

ISO 22000:2018

Food safety management systems

ISO/TC 34/SC 17



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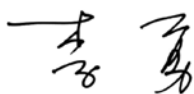
Foreword

The characteristic of food safety is the absence of foodborne hazards at the point of consumption. These hazards can occur at different stages of the food chain, therefore adequate controls throughout the network are essential. Food safety is ensured through the combined efforts of all the parties participating in the food chain, from feed producers and primary producers to food manufacturers, transport and storage operators and subcontractors, right through to retail and food service outlets. These work together with related organizations such as producers of equipment, packaging materials, cleaning agents, additives and ingredients, as well as service providers.

ISO 22000:2018, *Food safety management systems – Requirements for any organization in the food chain*, is recognized internationally as the most relevant document supporting the development of a food safety management system (FSMS). The International Standard defines what an organization needs to do in order to demonstrate its ability to control food safety hazards and ensure that food products are safe for consumption. This enables organizations to deliver food-related products and services with confidence throughout the supply chain. Authored by experts from SC 17, *Management systems for food safety*, a subcommittee of ISO's technical committee ISO/TC 34, *Food products*, this standard encapsulates the latest knowledge of food chain safety to support organizations in developing an effective FSMS.

Among the weaknesses identified by the subcommittee was the absence of adequate user assistance to implement ISO 22000:2018. In response to this need, a working group was formed, and they worked tirelessly to develop this handbook. ISO 22000:2018, *Food safety management systems – A practical guide*, offers a hands-on approach and a wide range of information for developing, documenting, implementing and maintaining a robust FSMS according to ISO 22000:2018. Readers will also come away with an in-depth understanding of the aim and outcome of the standard's different requirements.

Supporting the wider food industry, the International Organization for Standardization (ISO) and United Nations Industrial Development Organization (UNIDO) have joined forces to publish a handbook that will help users get the most from their food safety programme. We hope it will offer the support you need to implement the ISO 22000 management system in your organization.



Li Yong

Director General UNIDO



Sergio Mujica

Secretary-General ISO

Introduction

This handbook provides guidance for the implementation of ISO 22000:2018, *Food safety management systems — Requirements for any organization in the food chain*, to develop a food safety management system (FSMS) for an organization. You must read it in conjunction with ISO 22000:2018. Appendix B contains cross-references from ISO 22000:2018 to this handbook.

For the purpose of this handbook, references to “ISO 22000” are to the 2018 edition, unless otherwise specified.

This handbook is intended to provide guidance to any organization that is directly or indirectly part of the food chain.

It is not intended to be used by certification bodies to audit organizations seeking ISO 22000 certification.

Extract from the scope of ISO 22000:2018

This document specifies requirements for a food safety management system (FSMS) to enable an organization that is directly or indirectly involved in the food chain:

- 1.** to plan, implement, operate, maintain and update a FSMS providing products and services that are safe, in accordance with their intended use
- 2.** to demonstrate compliance with applicable statutory and regulatory food safety requirements
- 3.** to evaluate and assess mutually agreed customer food safety requirements and to demonstrate conformity with them
- 4.** to effectively communicate food safety issues to interested parties within the food chain
- 5.** to ensure that the organization conforms to its stated food safety policy
- 6.** to demonstrate conformity to relevant interested parties
- 7.** to seek certification or registration of its FSMS by an external organization, or make a self-assessment or self-declaration of conformity to this document

ISO decided to unify the structure of all management system standards (MSS) in order to facilitate their integration. For that purpose, a High Level Structure (HLS) was adopted. The HLS provides identical structure, text and common terms and definitions for all ISO MSSs facilitating full integration of several standards into one management system in a single organization (e.g. ISO 9001, ISO 14001, and ISO 45001).

