

AMBO UNIVERSITY WOLISO CAMPUS



COLLEGE OF BUSINESS AND ECONOMICS

DEPARTMENT OF AGRICULTURAL ECONOMICS

HANDOUT

OF

Food Safety and Quality Management in Value Chain;

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Introduction to Food Quality and Safety

Dear learners try to understand?

- What is food quality and food safety?
- What are the major food qualities attributes?
- Do you think that there is a difference between food quality and safety?
- Can you list stakeholders responsible for food quality and safety in value chain?
- What are the driving forces for food quality and safety standards?

Concepts and Definitions

Food safety and food quality are two important terms which describe aspects of food products and the reputations of the processors. Food quality and food safety principles and practices are applied to foods from farm produce and livestock production; manufactured and processed food products for consumers; and all raw materials, ingredients, processing aids, food-contact packaging materials, and food-contact surfaces that are used in the preparation of food and beverage products. The overall responsibility for food quality and food safety is shared by all segments of the food system, including the various food industry sectors, government regulatory agencies, and consumers in the food supply chain.

The terms food quality and food safety are important in any food manufacturing environment, and often used interchangeably, but there is a distinct relationship between food quality and food safety. -

Food Quality

Food product quality is a prime criterion in gaining access to competitive markets. Food quality can be defined as a total of traits and criteria which characterize food as regards its nutritional value, sensory value, convenience as well as safety for a consumer's health. Thus, it is a broader concept than food safety. Food quality, as distinct from food safety is the extent to which all the established requirements relating to the characteristics of a food are met in satisfying customers' satisfaction. In other words, good quality exists when the product complies with the requirements specified by the client. This means quality is a term defined by the consumer, buyer, grader, or any other client based on a number of subjective and objective measurements of the food product. Quality includes all other attributes that influence a product's value to the consumer."These may include measures of purity, flavor, color, maturity, safety, wholesomeness, nutrition, or any other attribute or characteristic of the food product.

Food safety

Food safety is a component of quality and an assurance that food will not cause adverse harm to the consumer when it is prepared and/or consumed according to its intended use to final consumers. Food safety is not negotiable. All requirements relating to the safety characteristics of a food must be met; there must be no unacceptable health risk associated with a food. Safety differs from many other quality attributes since it is a quality attribute that is difficult to observe. A product can appear to be of high quality, i.e. well colored, appetizing, flavourful, etc. and yet be unsafe because it is contaminated with undetected pathogenic organisms, toxic chemicals, or physical hazards. On the other hand, a product that seems to lack many of the visible quality attributes can be safe.

Food safety (hazard-free) is the most important feature of food quality, hence the food law regulates this issue, in order to assure consumers that the food they purchase meet their expectations as regards safety. It is also an increasingly important public health issue.

This distinction between food quality and food safety needs to be made, primarily because of the much greater importance that must be attached to protecting consumers from food-borne illnesses or injuries. A food that does not conform to the food safety requirements automatically does not conform to the food quality requirements. On the other hand, a food can conform to the food safety requirements, but not conform to the other quality requirements. This distinction between safety and quality has implications for public policy and influences the nature and content of the food control system most suited to meet predetermined national objectives.

Driving forces for food quality and safety standards

When agri-food production become industrialized and globalized, the nature of food quality and safety will be changed. Industrialized agri-food production will result in higher productivity and novel products, but it also involves new and greater risks relating to the mass production and distribution of food. In elongated but fragmented supply chains, agri-food products are exposed to possible contamination at multiple processing stages managed by different actors. Increased contract farming and food processing spread responsibilities of food safety among a wider set of actors. At the same time, it increases the burden of the processors and retailers that have prominent consumer brands and large market share to ensure the safety of the products they manufacture or sell. Therefore, creating equivalence or harmonization across different regulatory regimes and standards has yet to be accomplished,

despite a decade of efforts to establish international rules on food trade under the World Trade Organization (WTO).

There are two distinct aspects of food quality management for agro-enterprises yet they are both interrelated. The first approaches quality in terms of conforming to certain market requirements such as a perceptible superiority of desirable traits or characteristics like size, coloration, or organoleptic properties. The second approaches quality as a synonym for food safety, which can be also used as a marketing tool to move product in countries with high food safety standards.

Accessing New Markets

Product quality is a prime criterion in gaining access to competitive markets that demand a stable supply and a consistent quality. Standards for quality and reliability have already been established for most raw materials and value-added commodities by the international agro-industry markets. Any products which cannot reach equivalent levels of quality, functionality or reliability will not survive in competitive global markets except perhaps certain niche or ethnic markets.

Globalization Risks Associated with Poor Quality

The tenfold increase in food exports over the last thirty years has brought new concerns fuelled by high-profile incidents such as Alar in apples and Mad Cow disease. Certain consequences of the increased movement of goods and services must now be more carefully considered.

Challenges emerging from changing market access and demands

International standards and the ever-increasing quality demands of developed markets require developing countries to take a hard look at their approaches to quality management if they want to participate in those markets. While it may be difficult for many agricultural enterprises in developing countries to apply HACCP methods with any sort of rigor, Good Agricultural Practices (GAP) and Good Manufacturing Practices (GMP) are a practical step toward significantly improved quality and safety.

Food quality and food safety assurance along the food chain

Development of the profit-oriented food enterprises, growing consumers' expectations and concerns as regards food quality and safety, as well as increasing requirements of food chain actors, forced many companies to improve safety and quality of their products through implementation of the quality and safety assurance and management systems.

In order to preserve the various quality features in food products, various safety and quality assurance systems have been developed. Some of the systems are obligatory by law and some voluntary to be implemented by the food chain members. The distinction between obligatory and voluntary systems is based on the safety (hazard-free products) being the quality of food required by law. Thus, obligatory systems have been established to assure food safety, and are subsequently called "safety assurance systems". These include Good Hygiene Practices (GHP), Good Manufacturing Practices (GMP) which are generally called accepted best practices and Hazard Analysis and Critical Control Point (HACCP), which is preventive methods applied, to different extents, by most enterprises that export food in order to reduce the risk of microbial, chemical and physical contamination. Food safety management systems such as HACCP further strengthen preventive and systematic approaches to assuring food safety. The HACCP system is the most widely used methods and part of a strong trend in the more developed markets that are increasingly requiring their rigorous application. Traceability systems with communication and information flowing through the chain also contribute to ensuring food safety within ever complex food chains.

Traceability

Traceability is a concept developed in industrial engineering and was originally seen as a tool to ensure the quality of production and products through effective operation system in the production center.

In supply-chain management of agricultural produce, traceability is defined as the information system necessary to provide the history of a product or a process from origin to point of final sale.

Traceability (or product tracing) systems differentiate products for a number of reasons. Food traceability systems allow supply chain actors and regulatory authorities to identify the source of a food safety or quality problem and initiate procedures to remedy it. While traceability in the food sector has focused increasingly on food safety, agrifood and non-food sectors such as forestry and textiles (particularly cotton) have instituted traceability

requirements for product identification, differentiation, and historical monitoring for market success of their products.

In the context of agricultural policy, traceability refers to full traceability along the supply chain, with the identification of products and historical monitoring, and not just the separation of products under specific criteria at one or more stages of the chain.

Traceability is the ability to follow the movement of a food through specified stage(s) of production, processing and distribution. The traceability/product tracing tool should be able to identify at any specified stage of the food chain (from production to distribution) from where the food came (one step back) and to where the food went (one step forward), as appropriate to the objectives of the food inspection and certification system.

Traceability is an increasingly common element of public and private systems for monitoring compliance with quality, environmental, and other product and/or process attributes related to food. Small-scale farmers may lack the resources to comply with increasingly strict food safety standards, particularly traceability requirements.

Given the role of traceability in protecting consumers, ensuring food safety, and managing reputational risks and liability, it is vital to integrate and empower small-scale agricultural producers in the food supply chain through value chain

Traceability systems can be classified according their capacity for (1) internal traceability and (2) chain traceability. “Internal traceability” refers to data recorded within an organization or geographic location, whereas “chain traceability” involves recording and transferring data through a supply chain between various organizations and locations involved in the provenance of food. Food contamination may occur at the farm, during processing or distribution, in transit, at retail or food service establishments, or at home. Fundamentally, traceability systems involve the unique identification of food products and the documentation of their transformation through the chain of custody to facilitate supply chain tracking, management, and detection of possible sources of failure in food safety or quality.

Why is traceability needed?

- Traceability is a way of responding to potential risks that can arise in food and feed, to ensure that all food products in the EU are safe for European citizens to eat.

- It is vital that when national authorities or food businesses identify a risk they can trace it back to its source in order to swiftly isolate the problem and prevent contaminated products from reaching consumers.
- In addition, traceability allows targeted withdrawals and the provision of accurate information to the public, thereby minimizing disruption to trade.
- Past food crises, such as dioxin contamination and Bovine Spongiform Encephalopathy (BSE), have illustrated the particular importance of being able to swiftly identify and isolate unsafe foodstuffs in order to prevent them from reaching the consumer.

Good practices in traceability entail making the lot number and name of the production facility visible on each case of product and recording the lot number, quantity, and shipping location on invoices and bills of lading. Traceability requires each facility to record data when a product is moved between premises, transformed/further processed, or when data capture is necessary to trace the product.

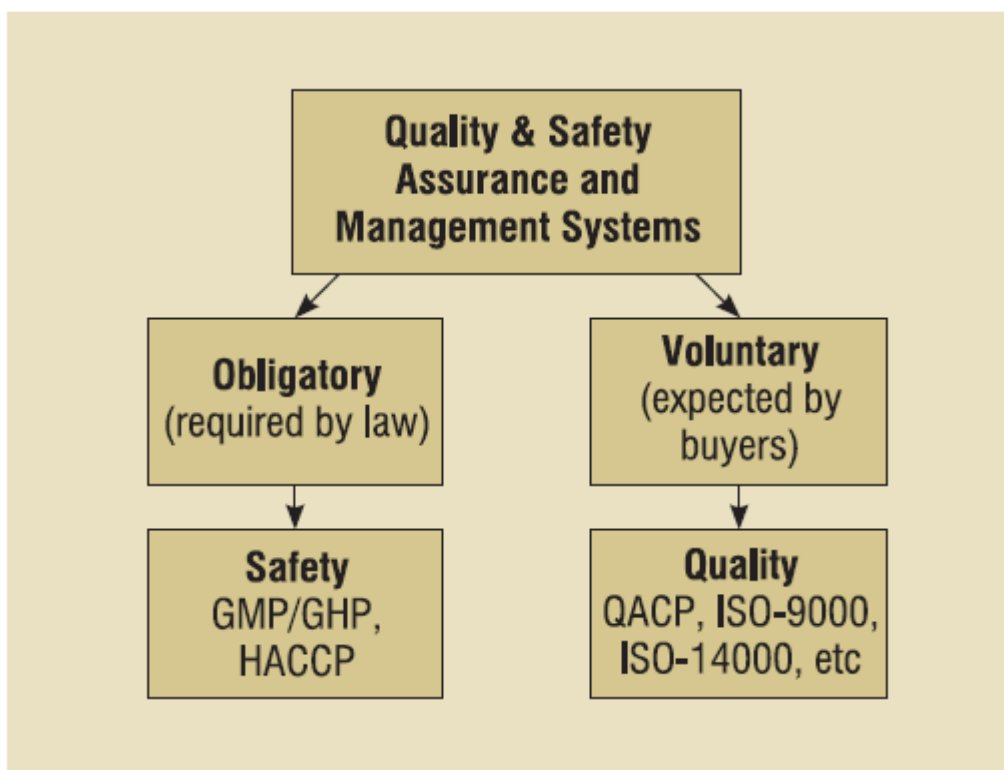


Figure 1. Diagram of voluntary vs. obligatory quality and safety systems

Definitions

- **Best practice:** A superior method or innovative practice that contributes to the improved performance of an organization, usually recognized as “best” by other peer organizations (QP, 2002).
- **Good manufacturing Practices (GMP):** is a set of guidelines specifying activities to be undertaken and conditions to be fulfilled in food manufacturing processes in order to assure that the food produced meets the standards of food safety.
- **GHP:** All practices taken to ensure the food safety suitability or constitute a set of guidelines specifying activities to be undertaken and hygienic conditions to be fulfilled and monitored at all steps of the food chain in order to assure food safety. It is Traditional food safety assurance system.
- **HACCP:** It is a systematic food safety assurance method to identify, evaluate and control of food hazards.

Agribusinesses, must implement appropriate food quality and safety assurance systems that can reduce and manage food safety risks through the food chain from farm to table. This requires strong collaboration between governments and the private sector so as to develop technical resources as well as appropriate know-how within the agrifood industry.

Monitoring food safety is the responsibility of all stakeholders along the food marketing chain from farm to fork. This responsibility is built on the premise that all foods should meet acceptable food safety and quality parameters set down in legislation, to protect consumer health and prevent misinformation or poor quality foods reaching the consumer. Yet it is also in the business interest of agro-enterprises to produce safe products in order to retain their customers and to avoid expensive claims of food poisoning.

Food industry stakeholders are primarily responsible for demonstrating all possible actions taken to assure food safety and quality, but they do not work in isolation from the official food control services. A modern, effective and efficient food control system consists of up-to-date food laws, regulations and standards; clear and well-functioning food control management systems; risk-based food inspection systems; supportive and effective laboratory services; and delivery of information, education and advice to stakeholders across the farm-to-table continuum. Partnership and dialogue between public and private sector with input from the scientific community will maximize the effectiveness of food safety guarantee systems in agro-industries and ensure that information on potential risks from foods are properly passed on to consumers.

Quality Assurance and Management Systems

Maintenance and/or introduction of the remaining qualities in food (nutritional, sensory and convenience values), is not requested by law, albeit desirable by customers. Voluntarily implemented systems, known as quality assurance and management systems, include for example Quality Assurance Control Points (QACP), the well-known ISO-9000 (quality management) and ISO-14000 (environmental management).

Quality Assurance Control Points (QACP) is one of the quality assurance systems in food production, created based on the HACCP concept. In case of HACCP, Critical Control Points

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(eliminating hazards), parameters and their critical limits are determined, while in QACP – Control Points (quality assurance, not safety), parameters and their critical values⁴. Likewise in HACCP, QACP is unique for each company and must be introduced individually for each enterprise and production line.

Having implemented GMP/GHP, HACCP and QACP systems, the next step could be to implement other quality systems, e.g. ISO-9000. The ISO-9000 series of standards represent the requirements which have to be addressed by every enterprise to assure the reliable production and timely delivery of goods and services to the marketplace. Many food chain actors require their suppliers to become registered to ISO-9000 and because of that, those who registered find that their market opportunities have increased.

There is deference between assurance and management. The term “assurance” relates to a product itself and involves all the safety assurance systems (GMP, GHP and HACCP) and the quality assurance system QACP. On the other hand, the term “management” corresponds to a company’s overall organisation as regards the products’ quality (including safety), and involves the remaining Quality Management Systems QMS (ISO-9000, ISO-14000, etc.) as well as Total Quality Management TQM.

