditor/Lead Auditor Training", (Based on ISO 22000: 2005), (8 February 2008) available at Hhttp://www.unido.org/fileadmin/import/86843 16001580ZP TOR.pdfH

The challenges to come are⁵³:

- Still many small and medium-sized companies are waiting for action by three main market drivers: the major multinational food companies, public authorities and retailers.
- The authorities must define acceptable levels for different areas such as salmonella, coli bacteria and campylobacter, and the companies have to incorporate control measures to ensure that these hazards are kept to specific levels.
- To develop a structure of well-described prerequisite programme guidelines that ISO 22000-certified companies must implement.

⁵³ Source: Jacob Faergemand, "*Market feedback on ISO 22000*", ISO Management Systems (May-June 2008) p.32-34

ANNEX I

Beijing Declaration on Food Safety

BEIJING DECLARATION ON FOOD SAFETY

Adopted by consensus by the High-level International Food Safety Forum "Enhancing Food Safety in a Global Community"

held in Beijing, the People's Republic of China on 26 and 27 November 2007



中华人民共和国卫生部 Ministry of Health, PRC



In recalling that access to safe food and a nutritionally adequate diet is a right of each individual¹ and in recognition that:

- Oversight of food safety is an essential public health function that protects consumers from health risks posed by biological, chemical and physical hazards in food as well as by conditions of food;
- Foodborne risks, if not controlled, can be major causes of disease and premature death as well as lost productivity and heavy economic burdens;
- Equal application of food safety measures between countries as well as within countries can improve global food safety;
- Integrated food safety systems are best suited to address potential risks across the entire food-chain from production to consumption;
- Food safety measures should be based on sound scientific evidence and risk analysis principles and should not unnecessarily create barriers to trade;
- Production of safe food is primarily the responsibility of the food industry;
- Education of consumers is critical in promoting safe food practices in the home; and,
- Interactive communication with consumers is important for assuring that societal values and expectations are considered in the decision-making process.

Therefore, all countries are urged to:

- Establish competent food safety authorities as independent and trusted public health bodies within a comprehensive production-to-consumption legislative framework;
- Develop transparent regulation and other measures based on risk analysis to ensure safety of the food supply from production to consumption, harmonized with the guidance of the Codex Alimentarius Commission and other relevant international standards-setting bodies;
- Ensure adequate and effective enforcement of food safety legislation using risk-based methods, such as the Hazard Analysis and Critical Control Point system, where possible;
- Establish food and total diet monitoring programmes with linkages to human and food-animal disease surveillance systems to obtain rapid and reliable information on prevalence and emergence of foodborne diseases and hazards in the food supply;
- Establish procedures, including tracing and recall systems in conjunction with industry, to rapidly identify, investigate and control food safety incidents and to advise WHO of those that fall under the International Health Regulations (IHR) (2005) through the International Food Safety Authorities Network (INFOSAN) and the National IHR Focal Point;
- Communicate and consult effectively with consumers, the food industry, and other stakeholders in developing, implementing and reviewing food safety policies and priorities, including education and other matters of concern; and,
- Expedite the strengthening of food safety capacities through effective cooperation between developing and developed countries as well as among developing countries, thus promoting safer food for all.

ANNEX II

The ISO 22000 Family of Standards

- ISO 22000:2005, Food safety management system Requirements for any organization in the food chain
- ISO/TS 22003:2007, Food safety management systems Requirements for bodies providing audit and certification of food safety management systems
- ISO/TS 22004:2005, Food safety management systems Guidance on the application of ISO 22000
- ISO 22005:2007, Traceability in the feed and food chain General principles and basic requirements for system design and implementation

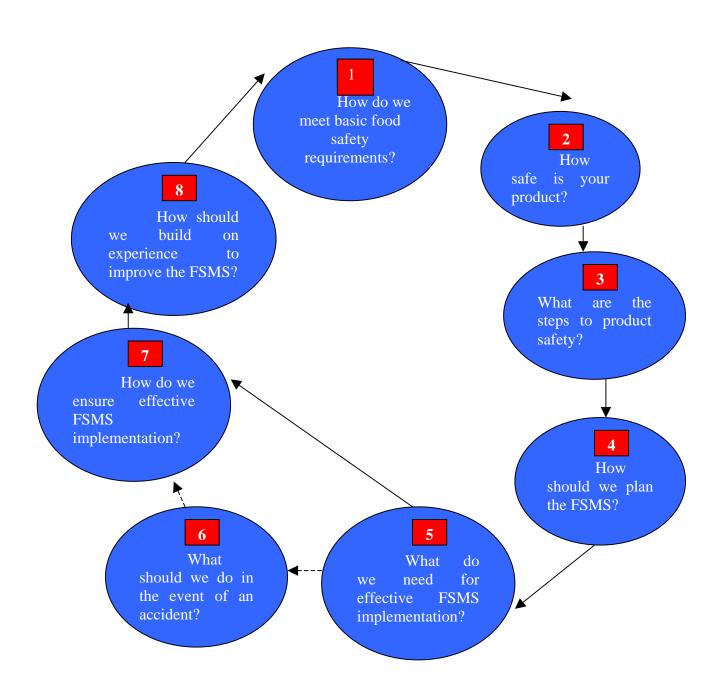
ANNEX III

ISO 22000:2005 - Contents

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

ANNEX IV

Eight keys to an ISO 22000:2005-based FSMS



ANNEX V

Useful Websites Links

American Society for Quality ⇔ <u>http://www.asq.org</u>

Codex Alimentarius Commission (Codex) ⇔ <u>http://www.codexalimentarius.net</u>

Food and Agriculture Organization of the United Nations ⇔ <u>http://www.fao.org</u>

International Accreditation Forum ⇔ <u>http://www.iaf.nu</u>

International Organisation for Standardisation (ISO) ⇔ <u>http://www.iso.org</u>

International Plant Protection Convention (IPPC) ⇔ <u>http://www.ippc.int</u>

International Portal on Food Safety, Animal and Plant Health http://www.ipfsaph.org

International Trade Centre (ITC) ⇔ <u>http://www.intracen.org</u>

SPS Information Management System ⇔ <u>http://spsims.wto.org</u>

Standards and Trade Development Facility (STDF) ⇔<u>http://www.standardsfacility.org</u>

United Nations Organisation for Industrial Development ⇔ <u>http://www.unido.org</u>

United Nations Conference on Trade and Development (UNCTAD) ⇔ <u>http://www.unctad.org</u>

World Health Organisation (WHO) ⇔ <u>http://www.who.int</u>

World Organization for Animal Health (OIE) ⇔ <u>http://www.oie.int</u>

World Trade Organisation (WTO) ⇔ <u>http://ww.wto.org</u>





Street address International Trade Centre 54-56 Rue de Montbrillant 1202 Geneva, Switzerland

P: +41 22 730 0111 F: +41 22 733 4439 E: itcreg@intracen.org www.intracen.org Postal address International Trade Centre Palais des Nations 1211 Geneva 10, Switzerland

The International Trade Centre (ITC) is the joint agency of the World Trade Organization and the United Nations.