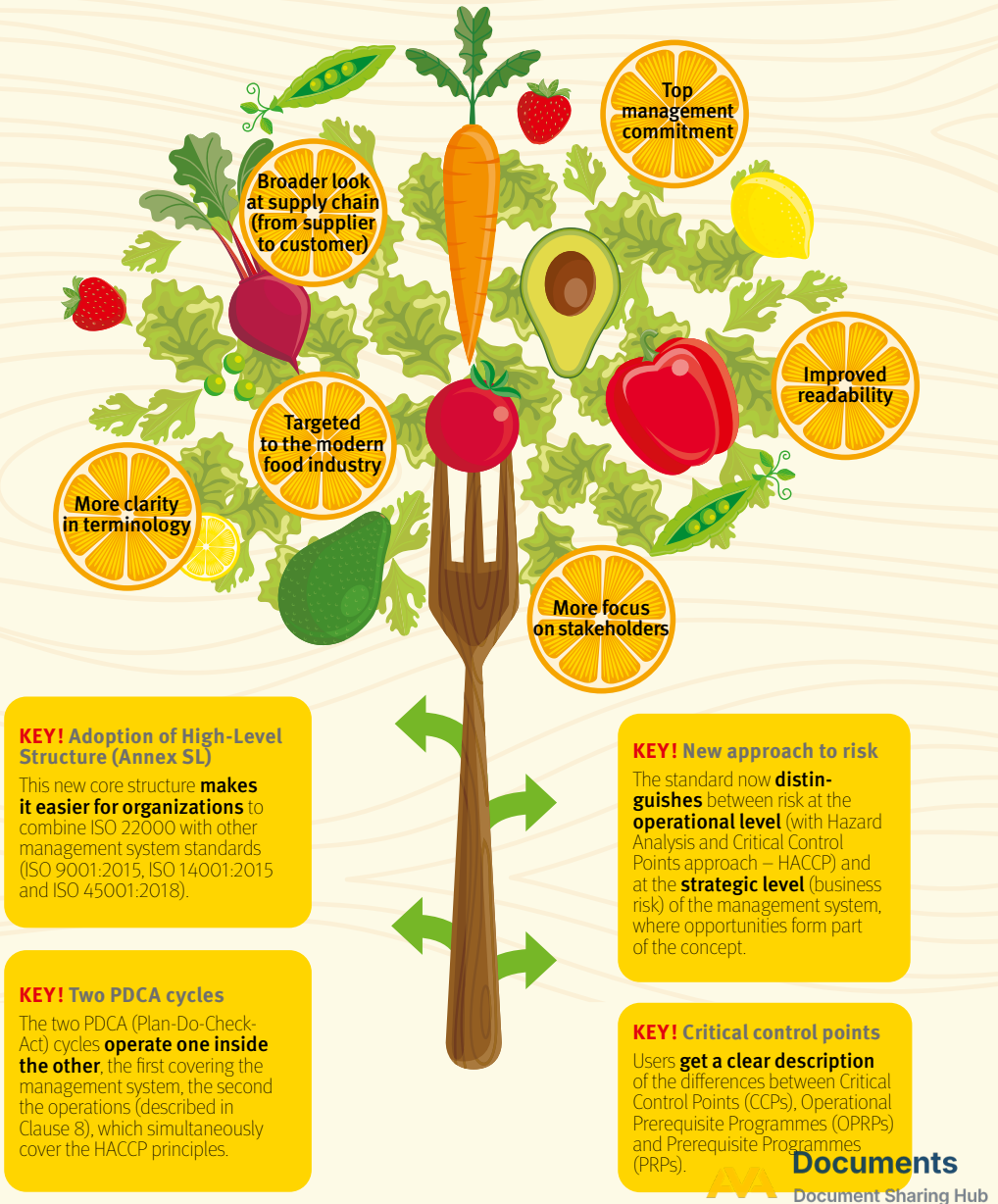
ISO 22000, like other ISO MSS, is built around the concept of the PDCA (Plan-Do-Check-Act) cycle. In ISO 22000, this concept is applied at two levels (see Chapter 1, Topic 3).

The FSMS is designed to reduce the risk of manufacturing a product that is not safe. This handbook is designed to help an organization to develop a robust FSMS according to ISO 22000.