3.1.2. Food quality and safety framework – policies, standards and institutions

Pre Test

- Describe the role of food standards and policy
- Explain International and national policies related to foods
- Identify institutions responsible for food quality and safety

Definitions: Food standards and food policy

Food standard: standards are documents ,established by consensus and approved by a recognized body ,that provide ,for common and repeated use ,rules ,guidelines or characteristics for products or related processes and production methods .

Standards are normative documents, which are broadly used in industry and trade, as self regulatory mechanism and as a description of the state-of-the-art.

Food policy is the area of public policy concerning how food is produced, processed, distributed, and purchased. Food policies are designed to influence the operation of the food and agriculture system. The policy consists of setting goals for food production, processing, marketing, availability, access, utilization and consumption, and describes the processes for achieving these goals. Food policy can be on any level, from local to global, and by a government agency, business, or organization. In addition, food policy involves schools, regulations, and eligibility standards for food assistance programs; and it involves health and safety, food labeling, and even the qualifications of a product to be considered organic.

Overview of the global framework governing food quality and safety standards.

In addition to food laws and regulations, food standards also establish requirements for the safety and quality of foods; however, unless a food standard is part of food regulations identity it is not a legal requirement. The Codex Standards are the best examples of food standards. The Codex Alimentarius Commission has the mandate to implement the joint Food and Agricultural Organization (FAO)/World Health Organization (WHO) Foods Standards Program. This has resulted in the Codex Alimentarius, a collection of standards for food quality, food suitability, and food safety. These food standards have been adopted by countries worldwide and are intended primarily to protect consumers and to facilitate international food trade. They include codes of practice such as The Codex General Principles of Food Hygiene, standards for maximum residual levels (MRL) for pesticides and for veterinary drugs in foods, and standards for specifications for food additives.

Evolving Global Context for Food Safety

The strategic development of a food chain approach to food safety must be considered within a global context that is constantly evolving and dynamic. Globalization of food trade requires the development of a more integrated and preventive approach within food safety systems. As international trade in food and farm products increases, it will become increasingly difficult to resolve food safety problems of any one country without collaborative international efforts to develop integrated, preventive strategies. Increased trade also implies

potentially increased costs, as food scares become increasingly global. The economic consequences of contaminated food and farm products can be potentially devastating, with the estimated US\$6 billion in costs incurred by the United Kingdom in response to the Bovine Spongiform Encephalopathy (BSE) crisis but one recent example. Failure to attain international food safety standards can result in significant financial losses for food exporting countries (for example, exporters of groundnuts with aflatoxin problems – a food quality issue related to safety). The close relationship between health and economic development must also be considered in terms of more globalised food safety systems. Food (and the water used for its production, processing and preparation) is a likely vector of many microbiological, chemical and physical hazards.

Food safety must be considered within a global context that is dynamic and evolving as part of the globalization process. Globalisation is generally characterized by increased international trade, more integrated markets, more rapid adoption of new technologies, increased market concentration and information transfer. All of these aspects have important implications, both positive and negative, for food safety and the development of a food chain approach to food safety strategy. Increasingly open trade in food and farm products can potentially benefit both consumers and producers through greater variety of foods/products or new export income earning opportunities. However, the potentially negative impacts of this trend include the possibility that food-borne diseases are more easily transmitted among countries even more rapidly - posing health risks to consumers and financial risks to food producers/processors who fail to attain rigorous and increasingly *globalised* food safety standards.

Globalization is also changing how food and farm products are processed and traded. Fresh produce and processed products are increasingly marketed globally, with greater concentration of market power in a few dominant food multinationals. These companies generally have the financial and technological capacity to ensure that their fresh produce and food products are safe and that any sources of food contamination may be more easily traced. However, given the more integrated and global nature of these firms, once unsafe and/or contaminated food enters the food chain, it is very likely to be more rapidly distributed and thus expose a greater number of people to increased risk.

The increasing role of new and more innovative technology in food production, post-harvest treatment, processing, packaging and sanitary treatment is also significant in the context of food safety and more globalised food trade. The use of recombinant DNA in plant and animal production, and food irradiation, are important examples of new technologies that - while potentially of great benefit – may pose risks to food safety due to their recent introduction or the relative lack of experience in their application to a wide variety of environments. New technologies may not always be correctly applied, and they may have unsuspected and harmful side effects over the longer term.

Increasing public awareness of food safety hazards, concern over threats to health attributable to food hazards and reduced confidence in the ability of current food supply systems to manage food safety risks are additional factors to be considered in the development of a food chain strategy. Information is rapidly disseminated and the media quickly spreads news of food safety emergencies. Consumer organizations concerned with food safety issues continue to increase their political influence and this trend is of great benefit to the consumer. However, food-safety concerns and food scares that are not scientifically substantiated may create unnecessary obstacles and potentially hinder development of potentially useful new technology. Consumers are now equally concerned about the quality of their diet with relation to health and risk of chronic diseases. The need to address their concerns with regard to the nutritional quality of the diet can be easily and closely interwoven with food safety during the development of the food chain strategy.

There are other widespread changes in the global food economy that impact on a food chain approach to food safety, ranging from the farm through to the consumer. For example, the increased intensification of food production (plant, livestock and fishery) practices may increase the risk of chemical contamination through pesticide and veterinary residues or microbiological pathogens, such as *Salmonella*. An increasing tendency to eat away from home in commercial settings, coupled with increased consumption of convenience and semi-cooked foods that require refrigeration (short shelf life), as well as the consumption of larger quantities of raw fruits and vegetables, may also directly increase the health risk from microbiological pathogens to consumers, particularly the emergence of new ones such as *E. coli* 0157.H7.

Intensified farm practices, integrated and increased trade through globalization and changes in consumer eating patterns have implications for how FAO can strategically react to the challenges posed by food safety and food safety-related quality issues. The development of a food chain approach in a future food safety strategy for FAO must incorporate not only the generalized elements of a more globalised, dynamic environment but also those broad characteristics of the differing food safety situations in developed and developing countries, noting that the countries in transition share certain elements from both country groups.

Framework for the Development of a Food Chain Approach to Food Safety

FAO defines the food chain approach as recognition that the responsibility for the supply of food that is safe, healthy and nutritious is shared along the entire food chain - by all involved with the production, processing and trade of food. As such, the implications of a food chain approach are much broader than those aspects limited to food safety systems. The broader implications of a food chain approach for production and post-production systems, biosecurity and nutrition are addressed in other COAG documents. This framework document, however, specifically outlines the most important issues in the development of a food chain approach to food safety.

Widespread changes in the global food economy and the dynamic environment in which food safety issues must be considered have led to a more profound appreciation of just how inter-related the needs of both developing and developed countries are in terms of the strategic development of a food chain approach to food safety. There are five broadly defined inter-related needs on which to base future strategic direction in support of a food chain approach to food safety:

- Food safety from a food chain perspective should incorporate the three fundamental components of risk analysis - *assessment, management and communication* – and, within this analysis process, there should be an institutional separation of science-based risk assessment from risk management – which is the regulation and control of risk. A prudent approach to risk assessment and management should also be adopted.
- **Tracing techniques** (*traceability*) from the primary producer (including food products and animal feed used in the production of animal products), through post-harvest treatment, food processing and distribution to the consumer must be improved.
- **Harmonisation of food safety standards**, implying increased development and wider use of internationally agreed, scientifically-based standards is necessary.
- **Equivalence in food safety systems** – achieving similar levels of protection against food-borne hazards whatever means of control are used – must be further developed, particularly as required by the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) of the WTO.
- Increased emphasis on **ex-ante risk avoidance or prevention at source** within the whole food chain – *from farm or sea to plate* – is necessary to complement the conventional ex-post approach to food safety management based on regulation and control.

The development of a framework for a food chain approach to food safety should be based on a strategic response to the complex set of challenges and needs areas described previously in this document. As such, a framework for the future development of a food chain approach to food safety should be broadly based on three key elements:

- Universally adopting a risk-based approach to food safety.
- Complementing the current, traditional emphasis on regulation and control of end products in food safety systems with a more pronounced and comparable emphasis on prevention of food contamination at source - including development and dissemination of good practices/safety assurance systems (i.e. Hazard Analysis and Critical Control Point/HACCP).
- Adopting a holistic approach to food safety that encompasses the whole food chain – from farm or sea to plate – and adheres to the FAO definition of a food chain approach in which responsibility for the production of safe food is shared along the entire food chain.

The key elements described above are based on ideas that have received increasingly widespread support among national and international institutions concerned with food safety. These concepts are timely, relevant and critically important to the successful future

development of food safety strategy within FAO. The inter-related nature of these key action areas implies that enhanced collaboration with international and national partners in food safety matters (potentially beyond the remit of FAO) would be necessary.

FAO's work in support of these broad strategic elements (and within the framework of developing a new food safety strategy) would involve the appropriate balance of normative and field activities based on risk assessment, scientific advice, technology transfer, consumer education and capacity-building. Most importantly, FAO would continue to provide a valuable and significant forum for further discussion and information exchange in the area of food chain analysis and food safety systems. A more detailed discussion of the key elements outlined above provides further support for the inclusion of these concepts in a food chain approach to food safety.

Universal adoption of a risk-based approach to food safety is a relatively recent innovation that received additional impetus from the WTO SPS Agreement. A risk-based approach to the management of food safety hazards by definition implies risk analysis. Food control resources are thus directed to those hazards posing the greatest threat to public health and where the potential gains from risk reduction are large relative to resource use. Establishing risk-based priorities requires sound scientific knowledge and effective systems for reporting the incidence of food-borne diseases. Risk strategies also demand rigorous follow-up and improved international cooperation through information exchange and risk communication. However, while independent scientific research and knowledge are the foundation of sound risk assessment, it is important to note that risk management very often involves a political process. The political nature of governmental regulation and control of food safety (risk management), may partially explain why consumers are increasingly insistent that risk assessment and management are separate functions, despite the need for the responsible government authorities to interact to manage risk effectively. Food safety systems utilising a food chain approach would also benefit from cross-sectoral analyses that incorporate other risk domains and assessments related to plant and animal life and health and related topics, such as biosecurity.

Complementing the current emphasis on regulation and control of food safety systems with preventive measures to control the introduction of food contamination at-source is a critically important element in the development of a revised strategy. This necessitates the adoption of practices in food production, post-harvest treatment, processing and handling that reduce the risk of microbiological, chemical and physical hazards from entering the food chain (or controlling at source, if feasible). There are some cases in which the hazard simply cannot be removed from foodstuffs, for example, those hazards involving chemical contaminants. The adoption of sound practices along the food chain – based on the principles defined in Good Agricultural Practices (GAP) and Good Manufacturing Practices (GMP) – are the keys to discharging this responsibility along the food chain. In-plant controls of food processing operations should also be based on HACCP analysis - to the extent that capacity, experience

and resources permit. The core components of food safety systems, however, will remain the application (and compliance) of food product regulations developed through internationally agreed, science-based food standards.

Adopting a holistic, food chain approach to food safety recognizes that primary responsibility for supplying safe and palatable food lies with all those involved in food production, post-harvest treatment, processing and trade. This **'at-source'** responsibility encompasses all stakeholders throughout the food chain. Stakeholders may include farmers and the suppliers of farm inputs (especially animal feed and veterinary supplies), fisher folk, slaughterhouse and packing-house operators, fish processing plants, food manufacturers, transport operators, wholesale and retail traders, caterers, food service establishment operators, street food vendors and others. This responsibility also extends to the end consumer who must be educated to ensure that food is properly stored, hygienically prepared and food shelf lives are respected. A holistic, integrated food chain approach should further engender the need for close contact and collaboration between, for example, food control authorities and those responsible for environmental protection and water quality. Furthermore, this approach should permit greater *traceability* of food products and facilitate - not only the withdrawal from markets of hazardous or contaminated foods - but also the identification of weak hazard-promoting links in the chain.

The three **strategic elements** discussed in this section recognize that the responsibility for ensuring food safety (as well as adequate quality related to safety) is shared by the food, agriculture and fishery sectors and all involved with the production, post-harvest treatment, processing and trade of food. Diverse government ministries, such as public health, industry, consumer affairs, environment, agriculture and fisheries, are often jointly responsible for the development of official standards, technical regulations and enforcement of food safety. However, often it is the private sector that must make daily, practical decisions on investment, management and costs to ensure that food production, post-harvest treatment; processing and distribution comply with food safety standards. Food safety systems that incorporate the key elements described above will ensure a food chain approach and the continued and improved collaboration between public and private sector bodies throughout the entire food chain.

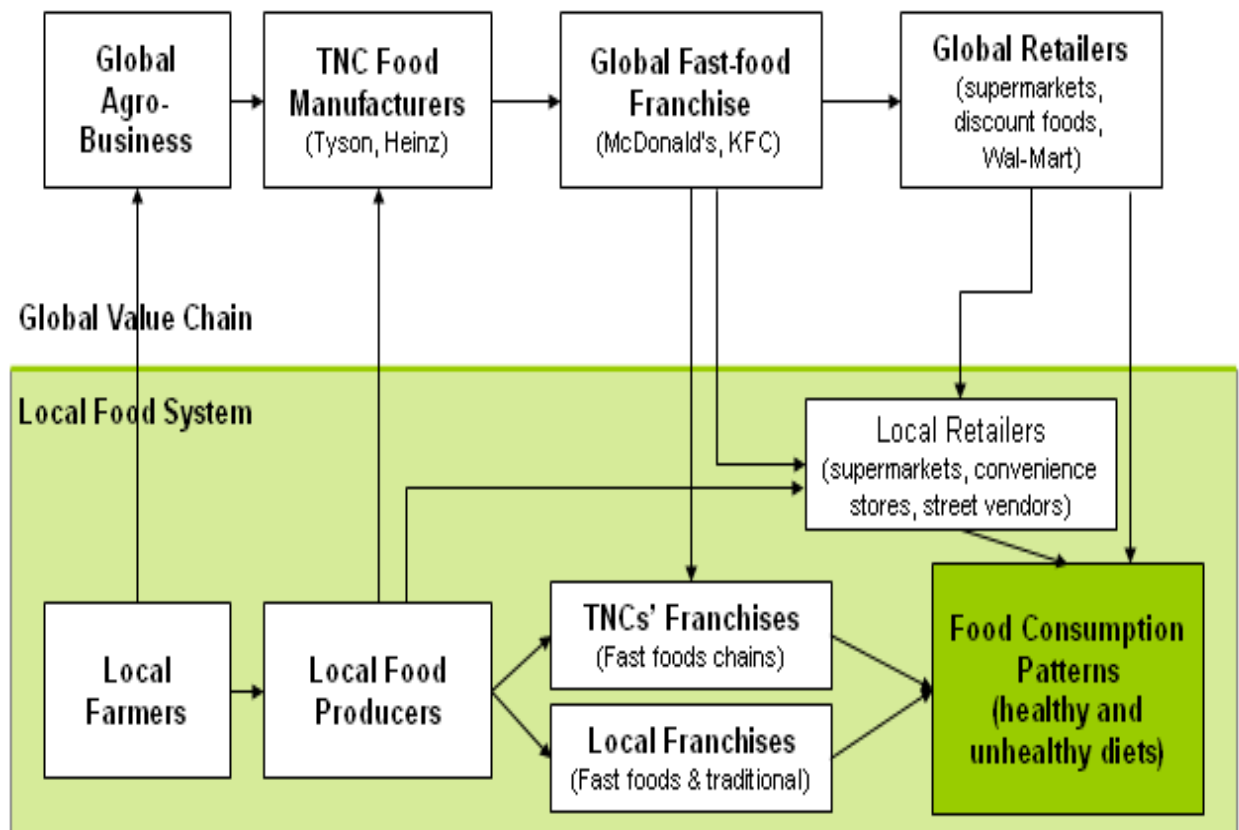


Figure 2: Interaction of Global and Local Food Value Chains

Food safety and quality standards in transition

As agri-food production became industrialized and globalized, the nature of food safety changed. Industrialized agri-food production has resulted in higher productivity and novel products, but it also involves new and perhaps greater risks relating to the mass production and distribution of food. In elongated but fragmented supply chains, agri-food products are exposed to possible contamination at multiple processing stages managed by different actors. Increased contract farming and food processing spread responsibilities of food safety among a wider set of actors. At the same time, it increases the burden of the processors and retailers that have prominent consumer brands and large market share to ensure the safety of the products they manufacture or sell. Safety risks associated with the diffusion of production among a wider set of actors are magnified within the population as concentration in food production and retailing grows.

Food standards have evolved in response to this new landscape in the globalized and liberalized food production regime. Traditionally, food products were subject to minimum public quality standards for grain, and quality and safety standards for meat and dairy products. Facing growing health risks from food contamination, however, existing public regulations have tightened up and new public standards have proliferated in recent years. Furthermore, private food standards for safety and quality have emerged since the

1990s. Private standards are promulgated and enforced primarily by corporate actors in an individual or a collective manner.

There are public and private standards, defined by who promulgates and enforces them. Public institutions set food regulations and mandatory standards, making compliance compulsory. While the basic tenet of public regulations is to protect consumers, historically they also act to shape industrial structure by forcing actors who cannot comply out of competition. Private standards can be set by individual firms, often big retail chains, but market participants can also set guidelines collectively in a formal process. Standards can be either mandatory or voluntary, depending on the extent to which they are legally binding. Some private standards are mandatory in a *de-facto* (if not *de jure*) sense, when they gain overwhelming market share and influence and abiding by them becomes critical to gain access to the supply chain.

Finally, as supply chains become more global, so do private standards. The EUREPGAP1 standards for fresh fruits and vegetables, for example, were initiated by 13 European retailers in the late 1990s, responding to the demands of the U.K.'s Food Safety Act. The name of the program was changed in September 2007 to GLOBALGAP to reflect its expanding international role as one of the major international private standards that link farmers and other suppliers to a growing number of international retailers.

Table 2: Public and private Food safety and quality standards

	Public Mandatory	Public Voluntary	Private	
			Collective	Individual firms
National	<ul style="list-style-type: none"> National Legislation (e.g., pesticide uses, sanitary inspections) 	<ul style="list-style-type: none"> Food Safety Enhancement Program HACCP Advantage SQF (until 2003) USDA's National Organic Program 	<ul style="list-style-type: none"> Dutch HACCP Standard BRC Global Standard Assure Food Standards Qualitat und Sicherhei Intergrale Keten Beheersing US's Pork Quality Assurance Program 	<ul style="list-style-type: none"> Nature's Choice (Tesco Stores, UK) Field-to-Fork (Marks & Spencer, UK) Filiere Agriculture Raisonnee (Auchan, France) Filiere Qualite (Carrefour, France) Terre et Saveur (Casino)
International	<ul style="list-style-type: none"> European Union Regulations WTO regulations 	<ul style="list-style-type: none"> ISO 9000 ISO 22000 	<ul style="list-style-type: none"> International Food Standard SQF 1000/ 2000/ 3000 GLOBALGAP (formerly EUREPGAP) 	The same as above (for multinational companies)

Analytical Framework: Value Chain Governance and Food Standards

The following figure presents four different situations depending on the degree of concentration in the markets for supply (food processor or supplier) and demand (retailer or buyer). Each box has different characteristics of value chain governance (i.e., who drives and

governs the value chain), as well as in the type of food standards most likely to be associated with each kind of market structure. The logic this typology is that the more a particular value chain is concentrated and governed through tight explicit coordination by a few consolidated actors, the more the value chain is likely to contain comprehensive private standards to regulate food safety and quality. Conversely, fragmented value chains at both the supply and demand ends are likely to encounter more limited public standards.

		Food Demand (retailer/buyer)	
		Concentrated	Fragmented
Food Supply (processor/supplier)	Concentrated	(A) Bilateral oligopolies → Private / Most comprehensive standards	(C) Producer-driven chains → Public + private / Safety & quality-focused process standards
	Fragmented	(B) Buyer-driven chains → Public + private / Safety & quality-focused product standards	(D) Traditional markets → Limited public standards / Least comprehensive standards

Figure 3: Analytical model - Value Chain governance and Food standards

In Box A, where buyers and suppliers are concentrated, both sets of value chain actors have significant market and brand power, resources, and leverage to govern the value chain. In a value chain that is highly concentrated in both supply and retail, private standards driven by food processors and retailers are likely to be the leading mechanism for regulating agri-food production with the most comprehensive safety and quality requirements. In the U.S. chicken value chain, as shown above, both processors and retailers are consolidated and have consumer brands and resources to implement their own private standards. Furthermore, competition is increasingly based on diversified processed products. In the chicken sector, one of the fastest growing organic food sectors in the United States, there are multiple types of government-regulated or non-regulated labels for organic chicken, such as “Free Range,” “Natural,” “Antibiotics” and “No Hormones” for the former, and “Cage-Free” and “Pastured Poultry” for the latter .

Box B, where buyers are concentrated while suppliers are not, represents a buyer-driven value chain where “large retailers, brand-name merchandisers and trading companies play the pivotal role in setting up decentralized production networks in a variety of exporting countries”. This type of chain is frequently observed in many tradable agri-foods from developing to developed countries. Here the leading buyers (retailers in developed countries) have strong power, resources and leverage that allow them to impose their private standards on fragmented suppliers (farmers in developing countries).

In general, the agri-food value chain is characterized by the presence of strong retailers as lead firms, given the heightened consolidation in the retail segment. Even producer-driven chains (Box C), once dominated by large brand-name processors like Heinz and Nestle, have tilted toward a bi-polar value chain (Box A), as powerful retailers began to challenge their power. As long as most of its production activities are done in house, the producer may have less incentive than the retailer to develop its own standards for suppliers, whose private label products are mostly made by independent suppliers. As more inputs and tasks are outsourced, however, the producer’s buying activities become as important as its own production. These producers may focus more on process standards to ensure the suppliers follow the defined procedures. The best examples of this type of chain are products that are sold in grocery stores as well as other retail outlets, such as gas stations.

Finally, despite overall increased concentration in agri-food production and retail, the level of concentration varies by product, and by importing and exporting countries. When both the supply and demand for food are fragmented (Box D), there is likely to be no or limited public standards that only cover basic safety concerns. Private quality and social and environmental standards are least developed here compared to the other three boxes. This can be the case for traditional agricultural commodities that are traded in local farmers’ markets oriented toward domestic consumption, rather than exported to foreign markets. Actors in this type of chain have no brand recognition and transactions among them are largely price-based. The vacuum in standards can make this type of value chain more prone to food contamination and other food scandals.

Overview of International and national policies and institutions responsible for food quality and safety: Food Law and Regulations

The development of relevant and enforceable food laws and regulations is an essential component of a modern food control system. Many countries have inadequate food legislation and this will impact on the effectiveness of all food control activities carried out in the country. Food law has traditionally consisted of legal definitions of unsafe food, and the prescription of enforcement tools for removing unsafe food from commerce and punishing responsible parties after the fact. It has generally not provided food control agencies with a clear mandate and authority to *prevent* food safety problems. The result has been food safety programmes that are reactive and enforcement-oriented rather than preventive and holistic in

their approach to reducing the risk of food borne illness. To the extent possible, modern food laws not only contain the necessary legal powers and prescriptions to ensure food safety, but also allow the competent food authority or authorities to build preventive approaches into the system. In addition to legislation, governments need updated food standards.

In recent years, many highly prescriptive standards have been replaced by horizontal standards that address the broad issues involved in achieving food safety objectives. While horizontal standards are a viable approach to delivering food safety goals, they require a food chain that is highly controlled and supplied with good data on food safety risks and risk management strategies and as such may not be feasible for many developing countries. Similarly, many standards on food quality issues have been cancelled and replaced by labeling requirements. In preparing food regulations and standards, countries should take full advantage of Codex standards and food safety lessons learned in other countries. Taking into account the experiences in other countries while tailoring the information, concepts and requirements to the national context is the only sure way to develop a modern regulatory framework that will both satisfy national needs and meet the demands of the SPS Agreement and trading partners

Food legislation should include the following aspects:

- It must provide a high level of health protection;
 - It should include clear definitions to increase consistency and legal security
 - It should be based on high quality, transparent, and independent scientific advice following risk assessment, risk management and risk communication;
 - It should include provision for the use of precaution and the adoption of provisional measures where an unacceptable level of risk to health has been identified and where full risk assessment could not be performed;
 - It should include provisions for the right of consumers to have access to accurate and sufficient information;
 - It should provide for tracing of food products and for their recall in case of problems;
 - It should include clear provisions indicating that primary responsibility for food safety and quality rests with producers and processors;
 - It should include obligation to ensure that only safe and fairly presented food is placed on the market;
 - It should also recognize the country's international obligations particularly in relation to trade; and
- It should ensure transparency in the development of food law and access to information.

Global Considerations

(a) International Trade

With an expanding world economy, liberalization of food trade, growing consumer demand, developments in food science and technology, and improvements in transport and communication, international trade in fresh and processed food will continue to increase.

Access of countries to food export markets will continue to depend on their capacity to meet the regulatory requirements of importing countries. Creating and sustaining demand for their food products in world markets relies on building the trust and confidence of importers and consumers in the integrity of their food systems. With agricultural production the focal point of the economies of most developing countries, such food protection measures are essential.

(b) Codex Alimentarius Commission

The Codex Alimentarius Commission (CAC) is an intergovernmental body that coordinates food standards at the international level. Its main objectives are to protect the health of consumers and ensure fair practices in food trade. The CAC has proved to be most successful in achieving international harmonization in food quality and safety requirements. It has formulated international standards for a wide range of food products and specific requirements covering pesticide residues, food additives, veterinary drug residues, hygiene, food contaminants, and labeling etc.

The Codex recommendations are used by governments to determine and refine policies and programmes under their national food control system. More recently, Codex has embarked on a series of activities based on risk assessment to address microbiological hazards in foods, an area previously unattended. Codex work has created worldwide awareness of food safety, quality and consumer protection issues, and has achieved international consensus on how to deal with them scientifically, through a risk-based approach. As a result, there has been a continuous appraisal of the principles of food safety and quality at the international level. There is increasing pressure for the adoption of these principles at the national level. See Annex 4 for further details.

(c) SPS and TBT Agreements

The conclusion of the Uruguay Round of Multilateral Trade Negotiations in Marrakech led to the establishment of the WTO on 1 January 1995, and to the coming into force of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) and the Agreement on Technical Barriers to Trade (TBT). Both these Agreements are relevant in understanding the requirements for food protection measures at the national level, and the rules under which food is traded internationally. The SPS Agreement confirms the right of WTO member countries to apply measures to protect human, animal and plant life and health. The Agreement covers all relevant laws, decrees, regulations; testing, inspection, certification and approval procedures; and packaging and labeling requirements directly related to food safety. Member States are asked to apply only those measures for protection that are based on scientific principles, only to the extent necessary, and not in a manner which may constitute a disguised restriction on international trade.

The Agreement encourages use of international standards, guidelines or recommendations where they exist, and identifies those from Codex (relating to food additives, veterinary

drugs and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practices), to be consistent with provisions of SPS. Thus, the Codex standards serve as a benchmark for comparison of national sanitary and phytosanitary measures. While it is not compulsory for Member States to apply Codex Standards, it is in their best interests to harmonize their national food standards with those elaborated by Codex. The TBT Agreement requires that technical regulations on traditional quality factors, fraudulent practices, packaging, labeling etc imposed by countries will not be more restrictive on imported products than they are on products produced domestically. It also encourages use of international standards.

Compliance costs to public sector

Concerns with food safety and quality have persistently been present on the agenda of policy Makers and managers concerned with food production and processing. Though not novel, the interest in quality and safety issues has certainly been widened by recent changes in agri-food.

From a historical perspective, until the later part of the last century, food product standards primarily focused on the safety issue. They built on the international agreements expressed in the 'Codex Alimentarius' (CA), an initiative jointly supported by the World Health Organization (WHO) and the Food and Agriculture Organization of the United Nations (FAO), or were developed within the framework of the World Trade Organization's (WTO) agreement on the application of 'Sanitary and Phytosanitary Measures' (SPS). As such, the agreements concentrated on limits of potentially hazardous residues and on the implementation of HACCP concepts for food safety control.

While these developments took place primarily in Europe, with the advent of the Global Food Safety Initiative (GFSI) their reach was widened to a more global scale. Private standards have a global effect and ultimately establish the quality and safety benchmarks for many agrifood products. Private standards reach as far upstream in the value chain as the agricultural production segment. Indeed, the European retail groups' Eurep GAP (Euro Retailer Produce Good Agricultural Practices) standard for agricultural production has become a global initiative and a *de facto* benchmark within a short time since its implementation. The standards of the global retail chains (British Retailer Consortium (BRC), International Food Standards (IFS), etc.) consider, as a general framework, the requirements stated in the CA and SPS agreements. However, by definition they reach beyond the scope of the agreements and non-tariff trade barriers that are set independently of the WTO negotiations and CA developments.

They do not constitute classical trade barriers between countries, but are instead seen as trade barriers between those enterprises that have been approved by retail chains as potential suppliers and those which have not been approved. Such chain induced, non-tariff trade

barriers, cannot be subject to any trade agreements as long as product liability laws make retailers fully liable for any harm their products might inflict on consumers. The switch from country-based trade barriers to value-chain based global trade barriers is only slowly being comprehended by policy makers. However, it puts the emerging quality and safety systems into a prominent position for consideration in discussions on the future development of the global agrifood system.