An “expert panel” was formed as ISO/TC 34/SC 17/AG 1, with the purpose to support the users of standards within the ISO 22000 family. It consists of a selection of SC 17 delegates who are geographically diverse with different technical/business backgrounds across various food sectors.

Its role is to assist SC 17’s secretariat in addressing generic questions that need official interpretation and to gain a greater understanding of the application of the ISO 22000 family of standards. Therefore, its role is not to address specific questions related to schemes, on how an organization will specifically address standard(s) requirements, and on non-ISO documents.

Questions to the expert panel may be sent via SC 17’s secretary. More information can be found here: <https://committee.iso.org/sites/tc34sc17/home/projects/expert-panel.html>.



What is new in ISO 22000:2018?

The following are new concepts introduced in ISO 22000:2018 :

- ▶ The ISO 22000 standard has been restructured to align with other MSS (see **Chapter 1, Topic 1**)
- ▶ The concept of the process approach has been made explicit (see **Chapter 1, Topic 2**)
- ▶ The PDCA cycle is now introduced at two levels : organizational and operational (see **Chapter 1, Topic 3**)
- ▶ The concept of risks and opportunities (see **Chapter 1, Topic 4**) has been introduced
- ▶ The scope has been widened to include food for animals (food is intended for consumption by humans and animals and includes feed and animal food ; feed is intended to be fed to food-producing animals ; animal food is intended to be fed to non-food-producing animals, such as pets)
- ▶ The term “product” has been defined and clarified to include service (see Clause 3 of ISO 22000)
- ▶ New terms have been defined, e.g. “acceptable level”, “action criterion”, “significant food safety hazard”, (see Clause 3 of ISO 22000)
- ▶ Some definitions have been revised and improved, e.g. for “control measure”, “critical control point (CCP)”, “operational prerequisite programme (OPRP)”, and “prerequisite programme (PRP)” (see Clause 3 of ISO 22000)
- ▶ The understanding of interested parties needs and expectations has been introduced (see **Chapter 2, Task 2.2**)

- ▶ The leadership role of the top management (commitment, responsibilities and authorities) has been strengthened (see **Chapter 3, Tasks 3.1 and 3.2**).
- ▶ How to use and control the externally developed elements of the FSMS has been clarified (see **Chapter 3, Task 3.5**).
- ▶ The concept of documented information has been introduced (see **Chapter 3, Task 3.8**).
- ▶ The concept of a hazard control plan has been introduced (see **Chapter 5, Tasks 5.5 to 5.8**).

Scope

This handbook provides generic guidance to assist all organizations (including small and medium-sized) that recognize the potential benefits of implementing a FSMS in accordance with ISO 22000:2018.

Organizations, regardless of size and complexity, very often need support and/or clarification on how to develop, document, implement and maintain an FSMS using ISO 22000. In addition, organizations often underestimate the depth of commitment required to maintain such a system and the training required to do so. This handbook describes the ISO 22000 implementation process. For organizations considering certification, the handbook also provides information on the certification process. Each key step is explained in more detail in the relevant chapters of this handbook.

Structure of this handbook chapters

Structure of this handbook chapters

For the purpose of this handbook, references to “ISO 22000” are to the 2018 edition, unless otherwise specified.

The following structure is used in Chapters 2 to 6 of this handbook.

Key points

Summarizes the purpose of the chapter..

Objectives of this chapter

This paragraph explains how the chapter relates to ISO 22000.

Topics covered by the chapter

Each topic is divided into tasks and is presented as follows:

Task XX: Description of the required actions

- ▶ Reference(s): ISO 22000:2018, clause/subclause XX
- ▶ Your main aim should be to:
- ▶ Description of action(s) to be implemented.
- ▶ Practical advice:
- ▶ Practical explanations of why/how these actions could be implemented.
- ▶ Types of documented information supporting the implementation of the FSMS and related task(s): example(s)
- ▶ What questions do you need to ask yourself (to which an affirmative reply is required) before continuing?

Glossary

The terminology from ISO 22000:2018 is used throughout this handbook.