The European retail chains have assumed a leading role in the formulation of food safety and quality standards. Their international supplier base, especially in developing countries, needs to adapt and comply, if they wish to continue trading with major retailers. Furthermore, other retail groups outside Europe, including the international subsidiaries of European groups, are bound to eventually join and thus plausibly establish the private standards as the true international benchmark for food safety and quality. Under such a scenario, production groups in developing countries with trading interests with less developed economies are not in a position to establish standards for quality systems on their own. They must comply or else be excluded from trade. In this situation, it is important for enterprises to be able to:

- a) Follow the economic minimization principle, i.e. fulfill the necessary requirements of certain standards required by their trading partners with the lowest possible costs or, alternatively;
- b) Follow the economic maximization principle, i.e. to utilize a certain budget to adapt their production system to as many standards of potential trading partners as possible.

The subsequent section analyses legal requirements as a basis for 'quality' actions in enterprises and provides insights into the structure of quality and safety systems. The existing literature on the impact of methodologies and approaches for cost-benefit-estimations for agrifood quality and safety improvements is then reviewed. The text proceeds with a section dealing with the discussion of costs and benefits which could arise in quality and safety improvement processes at the level of the enterprise, value chain, market and public sector. Further, a methodological concept for the estimation of cost and benefits of quality and safety standards is presented and a case study illustrating the estimation of costs and benefits under the proposed approach is provided. Finally, the document concludes with recommendations for public policy to improve the actual and the future situation of quality and food safety.

The challenges of measuring cost and benefits of agrifood quality systems

The agrifood system can be viewed as a network composed of different subsystems in which multiple products are produced and marketed by different actors. Cooperation in such networks is characterized by vertical or horizontal interactions, competitive relations and cross cutting interactions among different subsystems located in one or more countries. This

complex organization represents a challenge for any identification/ isolation of effects of management activities, such as the improvement initiatives towards the quality and safety of agrifood products, the consequences of which reach beyond the limits of the individual enterprise.

In this framework, improvements in the quality and safety of food products build on decisions linked to requirements. These are defined by general legislation, by agreements within the scope of the CA that could be enforced within the WTO trade accords, and by quality standards devised by public or private groups that cannot be enforced by administrative rules, but through markets and its participants. Enterprise decisions on the adoption of quality and safety standards might focus on the implementation of individual requirements or of comprehensive systems. Policy decisions by public or private agencies might on the other hand focus on the provision of support for sector developments in quality and safety improvements, beyond legal regulations. In both cases, decisions will have to deal with the feasibility of implementation and on an analysis of its consequences, involving those related to costs and benefits.

Meeting standards could become a major difficulty for enterprises, as the adoption of the associated requirements may require specific technical skills, facilities, and equipment. Problems could also arise during the implementation of different quality systems by an individual enterprise, as there might be conflicting requirements; while one system might call for intensive cleaning and disinfection, another might ask for minimization in the use of cleaning and disinfection agents. In principle, enterprises have to search for the best solution regarding the adherence to particular sets of standards and improvements in food safety and quality with a view on cost and overall benefits. The analysis of costs and benefits is a traditional approach for decision support in economics. However, the consideration of cost-benefit relationships linked to the implementation of quality improvements and quality management systems in the agri-food sector is less common. The few studies documented in the literature refer to costs and benefits of food safety as an integral part of quality management concerns. Other studies deal with trade and especially with the agreements on 'SPS' measures and on Technical Barriers to Trade (TBT).

Measuring costs and benefits of quality and food safety improvements faces practical and conceptual difficulties. Some of the difficulties are associated with the need to isolate the impact of individual standards. The same problem exists concerning benefits of a quality system. Challenges of valuing benefits involve the need to quantify items such as improved market access, enhanced corporate image (trusted supplier), and environmentally improved Products, improved health and higher overall efficiency. Quality of food has also been seen as a factor for small food industry competitiveness. In Asia, it has been found that food quality in traditional markets depends on the degree of economic benefits expected along the chain, while in Latin America studies in several countries found that traditional chains lack

the appropriate incentives to promote improvements in food quality and safety .Costs and benefits of safety and quality improvements depend on the internal and the external conditions under which an enterprise operates. The calculation of costs and benefits will therefore have to focus on individual enterprises or on groups of enterprises with similar characteristics regarding the implementation and the consequences of improvements in food safety and quality.

3.1.3.Food Quality and Safety Management: Roles of Stakeholders

Pre-test

What are the major food safety hazards?

Whom do you think are responsible for food safety and quality management?

What is the role of stakeholders in food safety and quality management?

Definitions: Hazards, quality assurance (QA) and quality management (QM) systems, good practices and HACCP

Hazard A biological, chemical, or physical agent in, or condition of, food with the potential to cause an adverse health effect. A biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

Quality assurance (QA)

Part of quality management focused on providing confidence that quality requirements will be fulfilled (ISO9000:2000). All those planned or systematic actions necessary to provide adequate confidence that a product or service will satisfy given needs. All the planned and systematic activities implemented within a quality system that can be demonstrated to provide confidence a product or service will fulfill requirements for quality.

Quality management system

Management system to direct and control an organization with regard to quality (ISO9000:2000).A formalized system that documents the structure, responsibilities and procedures required to achieve effective quality management.

Good practices

Good Agricultural practices GAP focus on the best practices to be used for producing agricultural products to ensure the quality and safety of the final product .GAP are guidelines,which ensure that all agricultural practices ,in particular pest and disease control ,are in accordance with Integrated crop Management (ICM) and Integrated Pest Management (IPM) practices .GAP aim at ensuring sustainable agriculture by minimizing hazards for the workforce ,other actors along the food chain ,consumers and the environment while ensuring economically viable production .With the increasing need for food quality and safety through the chain ,the trends goes towards integrating HACCP and traceability concepts into GAP systems .

Good Distribution practices

GDP guidelines aim at adjusting handling, transport and distribution procedures to the requirements of food safety.

Good Hygiene practice (GHP)

Guidelines for GHP aim at establishing processing ,handling, transport and distribution procedures that are apt to prevent perishing due to micro-organisms ,growth of pathogens on food stuff, contamination with chemical residues or contaminants (e.g.mycotoxins).Basic rules are set out in the ‘ Codex General Principles of Food hygiene ’.They include requirements for the design of facilities ,control of operations (including temperature ,raw materials, water supply ,documentation ,and recall procedures),maintenance and sanitation ,personal hygiene and training of personnel. Hygienic practices form an integral part of all food safety management systems, as for example within the HACCP system.

Good Manufacturing practices (GMP) There are many reactions occurring during processing and manufacturing of raw materials that cause changes in composition, nutritional value, physical structure and sensory properties .The objectives of GMP are to control these changes so as to develop the desired qualities in the product, to ensure food safety and to stop or slow down any deterioration in the food. Good Manufacturing Practices means understanding, analyzing and controlling the manufacturing process.

Hazard analysis critical control point (HACCP)

A system that identifies, evaluates, and controls hazards that are significant for food safety .A systematic approach to the identification, evaluation, and control of food safety hazards .HACCP, which is recognized for its science-based approach, consists of a set of seven principles that have been adopted internationally through the work of Codex Alimentarius Commission.

Food safety hazards

A food safety hazard is a biological, chemical or physical agent, or condition of food, with the potential to cause disease .The origin of these hazards in foods can be from naturally occurring substances or agents in foods, from deterioration or decomposition of foods, or from

contamination of the foods with the hazard at various stages of their production harvesting, storing, processing, distribution, preparation and utilization For many hazards, government regulatory agencies have established an acceptable level of the hazard in a food; the Codex Alimentarius has also established acceptable levels of certain hazards as part of its Food Standards Programme. For some hazards, such as pathogenic bacteria (e.g.,*Salmonella* spp.), there is zero tolerance; this means that the presence or the detection of the hazard in the food is unacceptable. The strategies used to address hazards in foods include the prevention or elimination of hazards, or the reduction of hazards to acceptable levels. These strategies are

employed it he HACCP system to cause harm or an adverse health affect when the food is eaten.

Controlling food safety hazards during production, harvesting and postharvest handling (trimming, grading, packing, transport etc) of fresh produce is important to protect consumer health and to gain access to markets

Food safety hazards can be classed as:

- Biological such as microorganisms
- Chemical such as chemicals, pesticides, cleaning agents and allergens
- Physical foreign objects that are not supposed to be in the food, such as timber, glass, packaging material and naturally occurring objects – bones, dust and grit.

Any business should aim to reduce the risk of these hazards in its food processing and service, ensuring the food is safe to consume. A food safety program outlines the systems in place to keep food safe and procedures which reduce the risk of the hazards which may occur in the food production and service business.

Physical hazards

Any potentially harmful extraneous material not normally found in food such as glass, bone splinters, twigs ,metals, buttons, etc. that are likely to cause choking, cuts ,injury or other adverse health effects.

Physical hazards which can be found in food include:

- Objects naturally present in the food (animal hair, bone chips, leaves, etc)
- Objects occurring in agriculture (dirt, manure, leaves, etc)
- Objects added during processing (glass, plastic, hair, metal, etc).

Reducing physical hazards is relatively simple in most hospitality businesses as they are physically visible in the food. They are normally controlled by procedures such as a visual inspection of food and good kitchen procedures such as a no wood or no glass policy, and keeping the food covered.

Chemical hazards

Chemical hazards which can be found in food include:

- Naturally occurring poisonous chemicals (poison plants such as rhubarb leaves and mushrooms, poisonous animals such as puffer fish, algal blooms, mould toxins, etc)
- Chemicals added via water
- Agricultural chemicals from soils, plants and animals (pesticides, antibiotics, dips, heavy metals, etc)

Food Safety and Quality Management course for ABVM Students

- Chemicals added during food processing (additives, cleaners, etc).

Some people have an allergic reaction to certain ingredients or parts of food. Common allergens include:

- soybeans and their products
- sesame
- cereals containing gluten
- milk and milk products
- sulphites
- egg and egg products
- peanuts and their products
- crustaceans and their products
- fish and fish products

Chemical hazards in foods can be controlled by:

- purchasing from an approved supplier
- covering food and protecting it from contamination
- having an allergen awareness, and strategies to prevent cross contamination from allergens
- separate chemical storage area, away from food
- use of food safe chemicals within the food preparation areas
- Correct cleaning procedures.

Biological hazards

Hazards which live within food can occur from multiple sources. These microorganisms (commonly called “germs”) are so small they can only be seen under a microscope. Not all microorganisms are harmful to humans. Pathogens are the microorganisms which cause harm to humans, when they reach a high level in food. Some examples are:

- Bacteria e.g. salmonella, staphylococcus aureus, bacillus cereus
- Viruses e.g. hepatitis A, influenza
- Yeasts
- Moulds
- Protozoa e.g. Guardia

Most food poisoning illness is a result of these microorganisms growing in food. When food is in moist, warm conditions, they multiply to an “infective dose” which makes a person ill.

Most food poisoning occurs due to the continued growth to dangerous levels of microorganisms, particularly bacteria, in food. Food handlers should know about food poisoning bacteria and the conditions they require for growth, to ensure food borne illness is avoided.

It is important to be aware of the different types of food safety hazards which may pose a significant risk to the safety of your customers. Situations when food safety hazards are likely to pose significant risks are:

- Handling “potentially hazardous foods” which are susceptible to microorganisms contamination and growth. These are low acid, high protein foods such as meat, eggs, poultry, and seafood and dairy items.
- handling raw food and fresh foods
- handling food with your hands, rather than using equipment
- cooking food - food needs to be cooked thoroughly to kill microorganisms
- chilling food - food needs to be chilled quickly to reduce the growth of microorganisms
- defrosting foods
- reheating foods
- displaying food on buffets or self service.

Food safety hazards and health risk

For a known food safety hazard, the extent of the harmful effects of the hazard on the health of the consumer is established by risk analysis and by hazard analysis. Risk analysis is usually conducted by a national food or health regulatory agency and addresses a public health concern regarding a particular food safety hazard associated with a sector of the food industry. A risk analysis is comprised of risk assessment, risk management, and risk communication. A primary objective of risk analysis is to establish a national food safety objective for a hazard in a food. The food safety objective for a hazard is the maximum frequency and concentration of a hazard in food at the time of consumption that provides the appropriate level of protection from the hazard. The food safety objective can be considered as the maximum acceptable level for the hazard in a food. At the level of production, processing, handling, or storage, a food company performs hazard analysis as part of the development of an HACCP plan for the food. Hazard analysis is the first of the seven HACCP principles, and is performed to determine the health risk associated with a hazard present in a food when it is produced, processed, handled, or stored, according to an established sequence of steps at a particular location. Once a food safety objective for a hazard has been established by risk analysis, it must be considered during the hazard analysis step of HACCP plan development.

Quality assurance (QA)/quality management (QM) systems

Quality Assurance (QA)

A food Quality Assurance (QA) system should have a defined structure with documented procedures for activities that can affect the quality of the final product. These activities may include pre-harvest ,harvest ,processing ,storage ,transport and distribution .It should include processes for monitoring the systems performance against stated aims .These processes should include detailed recordkeeping as well as internal and, where appropriate ,external auditing .selection and application of QA system can vary according to the stage within the food chain ,the size and capacities of the company ,type of product etc. Quality Assurance (QA) systems may include:

- Good Agricultural Practices (GAP)
- Good manufacturing Practices (GMP)
- Good Hygienic Practices (GHP)
- Good Distribution Practices (GDP)
- Hazard Analysis and Critical Control Point (HACCP) systems

Quality management systems

Quality management systems are elaborate management systems that can be use by any organization to develop and achieve its quality objectives .Quality management systems includequalityplanningandimprovementactivities,inadditiontoqualitycontrolandassuranceactivities.Thesesystemsareintendedtoprovideacompanywiththecapabilitytomeetallqualityrequirements.ThebestexampleofqualitymanagementsystemistheISO9001:2000Qualitymanagementsystemrequirementsstandard.

Total quality management

During the mid-1980s, the term total quality management (TQM) was introduced in North America. The term was associated with the management approach to quality improvement used in Japan for achieving long-term success. The TQM approach embodies both management principles and quality concepts, including customer focus, empowerment of people, leadership, strategic planning, improvement, and process management. These principles and concepts evolved during the second half of the twentieth century with substantial contributions from several recognized experts in the field of quality management. Of these contributions, the most widely recognized are the 14 points for quality management proposed by W.Edwards Deming. During the 1980s and 1990s many North American businesses adopted the TQM approach and developed the framework for its use in their quality management systems, with the objective of achieving competitive advantage in the global marketplace.

ISO 9000:2000 Quality management systems

Customer focus:

The success of an organization is dependent on the extent to which the current and future needs and requirements of customers are known, understood, and met. Therefore, the organization must devote substantial effort toward meeting the requirements of its customers and should strive to exceed the expectations of its customers.

Leadership:

Senior managers must establish the direction and the objectives of the organization, and must ensure that the conditions exist for achieving these objectives. This leadership is required to ensure there is a common purpose for everyone within the organization.

Involvement of people:

The involvement of everyone within the organization is essential to achieving the objectives. Personnel must have the responsibility, authority, abilities, and skills, and the tools required for them to contribute fully to the organization.

Process approach:

An organization's activities are performed more effectively and efficiently when managed as process. Therefore, an organization should use the process approach to manage its activities.

System approach to management:

The processes carried out by an organization should be identified, understood, and managed as an interrelated set of processes that form a complete system. The effectiveness and efficiency of the entire organization can be enhanced by adopting this system approach.

Continual improvement:

One of the ongoing objectives of an organization should be the improvement of its performance on a continual basis.

Factual approach to decision making:

An organization should compile and analyze information for use in decision making.

Mutually beneficial supplier relationships:

An organization can benefit from developing relationships with its suppliers; the relationships serve to enhance the performance of both the organization and its suppliers.

ISO 9000:2000 fundamentals of quality management systems:

The ISO 9000 standard recognizes the following 12 fundamentals, which are the basis for the contents of the ISO 9001:2000 and ISO 9004:2000 quality management system standards. These fundamentals, which incorporate the eight quality management principles, are:

Rationale for quality management systems:

A quality management system can provide benefits to an organization. In general, these benefits include:

- Assist in enhancing the satisfaction of the organization's customers
- Provide a framework for continual improvement in the organization

– Provide confidence to the organization and its customers that the organization has the capability to provide products that meet the requirements of customers, regulatory agencies and the organization

Requirements for quality management systems and requirements for products:

Quality management systems approach:

In the development, implementation, maintenance, and improvement of its quality management system, an organization needs to adopt an approach in which certain specified activities should be undertaken; the standard identifies these activities.

The process approach:

The process approach is described as systematic identification and management of an organization's processes and the interactions between these processes. This approach should be used to manage an organization.

Quality policy and quality objectives:

An organization's quality policy and quality objectives can provide a focus for the direction of the organization. The quality policy should provide a framework for establishing the quality objectives, which should be consistent with the quality policy.

Role of top management within the quality management system:

An organization's top management, through the use of quality management principles and its leadership and actions can create an environment for the involvement of its people and for effective operation of the organization's quality management system

Documentation:

Documentation is an essential feature of an organization's quality management system. Various types of documents are needed in a quality management system; each should serve a particular function.

Evaluating quality management systems:

An organization's quality management system should be assessed by evaluating the various processes within the system, by auditing the system, and by top management's review of the system. An organization should also carry out self-assessment of its activities and performance.

Continual improvement:

Quality management system should include activities that are devoted to continually improving the system.

Role of statistical techniques:

An organization should use statistical techniques to understand and solve problems such as variability, for continual improvement of its effectiveness and efficiency, and in making decisions.

Quality management systems and other management system focuses:

An organization's quality management system can be integrated with other management systems (e.g., financial management system, environmental management system, employee health and safety management system). The quality objectives of the quality management system can complement the objectives of the other management systems.

Relationship between quality management systems and excellence models:

The approach of ISO 9000:2000 family of standards has many similarities to those of excellence models. However, the ISO 9000 standards provide quality management system requirements (ISO 9001) and guidance for performance improvement (ISO 9004), while the excellence models provide assessment criteria for comparing an organization's performance against the performance of other organizations.

ISO 9001:2000 quality management systems—requirements

The ISO 9001 standard is the most widely used standard among the ISO 9000 family of standards. It is issued by companies seeking to have their quality management systems recognized through an independent registration process. This standard establishes requirements for an organization's quality management system. It is designed for use by an organization that aims to enhance the satisfaction of its customers and needs to demonstrate that it has the ability to provide products that meet requirements of customers, regulatory agencies, and the organization.

ISO 9004:2000 quality management

Systems—guidelines for performance improvements

The ISO 9004 standard provides guidelines, in contrast to the ISO 9001 standard, which specifies requirements. The ISO 9004 standard is designed for use by an organization that seeks to move beyond the requirements of ISO 9001, to improve the performance of the organization, and to satisfy its customers and its other interested parties. The ISO 9004 standard covers both the effectiveness and efficiency of an organization's quality management system. By contrast, the ISO 9000 standard covers the effectiveness of an organization's quality management system.

Roles of stakeholders in food quality and food safety assurance

The change in approaches from controlling the final product to process-oriented quality assurance systems through the supply chain proves to be beneficial for all operators

Stakeholders report that investments into Good Practice and Quality Assurance Systems (compliance costs) are justifiable and in many cases result in a more than reasonable return on investment, namely:

- reduced input costs through implementation of integrated crop/pest management
- higher labour productivity through improved work-flow
- improved market access through communication of the Good Practices applied
- improved long-term supplier-customer relationships through reliable and continuous food quality

Gender issues in Safety and Quality Management

Gender is the social meaning given to being a man or a woman, characteristics used to define a man or woman that do not stem from biological differences is what we mean gender. While sex is the biological difference that man and woman has.

The food safety and quality issue is a complex and multidimensional one extending “from the field to the table” and it has economic, social, cultural, environmental and political consequences. Food safety and quality, on the one hand, is associated with the type of agricultural production (e.g. intensive, extensive, organic), the place of production, the introduction and promotion of novel foods (i.e. foods not yet used for human consumption, in particular those containing or deriving from GMOs), animal health and welfare, storage conditions, marketing, hygienic standards and regulations, consumers’ awareness and lobbying and nutritional characteristics. However, it also encompasses different socio-cultural and political relations and divisions among various social actors (men and women as individuals, groups and institutions in their multiple roles as producers, consumers, etc.) throughout the process “from the field to the table”.

For this reason a more holistic attitude towards food safety and quality is called for which should include adequate participatory and gender considerations. Although both rural women and rural men each have different and complementary roles in guaranteeing food security at the household and community levels, women often play a greater role in ensuring nutrition, food safety and quality. In much of the developing world, women produce most of the food that is consumed in their homes, and are generally responsible for processing and preparing food for their households. Women tend to spend a considerable part of the cash income that they generate from marketing activities on household food requirements.

3.1.4. Accreditation and certification systems in food quality and safety

Pre-test

What do you understand by accreditation, certification in the context of value chain?

Do you have some ideas about certification systems of import and export food products?

Outline certification scheme for fitness to conformance in produce market success?

Can you elaborate how accreditation and certification will be related to quality auditing?

What does accredited certification mean?

Where does it fit within the value chain benchmarking process?

What significance does it have on the integrity and value of the food safety audit process?

Introduction

Accreditation and certification are terms that are often used incorrectly within industry in general, and the food sector is no exception. In an industry that abounds with auditable schemes, standards, regulations, and requirements, it is little wonder that even the most

seasoned professionals become confused by the jargon that surrounds the audit processes they undertake.

Throw in terms like ‘accredited certification body’ sometimes known as ‘accredited registrar’, and ‘conformity assessment’ and the confusion increases. Other terms such as ‘third-party audit or certification’ and ‘auditor competence’ are closer to home and more widely accepted, but the difference in rigour and outcome of a third party audit from a non-accredited audit agency as compared to an accredited certification body is not always understood. Similarly ‘management system certification’ and ‘product certification’ are also misunderstood.

In recent years third party food safety audits have come under critical scrutiny from the mainstream media, particularly in the US. Food plants with reportedly excellent ratings by these independent auditors have been linked to outbreaks associated with serious illness and death, and have subsequently been closed down by regulators. In most reported cases to date, these instances were one-to-one arrangements between suppliers and independent non-accredited audit agencies, without any oversight or recognition.

Accredited certification does not deliver a guarantee of food safety nor prevent food safety incidents. It provides a proven framework of checks and balances that significantly improves the rigour of the audit process and reduces the risk of food safety failures. Food businesses should not rely solely on third party audits to provide evidence of their food safety compliance. However, accredited third-party certification audits, if used correctly, are worthwhile tools for any food business seeking to implement and maintain behaviours and practices within their facilities.

The History

Accredited certification is not new and is not unique to the food industry and in the food supply chain. The International Organisation for Standardisation (ISO) is an international collaboration of national standards setting organisations. Since 1947, ISO has developed and published commercial standards, many of which have become law and/or national standards in contributing countries. When GFSI introduced benchmarking of food safety management systems in 2001, there were numerous private standards, audit management schemes, and ISO standards that covered the food supply chain with multiple audits and varying degrees of diligence. GFSI recognised the credibility, rigour and consistency offered by the accredited certification system, and from the start applied the same principles to the GFSI benchmarking process. Schemes applying for benchmarking had to agree to operate according to the principles of ISO/IEC Guide 65, and include a standard that could only be audited by Certification Bodies accredited to ISO/IEC Guide 65. This has since been widened to include ISO/IEC 17021, supplemented by ISO/TS 22003 to ensure the approach is equivalent to that of ISO/IEC Guide 65.

Accredited certification framework

Starting from the bottom, a food business applies to a GFSI recognised scheme for certification and then selects a Certification Body (CB) to audit and certify the selected standard. CBs are sometimes referred to as 'Conformity Assessment Bodies' (CABs) or 'Accredited Certification Bodies', because they must, under the GFSI Guidance and scheme rules, be accredited to either ISO/IEC Guide 65, or ISO/IEC 17021 (with ISO/TS 22003) for the delivery of the particular GFSI recognised scheme being applied for.

Certification, according to ISO/IEC 17000:2004, is "third party attestation related to products, processes, systems or persons." What that means in food industry parlance, is the process by which CBs, based on conformity assessments (or audits), provide written assurance that an audited food business has identified all potential food safety hazards, implemented effective controls, continues to validate and verify these controls, and has a management system in place that conforms to the requirements of the scheme's standard.

The CB must also have systems in place to ensure the capability of all management, technical, and administrative personnel, and in particular the competence of auditors involved in the certification process. Auditors must be competent in food safety management as applied to the industry sector(s) they are auditing, and the requirements of the specific scheme. For the GFSI recognised schemes, Accreditation Bodies, in turn, assess the Certification Bodies against one of two ISO standards: ISO/IEC Guide 65 or ISO/IEC 17021, supplemented by ISO/TS 22003.

Accreditation activities are conducted by Accreditation Bodies (ABs), which are not-for-profit organisations, either government owned or under agreement with government, charged with ensuring that participating Certification Bodies in the country are subject to oversight by an authoritative body. ABs may not be high profile in each country, but play a key role in the accredited certification process and ensuring international consistency in conformity assessment. They include for example UKAS in UK, ANAB and ANSI in USA, RvA in the Netherlands, and JAS-ANZ in Australia and New Zealand.

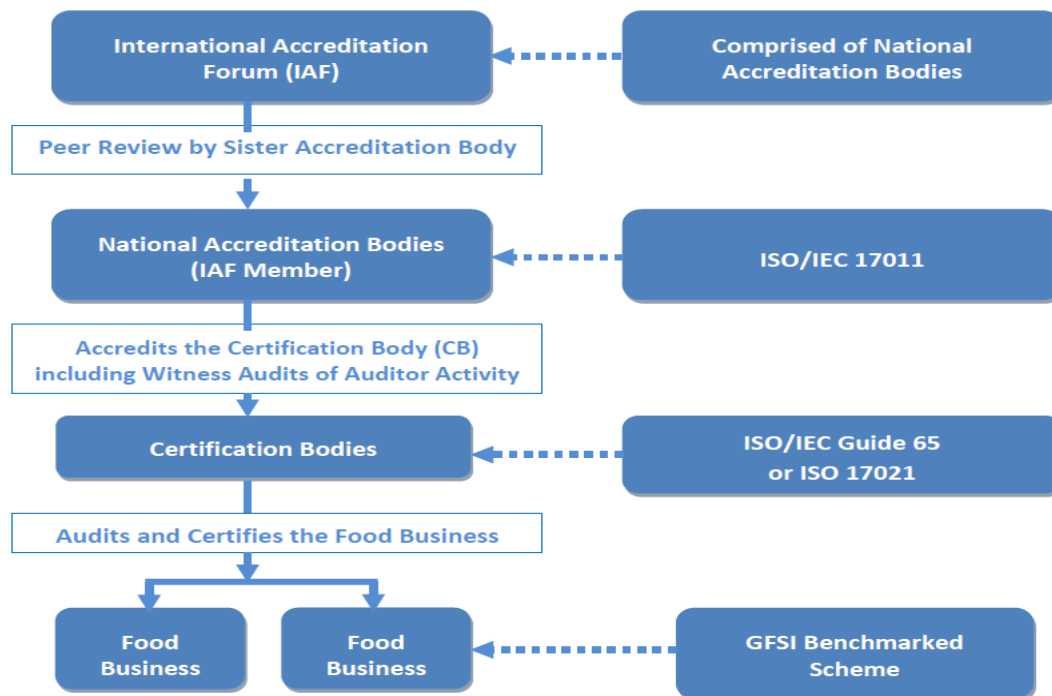


Figure 4: Accreditation and certification scheme among different stakeholders

Definitions

Accreditation

Accreditation is authoritative process by which a certification body is assessed in its skills and capacities by the accreditation body to carry out certification in compliance with the relevant guidelines or a process by which an authoritative body gives formal recognition of the competence of a certification body to provide certification services against an international standard. Accreditation reduces risk for business and its customers by assuring them that accredited bodies are competent to carry out the work they undertake.

Accreditation body

Authoritative body that evaluates and officially accredits the certification (and inspection) body

Certification

Certification is procedure by which a third party gives written assurances that a product or a process is in conformity with a corresponding standard or conformance to specified requirements. With certification, a product or process may be labelled as certified. Certification is the procedure by which official certification bodies or officially recognized certification bodies provide written or equivalent assurance those foods or food control systems conform to requirements. Certification of food may be, as appropriate, based on a range of inspection activities which may include continuous on-line inspection, auditing of quality assurance systems, and examination of finished products.

Concepts of accreditation and certification

Official and officially recognized inspection and certification systems are fundamentally important and very widely used means of food control; the following principles apply to such systems. The confidence of consumers in the quality (including safety) of their food supply depends in part on their perception as to the effectiveness of food control measures. A substantial part of the worldwide trade in food, for example in meat and meat products, depends upon the use of inspection and certification systems. However, inspection and certification requirements may significantly impede international trade in foodstuffs. Consequently it is desirable that the design and application of these systems should reflect appropriate principles.

Inspection of food may occur at any stage in the production and distribution process. For some foods, inspection oversight of harvesting, processing, storage, transport, and other handling of product may be the most appropriate means of ensuring food safety. According to the methods of preservation used, it may be necessary to maintain inspection oversight on a continuous basis up to the time of retail sale. Inspection systems may be focused on the foodstuffs themselves, on the procedures and facilities employed in the production and distribution chain, on the substance and materials which can be incorporated into or contaminate foodstuffs.

Inspection should be carried out at the most appropriate stages (e.g. control of refrigeration at every stage of the cold chain). For some requirements, e.g. those pertaining to product description, it may be possible to limit inspection to the distribution process and prior to final sale. In both design and use, food inspection and certification systems should be governed by a number of principles which will ensure an optimal outcome consistent with consumer protection and facilitation of trade.

The International Accreditation Forum

Even ABs are not immune from further scrutiny. Sitting over the top of the accredited certification framework is the International Accreditation Forum (IAF). The IAF is the world association of conformity assessment Accreditation Bodies. Its primary function is to develop a single worldwide program of conformity assessment which reduces risk for business and its customers by assuring them that accredited certificates may be relied upon. The mechanism by which IAF implements its objective is the IAF Multilateral Recognition Arrangement (MLA).

To put it simply, the IAF helps to ensure that all ABs are following the rules of accreditation and applying the standards to affirm consistent delivery of the certification schemes. This is achieved by peer evaluation to ISO/IEC 17011: 2004 – General Requirements for

Accreditation Bodies Accrediting Conformity Assessment Bodies. To assist in this process and ensure it applies to the food industry.

The need of two Accreditation Standards

GFSI recognises two ISO standards for accreditation purposes. One is ISO/IEC Guide 65, and the other ISO/IEC 17021, supplemented by ISO/TS 22003. Both of these standards contain similar requirements for how a certification body must operate. They both address issues of preventing conflict of interest, managing customer information, properly qualifying personnel, auditor calibration, and many other aspects involved with the certification process.

Both ISO/IEC Guide 65 and ISO/IEC 17021/ISO22003, require the accreditation body to observe auditors in the field as well as conduct a detailed office review of policies, procedures, and document control. It is only after the successful assessment of auditors and the certification body operations that accreditation can be granted.

But there is a distinct difference between the two. ISO/IEC 17021 covers conformity assessment of ‘management systems’, and is applied in combination with ISO/TS 22003, which covers audit and certification of food safety management systems. However ISO 17021/ISO 22003 “does not attest to the safety or fitness of the products of an organization within the food chain” (ISO/TS 22003:2007). It is not product specific. ISO/IEC Guide 65, on the other hand, is concerned with verifying that particular products or services meet specified requirements. The type and scope of GFSI benchmarked scheme selected, determines the accreditation standard which applies. The majority of GFSI recognised schemes fall under ISO/IEC Guide 65 accreditation requirements, whereas only two currently recognised schemes are management system schemes accredited to ISO 17021/ISO22003.

Principles for food import and export inspection and certification

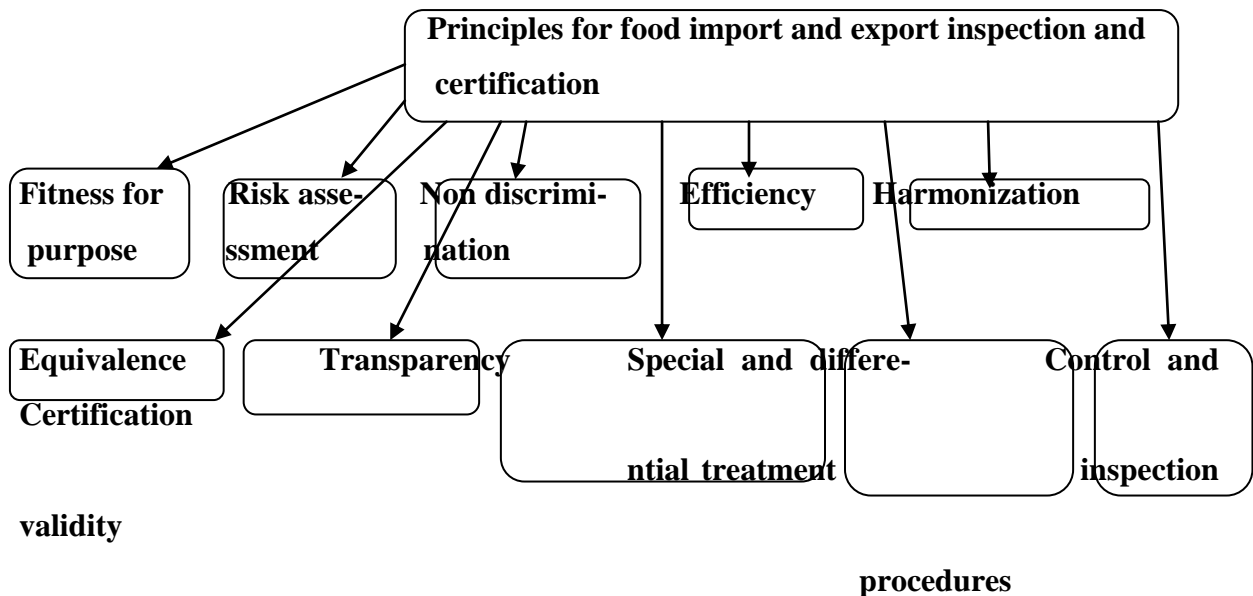


Figure 5: Flow sheet for principle of import and export inspection and certification

Principles

Food inspection and certification systems should be used wherever appropriate to ensure those foods, and their production systems, meet requirements in order to protect consumers against food-borne hazards and deceptive marketing practices and to facilitate trade on the basis of accurate product description.

Inspection is the examination of food or systems for control of food, raw materials, processing, and distribution including in-process and finished product testing, in order to verify that they conform to requirements.

Official inspection systems and official certification systems are systems administered by a government agency having jurisdiction empowered to perform a regulatory or enforcement function or both.

Officially recognized inspection systems and officially recognized certification systems are systems which have been formally approved or recognized by a government agency having jurisdiction.

Requirements are the criteria set down by the competent authorities relating to trade in foodstuffs covering the protection of public health, the protection of consumers and conditions of fair trading.

Risk assessment is the evaluation of the likelihood and severity of adverse effects on public health arising, for example, from the presence in foodstuffs of additives, contaminants, residues, toxins or disease-causing organisms.

Fitness for purpose

Inspection and certification systems should be fully effective in achieving their designated objectives having regard to the determination of the acceptable level of protection which is required.

Risk assessment

Inspection systems to ensure food safety should be designed and operated on the basis of objective risk assessment appropriate to the circumstances. Preferably the risk assessment methodology employed should be consistent with internationally accepted approaches. Risk assessment should be based on current available scientific evidence. Inspection systems should be applied to particular commodities and Processing methods in proportion to the assessed risks. In undertaking a risk assessment or in applying the principles of equivalence, importing countries should give due consideration to statements by exporting countries on a national or area basis of freedom from food- related disease.

Non-discrimination

Countries should ensure that they avoid arbitrary or unjustifiable distinctions in the level of risk deemed to be appropriate in different circumstances so as to avoid discrimination or a disguised restriction on trade.

Efficiency

Inspection and certification systems should have adequate means to perform their task. In the choice of inspection and certification systems, there should be regard to costs to consumers and to the costs in money and time to the affected food industry and government consulting with interested bodies as appropriate. Such systems should be no more restrictive of trade than is necessary in order to achieve the required level of protection.

Harmonization

Member countries should use Codex standards, recommendations and guidelines (or those of other international organizations whose membership is open to all countries) whenever appropriate as elements of their inspection and certification systems. Countries should participate actively in the work of the Codex Alimentarius Commission and other relevant international bodies to promote and facilitate the development, adoption and review of Codex norms.

Equivalence

Countries should recognize that different inspection/certification systems may be capable of meeting the same objective, and are therefore equivalent. The obligation to demonstrate equivalence rests with the exporting country.

Transparency

While respecting legitimate concerns to preserve confidentiality, the principles and operations of food inspection and certification systems should be open to scrutiny by consumers and their representative organizations, and other interested parties.

Importing countries should provide information on existing requirements and proposed changes to requirements should be published and, except in the case of serious and immediate danger, an adequate time period permitted for comment. The views of exporting countries, and particularly those received from developing countries, should be taken into account in taking a final decision. A reasonable period should be allowed before a new requirement takes effect in order to permit exporting countries, and in particular developing countries, to make necessary changes to methods of production and control measures. Importing countries should make available to the exporting countries, upon request, timely advice as to the basis of the decision they have taken regarding the compliance of foods with their relevant requirements. Upon request by the competent authorities of the importing countries, the exporting countries should provide access to view and assess the actual working of their relevant inspection and certification systems.

Special and differential treatment

In the design and application of food inspection and certification systems, importing countries should take into account of the capabilities of developing countries to provide the necessary safeguards.

Control and inspection procedures

Importing countries should complete without undue delay any procedures necessary to assess compliance with requirements. Information requirements and any fees imposed by importing countries should be limited to what is reasonable and necessary.

Certification validity

Countries that certify exports of food and those importing countries which rely on export certificates should take measures to assure the validity of certification. Validation measures by exporting countries may include achieving confidence that official or officially recognized inspections systems have verified that the product or process referred to in the certificate conforms to requirements. Measures by importing countries may include point of entry inspection systems, audit of exporting inspection systems, and ensuring that certificates themselves are authentic and accurate.

The Food Certification Process

Food Safety System Certification 22000 (FSSC 22000) is a robust, ISO-based, internationally accepted certification scheme for auditing and certification of food safety in the whole supply chain. FSSC 22000 uses the existing standards ISO 22000, ISO 22003 and technical specifications for sector PRPs, which were developed through a wide and open consultation with a large number of related organizations. ISO 22000 certified manufacturers can obtain full GFSI accepted FSSC 22000 certification by meeting the requirements of technical specifications for sector PRPs and the additional scheme requirements.

The food business generally does not need to have any contact with IAF or the Accreditation Bodies, but does need to know that there is a robust accredited certification framework behind the scheme, recognised by GFSI, that helps to protect the interests of the food business and the scheme owner. For the most part, the only points of contact for the food business are the scheme owner and the Certification Body (CB). The points to consider are:

- A. **Select the Right Scheme:** All GFSI recognised food safety schemes include a standard – which is the auditable set of requirements that is applied to the food business. The first step in the certification process is selecting the scheme with a standard that best fits with the products and processes of the business, and helps meet customer requirements. This may be requested by a retailer, food service business, or manufacturing customer, or may be to confirm the business's internal food safety protocols and controls.
- B. **Select a Certification Body:** Each of the scheme owners maintains a list of accredited CBs that are licensed to certify to their standard. The Accreditation Bodies also maintain a list of accredited CBs. When selecting a certification body, it is important for food businesses to consider a number of aspects including availability of qualified auditors, regional presence, seasonality, scheduling, audit duration, and overall costs.
- C. **Apply for Certification:** The certification process is essentially the same, irrespective of the scheme or CB selected. The process officially starts with completion of CBs

application documents which allow the certification body to fully understand the scope of a facility's operations and the products to be covered by certification. It also becomes the basis of the contract between the CB and supplier, and is critical for calculating audit duration and proper assignment of an auditor with expertise in the appropriate food sector category(s).

- D. **Scheduling:** The CB contacts the facility to schedule a mutually acceptable date for the certification audit. Most GFSI benchmarked schemes specify time limits within which certification and re-certification audits must occur to maintain certification. However, within these limits, the audit must be scheduled on a date that suits both the facility and the auditor, and within a peak production period.
- E. **Certification Audits:** All food safety standards require an on-site third-party certification audit. Some schemes also require a document review prior to the certification audit. The role of the audit is to determine how well a facility identifies and implements food safety controls and complies with the requirements of the applicable standard.

Certification audits are always non-consultative, which means that the auditor is not permitted to instruct or advise the facility on how to meet requirements of the schemes. The auditor reviews HACCP plans, procedures, policies, physical conditions, and records and observes the implementation of food safety plans within the facility. Any non-conformances observed during the audit are documented in the audit report. At the conclusion of the audit, the facility is informed of all observed non-conformances.

- F. **Closure of Non-Conformances:** To achieve certification the food business is required to take actions necessary to sufficiently correct any non-conformances noted during the audit, and to prevent their recurrence. Each certification schemes has unique time-line requirements for non-conformance closure. The CB reviews the evidence submitted and accepts the corrective actions if they are sufficient to resolve the noted non-conformance. If the submitted corrective actions do not sufficiently resolve the non-conformance, the CB rejects them, and the food business is required to re-submit within a specific timeframe. In some cases or as prescribed by the scheme, the CB can undertake a further site visit to verify closure of non-conformances. A certificate can only be issued when non-conformances have been appropriately addressed.
- G. **Certification Decision and Issuance:** The auditor does not make the decision on certification. An individual within the CB, independent of the original site audit, makes the final determination on certifications based on a review of the audit report and evidence of close-out of non-conformances. Only after a successful certification decision can a certificate be issued. The entire process from the completion of the audit to the issuance of the certificate is typically about 45 days.
- H. **Annual Recertification:** Each year a certified food business is required to undertake a recertification audit to maintain certification. The rules around the timing of this may vary based on a scheme's rules and procedures, but typically the recertification audit will take place very close to the anniversary date of their initial certification audit. Just as in

initial certification audits, the facility must address non-conformances prior to being issued a certificate.

- I. **Appeals:** A third party audit is a process of obtaining objective evidence of conformance or non-conformance to a specified standard. The auditor obtains objective evidence by observation, interview, and review of documented procedures and records. However there are occasions where food businesses do not accept the outcomes of the audit, feel the auditor was not objective, was superficial, or did not adequately understand the process or technology.

All CBs auditing GFSI benchmarked schemes are required to have a complaints and appeals process in place to deal with such occasions. Where a food business justifiably feels that the CB or its representative (i.e. the auditor) have not fulfilled their side of the agreement, the food business must first report it to the CB and work through their complaints and appeals process.

If it cannot be satisfactorily resolved at that level, it is then escalated to the scheme owner’s complaints and appeals process. There are “checks and balances” procedures defined in the accreditation and certification framework supported by GFSI and the recognised schemes that addresses situations where there is misconduct on behalf of an auditor or CB.

Guidelines for the design, operation, assessment and accreditation of food import and export inspection and certification systems

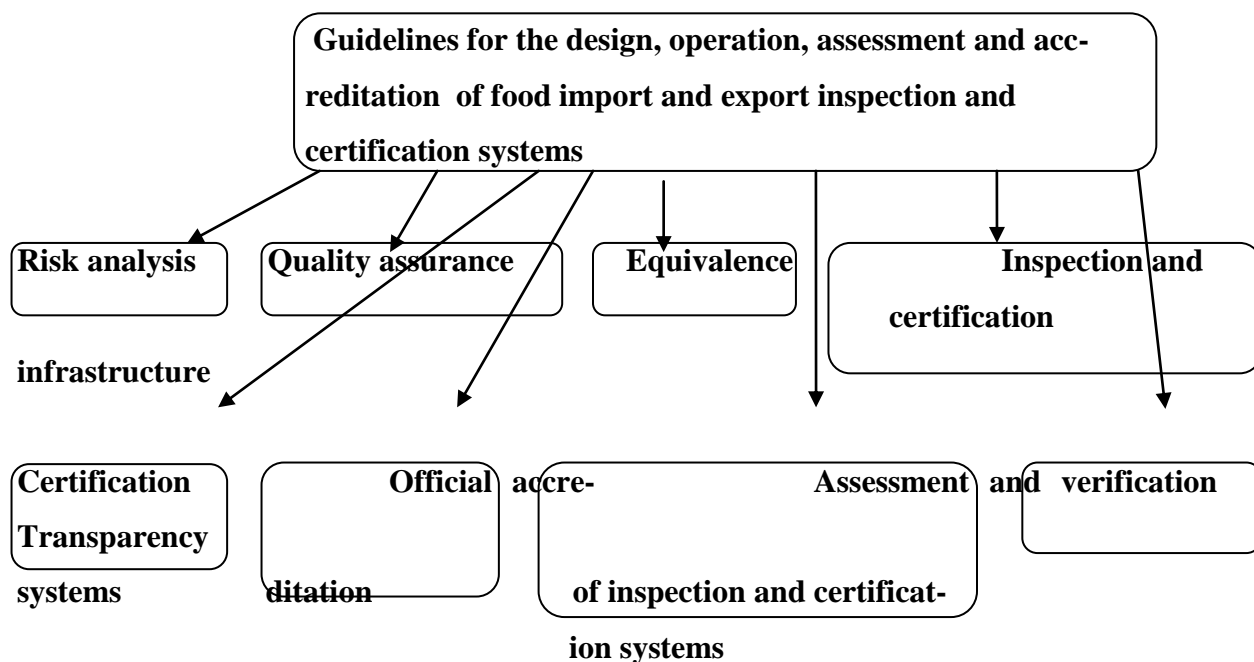


Figure: flow sheet for overview of guidelines for food import and export inspection and certification system

Risk analysis

Consistent and transparent application of risk analysis will facilitate international trade by increasing confidence in the food safety and in the inspection systems of trading partners.

Quality assurance

The voluntary utilization of quality assurance by food businesses should also be encouraged in order to achieve greater confidence in the quality of products obtained. If safety and/or quality assurance tools are used by food businesses, the official inspection and certification systems should take them into account in particular through the adaptation of their control methodologies.

Equivalence

The recognition of equivalence of inspection and certification should be facilitated where it can be objectively demonstrated that there is an appropriate system for inspection and certification of food by the exporting country in accordance with these guidelines. The application of equivalence principles may be in the form of agreements or letters of understanding established between governments either for inspection and/or certification of production areas, sectors or parts of sectors. Equivalence may also be established through the administration of a comprehensive agreement which would cover inspection and certification of all food commodity forms traded between two or more countries.

Inspection and certification system infrastructure

Countries should identify the main objectives to be addressed through import and export inspection and certification systems. Countries should have in place the legislative framework, controls, procedures, facilities, equipment, laboratories, transportation, communications, personnel and training to support the objectives of the inspection and certification programme. Where different authorities in the same country have jurisdiction over different parts of the food chain, conflicting requirements must be avoided to prevent legal and commercial problems and obstacles to trade.

Certification systems

Demand for certification should be justified by risk to health or risk of fraud or deception. Alternatives to certification should be considered wherever possible, in particular where the inspection system and requirements of an exporting country are assessed as being equivalent to those of the importing country. Bilateral or multilateral agreements, such as mutual recognition agreements or pre-certification agreements, may provide for dispensing with certification and/or the issuance of certificates which were previously required in certain cases. Certification should provide assurance of the conformity of a product or batch of products, or that a food inspection system conforms to specified requirements, and will be based, as appropriate, on: regular checks by the inspection service; analytical results; evaluation of quality assurance procedures linked to compliance with specified requirements; any inspections specifically required for the issuance of a certificate.

Competent authorities should take all necessary steps to ensure the integrity, impartiality and independence of official certification systems and officially-recognized certification systems. They should ensure that personnel empowered to validate certificates are appropriately trained and fully aware, if necessary from notes of guidance, of the significance of the contents of each certificate which they complete. Certification procedures should include procedures to ensure the authenticity and validity of certificates at all the relevant stages and to prevent fraudulent certification. In particular, personnel:

- should not certify matters without their personal knowledge or which cannot be ascertained by them;
- should not sign blank or incomplete certificates, or certificates for products which have not been produced under appropriate control programmes. Where a certificate is signed on the basis of another supporting document, the person signing the certificate should be in possession of that document;
- should have no direct commercial interest in the products being certified.

Official accreditation

Countries may officially accredit inspection or certification bodies to provide services on behalf of official agencies. To be officially accredited, an inspection or certification body must be assessed against objective criteria and must comply at least with the standards set out in these guidelines, particularly in relation to the competence, independence and impartiality of personnel. The performance of officially accredited inspection or certification bodies should be regularly assessed by the competent authority. Procedures should be initiated to correct deficiencies and, as appropriate, enable withdrawal of official accreditation.

Assessment and verification of inspection and certification systems

A national system should be subject to audit separate from routine inspection. Inspection and certification services should be encouraged to carry out self-evaluation or have their effectiveness evaluated by third parties. Self-assessment or third-party audits should be carried out periodically at various levels of the inspection and certification system, using internationally-recognized assessment and verification procedures. The inspection services of a country may undertake self-assessment for such purposes as assuring the adequacy of consumer protection and other matters of national interest, improving internal efficiency or facilitating exports. A prospective importing country may undertake a review with the agreement of the exporting country of the inspection and certification systems of an exporting country as part of its risk analysis process, with a view to determining requirements for imports from that country. Periodic assessment reviews may be appropriate following the commencement of trade.

For the purpose of assisting an exporting country to demonstrate that its inspection or certification systems are equivalent, the importing country should make readily available adequate information on its system and its performance. Exporting countries should be able to demonstrate adequate resources, functional capabilities and legislative support in addition to effective administration, independence in the exercise of their official function and, where relevant, performance history.

Transparency

Consistent with the principles on transparency contained in the Principles for Food Import and Export Inspection and Certification, and in order to promote consumer confidence in the safety and quality of their food, governments should ensure that the operations of their inspection and certification systems are as transparent as possible, while respecting any legitimate constraints of professional and commercial confidentiality and avoiding the creation of new barriers to trade by giving a misleading impression of the quality or safety of imported products in comparison with domestic products.

3.1.5. Quality auditing and its relation to accreditation and certification

Pre-test

What is quality audit?

What is an auditor?

Can you elaborate major type's audit?

What is the role of quality audits in the food company?

Do you think that auditing is related to certification for meeting quality?

Introduction

The ISO 9000 and ISO 14000 series of International Standards emphasize the importance of audits as a management tool for monitoring and verifying the effective implementation of an organization's quality and/or environmental policy. Audits are also an essential part of conformity assessment activities such as external certification/registration and of supply chain evaluation and surveillance.

This International Standard provides guidance on the management of audit programmes, the conduct of internal or external audits of quality and/or environmental management systems, as well as on the competence and evaluation of auditors. It is intended to apply to a broad range of potential users, including auditors, organizations implementing quality and/or environmental management systems, organizations needing to conduct audits of quality and/or environmental management systems for contractual reasons, and organizations involved in auditor certification or training, in certification/registration of management systems, in accreditation or in standardization in the area of conformity assessment.

The guidance in this International Standard is intended to be flexible. As indicated at various points in the text, the use of these guidelines can differ according to the size, nature and complexity of the organizations to be audited, as well as the objectives and scopes of the audits to be conducted. Throughout this International Standard, supplementary guidance or

examples on specific topics are provided in the form of practical help in boxed text. In some instances, this is intended to support the use of this International Standard in small organizations.

Clause 4 describes the principles of auditing. These principles help the user to appreciate the essential nature of auditing and they are a necessary prelude to clauses 5, 6 and 7.

Clause 5 provides guidance on managing audit programmes and covers such issues as assigning responsibility for managing audit programmes, establishing the audit programme objectives, coordinating auditing activities and providing sufficient audit team resources.

Clause 6 provides guidance on conducting audits of quality and/or environmental management systems, including the selection of audit teams.

Clause 7 provides guidance on the competence needed by an auditor and describes a process for evaluating auditors.

Where quality and environmental management systems are implemented together, it is at the discretion of the user of this International Standard as to whether the quality management system and environmental management system audits are conducted separately or together. Although this International Standard is applicable to the auditing of quality and/or environmental management systems, the user can consider adapting or extending the guidance provided herein to apply to other types of audits, including other management system audits. This International Standard provides only guidance; however, users can apply this to develop their own audit related requirements.

In addition, any other individual or organization with an interest in monitoring conformance to requirements, such as product specifications or laws and regulations, may find the guidance in this International Standard useful.

What is an audit?

Audit has been recognised as the mechanism to ensure effective food control systems have been implemented and maintained. A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives or Evaluation of past history, current practices, to give a future projection of performance. Inspection is a review of current practices in relation agricultural products value chain. The role of audit is therefore of increasing importance, and the relevant skill sets required by food ‘inspectors’ need to be defined and agreed at national and international level. Auditing food control systems using standard methods is now recognised as a challenge for the new millennium, for both industry and government, in the expanding and increasingly complex world of food protection.

Quality audits are programs designed to verify or examine a product or manufacturing process over time. It is a tool for continuous improvement and compliance. These can be classified as manufacturing quality audits, sanitation/GMPs audits, HACCP audits, product quality audits, and other special types of audits. A quality audit is a fundamental part of a quality assurance program. It allows for quality verification of a product during manufacture,

in the warehouse, in the distribution system, and in the market to assess performance over time or for comparison to competitor brands.

Each person with responsibility for a portion of the program should conduct regular assessments or reviews of the effectiveness of the quality program and its operation. Such assessments are a normal part of good process management. In addition, there should be a systematic review of the quality program by an authority that is not directly responsible for the process or its operations; such a review is a quality audit. A quality audit is a planned, systematic examination of a manufacturing program and its implementation to determine its adequacy and the degree of conformance to it. It concentrates on quality-related aspects of production.

A quality audit consists in examining a representative portion of the manufacturing program and drawing an inference about the total system based on this sample. There are two types of quality audits: internal audits and third-party audits. An internal quality audit is a review conducted by employees of the organization. A third-party audit is conducted by an outside organization.

In its role within the company, the activities of the quality assurance department include the responsibility to build these types of programs, to ensure that proper controls exist not only in communication, but also in the transfer of responsibility between departments and, most importantly, between individuals, both at the operational and at the managerial level. A quality assurance program in this context becomes a key element for a responsible and quality-oriented operation; by reporting errors in the manufacturing system so that these can be corrected and by identifying and suggesting process modifications, the quality assurance department contributes to a higher operation efficiency and thus higher productivity.

Differences between ISO and Food safety audit

The intention of the ISO 9000 series is a management philosophy, structured around twenty elements to enable a systematic process for manufacturing specific products. This standard has been revised, with the release of ISO 9000- 2000, with emphasis on continuous improvement and meeting customer needs.

With an increasing number of food industry and safety issues in food supply chain, executives now recognising that a soundly developed and implemented HACCP program, that includes the relevant support/ pre-requisite elements, represents an external “insurance policy” for commercial survival. This “insurance policy” also forms part of the food company’s demonstration of due diligence, necessary to protect the health and well being of their consumers, as well as their shareholders. This demonstration of due diligence in the food safety area is increasingly preoccupying corporate minds, with three key components required to come together:

1. Documented HACCP program = reasonable precautions to be taken,
2. Implementation of the HACCP program, and record keeping = due diligence is being exercised, and
3. The external audit process = recognition of adequacy/effectiveness of the food safety program.

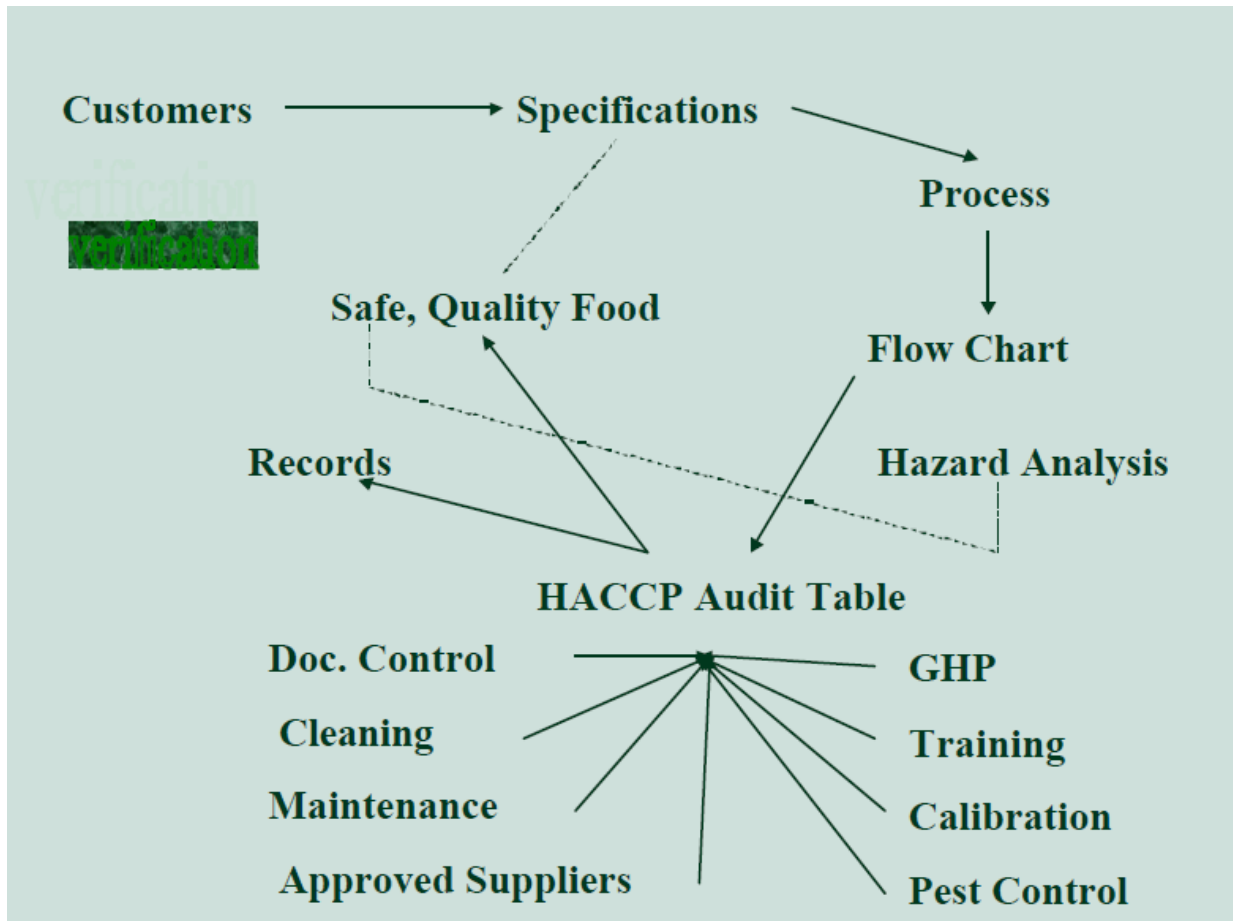


Figure 6: Model for HACCP based quality audit system

An immediate difference between ISO and food safety auditing becomes apparent. ISO undertake a sampling of elements over a three-year period, after the initial certification audit, to determine compliance with the twenty elements of the standard. This approach cannot be used for food safety auditing; a sampling of several elements from a food safety program every six months (eg pest control, calibration, and review of monitoring of one CCP) will not provide any confidence that the business is fully controlling its identified food safety hazards.

A food safety audit must examine all aspects of the HACCP plan (product description and intended use, flow diagrams, hazard analyses, HACCP audit tables, and verification activities) at each audit. Key support programs such as GHP (Good Hygiene Practices), cleaning/sanitation, and pest control as a minimum, need to be included in each audit. As noted above, this differs significantly from the ISO auditing approach, in terms of “core provisions. Food safety auditing has core elements, ISO does not necessarily have the same

focus – all twenty elements (where applicable) need to be covered over the three years, noting that there is a particular focus on Management Review and the Internal Audit process.

This signals that food safety auditing is a combination of systems auditing and compliance auditing – not only have all the elements of the food safety program been documented and implemented (systems perspective), but their content is appropriate and effective in all aspects (food safety compliance perspective). For many, this is a radical change and a new challenge, because food safety auditing also involves the people element – staff attitudes, staff potential to cross contaminate, staff abilities to recognise new food safety issues, and the effectiveness of staff training. It has always been stated that ISO auditing focuses on the system, not on the individual. Food safety auditing, however, focuses on the individuals as well as the system; the outcome of food safety auditing is external recognition that the practices in place at a food business, as well as the system, will prevent or eliminate identified food safety hazards, or reduce them to acceptable levels.

To further expand the differences between ISO auditing and food safety auditing, we need to look at the approach employed. Food safety auditing requires a thorough evaluation of the product and the process, on the day, by “walking the talk” – following the flow chart, either forward or backwards (depending upon the risk ranking of the process). During this process, it is critical for the food safety auditor to concentrate on the “3 H’s” and the “5 P’s” at each step in the flow chart.

3 Hazards:

- Biological
- Chemical
- Physical

5 “P’s”:

- Product (including ingredients and packaging introduced at that step)
- Premises (the potential hazards from the immediate environment)
- Plant (the potential hazards introduced by the equipment and services)
- Procedure (the potential hazards introduced by the methods)

People (the potential hazards introduced by the staff themselves)

This is unlike the ISO auditor, who does not have this “now time” responsibility to achieve a community outcome of safe food. This “walk the talk” is essential to confirm, or otherwise, the business identification of the potential hazards, and their assessment of significance to those hazards. This is a pro-active process of hazard confirmation by the food safety auditor.

These differences are further delineated by the focus that the food safety auditor needs to have on the business (auditee) achieving a safe food outcome; to be convinced that a food

company's program is appropriate for the type of food being prepared and the effectiveness in controlling food safety hazards. Unlike an ISO audit process, which seeks evidence of compliance with documented procedures, the food safety auditor needs to ask whether the elements of the food safety program are indeed appropriate for the risk classification of the food.

In determining whether the food safety program is effective, the food safety auditor needs to examine five perspectives, in order to have confidence in the business food safety program:

- evidence that all reasonable potential hazards have been identified and assessed;
- current CCP's are effectively controlling significant hazards;
- critical limits associated with CCP's have been validated, and therefore will achieve the necessary control of food safety hazards;
- support/pre-requisite programs, together with the documented HACCP plans, are being reviewed and maintained appropriately; and
- evidence that the whole program is and has been delivering safe food – end product microbiological results shelf life validation, reduction in complaints etc.

In addition to the aforementioned factors above contributing to ISO and safety auditors, the personal attributes of the food safety auditors themselves – the knowledge, skills and experience required to make judgement on the appropriateness and effectiveness of a food safety program.

Guidelines for quality management systems auditing

Scope

This International Standard provides guidance on the principles of auditing, managing audit programmes, conducting quality management system audits and environmental management system audits, as well as guidance on the competence of quality and environmental management system auditors.

It is applicable to all organizations needing to conduct internal or external audits of quality and/or environmental management systems or to manage an audit programme.

The application of this International Standard to other types of audit is possible in principle, provided that special consideration is paid to identifying the competence needed by the audit team members in such cases.

Normative references

For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative documents indicated below. For undated references, the latest edition of the normative document referred to apply. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary*

ISO 14050:2002, *Environmental management — Vocabulary*

Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 9000 and ISO 14050 apply, unless superseded by the terms and definitions given below.

A term in a definition or note which is defined elsewhere in this clause is indicated by boldface followed by its entry number in parentheses. Such a boldface term may be replaced in the definition by its complete definition.

Audit

Systematic, independent and documented process for obtaining **audit evidence** and evaluating it objectively to determine the extent to which the **audit criteria** are fulfilled

- Internal audits, sometimes called first-party audits, are conducted by, or on behalf of, the organization itself for management review and other internal purposes, and may form the basis for an organization's self-declaration of conformity. In many cases, particularly in smaller organizations, independence can be demonstrated by the freedom from responsibility for the activity being audited.
- External audits include those generally termed second- and third-party audits. Second-party audits are conducted by parties having an interest in the organization, such as customers, or by other persons on their behalf. Third-party audits are conducted by external, independent auditing organizations, such as those providing registration or certification of conformity to the requirements of ISO 9001 or ISO 14001.
- When a quality management system and an environmental management system are audited together, this is termed a combined audit.
- When two or more auditing organizations cooperate to audit a single **auditee**, this is termed a joint audit.

Audit criteria: set of policies, procedures or requirements

- Audit criteria are used as a reference against which **audit evidence** (3.3) is compared.

Audit evidence: records, statements of fact or other information, which are relevant to the **audit criteria** and verifiable.

- Audit evidence may be qualitative or quantitative.

Audit findings: results of the evaluation of the collected **audit evidence** against **audit criteria**

- Audit findings can indicate either conformity or nonconformity with audit criteria or opportunities for improvement.

Audit conclusion: outcome of an audit, provided by the audit team after consideration of the audit objectives and all audit findings.

Audit client: organization or person requesting an **audit**

- The audit client may be the auditee or any other organization which has the regulatory or contractual right to request an audit.

Auditee: organization being audited

Auditor: person with the competence to conduct an audit

Audit team: one or more auditors conducting an audit, supported if needed by technical experts

- One auditor of the audit team is appointed as the audit team leader.
- The audit team may include auditors-in-training.

Technical expert:

- Specific knowledge or expertise is that which relates to the organization, the process or activity to be audited, or language or culture.
- A technical expert does not act as an auditor in the audit team.

Audit programme: set of one or more audits (3.1) planned for a specific time frame and directed towards a specific purpose

- An audit programme includes all activities necessary for planning, organizing and conducting the audits.

audit plan: description of the activities and arrangements for an **audit**

audit scope: extent and boundaries of an **audit**

- The audit scope generally includes a description of the physical locations, organizational units, activities and processes, as well as the time period covered.

Competence: demonstrated personal attributes and demonstrated ability to apply knowledge and skills

Principles of auditing

Auditing is characterized by reliance on a number of principles. These make the audit an effective and reliable tool support of management policies and controls, providing information on which an organization can act to improve its performance. Adherence to these principles is a prerequisite for providing audit conclusions that are relevant and sufficient and for enabling auditors working independently from one another to reach similar conclusions in similar circumstances.

The following principles relate to auditors.

- a. Ethical conduct: *the foundation of professionalism*
- b. Fair presentation: *the obligation to report truthfully and accurately*
- c. Due professional care: *the application of diligence and judgement in auditing*

- d. **Independence:** *the basis for the impartiality of the audit and objectivity of the audit conclusions*
- e. **Evidence-based approach:** *the rational method for reaching reliable and reproducible audit conclusions in a systematic audit process*

Managing an audit programme

A. General

An audit programme may include one or more audits, depending upon the size, nature and complexity of the organization to be audited. These audits may have a variety of objectives and may also include joint or combined audits.

An audit programme also includes all activities necessary for planning and organizing the types and number of audits, and for providing resources to conduct them effectively and efficiently within the specified time frames. An organization may establish more than one audit programme.

Those assigned the responsibility for managing the audit programme should:

- a. establish, implement, monitor, review and improve the audit programme, and
- b. Identify the necessary resources and ensure they are provided.

B. Audit programme objectives and extent

i. Objectives of an audit programme

Objectives should be established for an audit programme, to direct the planning and conduct of audits.

These objectives can be based on consideration of

- a. Management priorities,
- b. Commercial intentions,
- c. Management system requirements,
- d. Statutory, regulatory and contractual requirements,
- e. Need for supplier evaluation,
- f. Customer requirements,
- g. Needs of other interested parties, and
- h. Risks to the organization.

ii. Extent of an audit programme

The extent of an audit programme can vary and will be influenced by the size, nature and complexity of the organization to be audited, as well as by the following:

- a. The scope, objective and duration of each audit to be conducted;
- b. The frequency of audits to be conducted;
- c. The number, importance, complexity, similarity and locations of the activities to be audited;
- d. Standards, statutory, regulatory and contractual requirements and other audit criteria;
- e. The need for accreditation or registration/certification;
- f. Conclusions of previous audits or results of a previous audit programme review;
- g. Any language, cultural and social issues;

- h. The concerns of interested parties;
- i. Significant changes to an organization or its operations.

C. Audit programme responsibilities, resources and procedures

i. Audit programme responsibilities

The responsibility for managing an audit programme should be assigned to one or more individuals with a general understanding of audit principles, of the competence of auditors and the application of audit techniques. They should have management skills as well as technical and business understanding relevant to the activities to be audited.

Those assigned the responsibility for managing the audit programme should

- a. establish the objectives and extent of the audit programme,
- b. establish the responsibilities and procedures, and ensure resources are provided,
- c. ensure the implementation of the audit programme,
- d. ensure that appropriate audit programme records are maintained, and
- e. monitor, review and improve the audit programme.

ii. Audit programme procedures

Audit programme procedures should address the following:

- a. planning and scheduling audits;
- b. assuring the competence of auditors and audit team leaders;
- c. selecting appropriate audit teams and assigning their roles and responsibilities;
- d. conducting audits;
- e. conducting audit follow-up, if applicable;
- f. maintaining audit programme records;
- g. monitoring the performance and effectiveness of the audit programme;
- h. reporting to top management on the overall achievements of the audit programme.

For smaller organizations, the activities above can be addressed in a single procedure.

D. Audit programme implementation

The implementation of an audit programme should address the following:

- a. communicating the audit programme to relevant parties;
- b. coordinating and scheduling audits and other activities relevant to the audit programme;
- c. establishing and maintaining a process for the evaluation of the auditors and their continual professional development
- d. ensuring the selection of audit teams;
- e. providing necessary resources to the audit teams;
- f. ensuring the conduct of audits according to the audit programme;
- g. ensuring the control of records of the audit activities;
- h. ensuring review and approval of audit reports, and ensuring their distribution to the audit client and other specified parties;
- i. ensuring audit follow-up, if applicable.

E. Audit programme records

Records should be maintained to demonstrate the implementation of the audit programme and should include the following:

- a) records related to individual audits, such as
 - audit plans,
 - audit reports,
 - nonconformity reports
 - corrective and preventive action reports, and
 - audit follow-up reports, if applicable;
- b) results of audit programme review;
- c) records related to audit personnel covering subjects such as
 - auditor competence and performance evaluation,
 - audit team selection, and
 - Maintenance and improvement of competence.

F. Audit programme monitoring and reviewing

The implementation of the audit programme should be monitored and, at appropriate intervals, reviewed to assess whether its objectives have been met and to identify opportunities for improvement. The results should be reported to top management.

Audit activities

A. General

This clause contains guidance on planning and conducting audit activities as part of an audit programme. The extent to which the provisions of this clause are applicable depends on the scope and complexity of the specific audit and the intended use of the audit conclusions.

- Initiating the audit
- Appointing the audit team leader
- Defining audit objectives, scope and criteria
- Determining the feasibility of the audit
- Selecting the audit team
- Establishing initial contact with the auditee.
- Conducting document review
- Preparing for the on-site audit activities
- Preparing the audit plan
- Assigning work to the audit team
- Preparing work documents
- Conducting on-site audit activities
- Conducting the opening meeting
- Communication during the audit
- Roles and responsibilities of guides and observers
- Collecting and verifying information
- Preparing audit conclusions

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- Conducting the closing meeting
- Preparing, approving and distributing the audit report
- Preparing the audit report
 - Completing the audit
 - Conducting audit follow-up

B. Competence and evaluation of auditors

i General

Confidence and reliance in the audit process depends on the competence of those conducting the audit. Auditors develop, maintain and improve their competence through continual professional development and regular participation in audits

ii. Personal attributes

Auditors should possess personal attributes to enable them to act in accordance with the principles of auditing.

iii. Knowledge and skills

- a. Generic knowledge and skills of quality management system and environmental management system auditors
- b. Generic knowledge and skills of audit team leaders
- c. Specific knowledge and skills of quality management system auditors
- d. Specific knowledge and skills of environmental management system auditors

C. Education, work experience, auditor training and audit experience

- a. Auditors
- b. Auditors should have education, work experience, auditor training and audit experience.
- c. Audit team leaders
- d. Auditors who audit both quality and environmental management systems
- e. An audit team leader should have acquired additional audit experience to develop the knowledge and skills.
- f. Auditors who audit both quality management systems
- g. Levels of education, work experience, auditor training and audit experience

D. Maintenance and improvement of competence

i. Continual professional development

Continual professional development is concerned with the maintenance and improvement of knowledge, skills and personal attributes. This can be achieved through means such as additional work experience, training, private study, coaching, attendance at meetings, seminars and conferences or other relevant activities. Auditors should demonstrate their continual professional development.

ii. Maintenance of auditing ability

Auditors should maintain and demonstrate their auditing ability through regular participation in audits of quality and/or environmental management systems.

E. Auditor evaluation

i. General

The evaluation of auditors and audit team leaders should be planned, implemented and recorded in accordance with audit programme procedures to provide an outcome that is objective, consistent, fair and reliable. The evaluation process should identify training and other skill enhancement needs.

ii. Evaluation process

The evaluation process involves four main steps.

Step 1: Identify the personal attributes, and the knowledge and skills to meet the needs of the audit programme

Step 2: Set the evaluation criteria

Step 3: Select the appropriate evaluation method

Step 4: Conduct the evaluation

Competencies assessed

1. To analyse data called related to food quality parameters
2. To compute ways statistical quality control in food supply chain
3. To assess the existing gap in relation to food quality issue
4. To control ways by which food quality and safety will be affected
5. To observe ways of writing report on certification for compliance

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