Note: The explanations of the terms provided in the glossary below are in no way to be considered as a revised version of ISO 22000 and other relevant ISO definitions. The glossary is provided as a tool to assist organizations to better understand basic principles.

Assessment	An objective evaluation or estimation.
Audit plan	A description of the activities and arrangements for an audit (e.g. time schedule, auditor name, department/activities/topics to be audited).
Audit programme	Arrangements for a set of one or more audits planned for a specific timeframe and directed towards a specific purpose (e.g. internal audits, supplier audits). See Subclause 9.2.2 of ISO 22000.
Auditor	A person with the competence (specifically educated and trained/qualified) to conduct an audit.
Batch	See 'Lot' (see ISO 22000:2018, 3.24).
Certification	A third-party attestation that specified requirements relating to the FSMS have been fulfilled. The certificate is granted by a certification body after a certification audit.
Chief executive	Leader of the organization (firm, company or enterprise), e.g. Chief Executive Officer (CEO), Chief Operating Officer (COO), Owner, President.

Codex Alimentarius Commission

Organization that develops international food standards, guidelines and related texts such as codes of practice under a Joint FAO/WHO Food Standards Programme. The main purposes of this programme are to protect the health of consumers, ensure fair trade practices in the food trade, and to promote coordination and harmonization of all food standards work undertaken by international governmental and non-governmental organizations.

It was created in 1963 by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO), a specialized agency of the United Nations.

Communication channel

A medium (print, electronic or verbal) through which a message (information) is transmitted to its intended audience.

Consumer

An individual member of the general public who purchases or uses goods, property or services for private purposes. A consumer can be also an animal.

Contaminant

Any biological or chemical agent, foreign matter or other substance not intentionally added to food that could compromise food safety or suitability.

Customer satisfaction

A measure of how the products and/or services supplied by an organization meet the customer's expectations. This term is frequently used in marketing.

Cross contamination

The transfer of hazard(s) from one food product to another by way of, for example, process equipment, a person's hands, air or other contaminated surfaces.

Expert	A person who has acquired knowledge and skill through study and practice in a particular field, and is recognized as a specialist who can be helpful in fact-finding or problem-solving.
External consultant	A person, not employed by the organization, who is hired to provide professional advice in a particular area (e.g. management, audit, technology). Consultants usually work for a consultancy firm or are self-employed. Their clients (organizations) purchase their services (outsourcing). The external consultant should have the appropriate competencies in the FSMS area.
Food suitability	Assurance that food is acceptable for consumption according to its intended use.
FSMS manual	A non-mandatory document in which the food safety policy of the organization is stated and its FSMS is described.
Indicator	Measurable variable used to monitor progress toward a goal.
Input/output data	Inputs are the information or data received by a process or system. Outputs are the data or information sent from it. For example, the results of internal audits are one type of input data used for a management review.
Procedure	A step-by-step sequence of activities that must be followed to correctly perform a task.

A procedure defines:

A step-by-step sequence of activities that must be followed to correctly perform a task.

A procedure defines:

- which process, task, work or activity
- how it should be done
- by whom (responsibility/authority)
- the resources required
- the documented information, as necessary

Process characteristics

All the specific features of a process: inputs, outputs, responsibility, activities, etc.

Process line

The specific unit operation for a category of products.

Record

A control document stating results achieved or providing evidence of activities performed (e.g. audit report, meeting report, surveillance of temperature, monitoring at CCPs and/or for an OPRP, microbiological analysis results).

Specification

A set of documented information providing requirements or characteristics to be satisfied by a material, a product, a supplier, a process or a service.

Abbreviated terms

CCP	critical control point
FSMS	food safety management system
GAP	good agricultural practices
GHP	good hygiene practices
GMP	good manufacturing practices
HACCP	hazard analysis and critical control point
HLS	High Level Structure
MSS	management system standard(s)
OPRP	operational prerequisite programme
PDCA	Plan-Do-Check-Act
PRP	prerequisite programme

Chapter 1

HLS, two PDCA cycles and ‘risk-based thinking’ in the context of ISO 22000:2018

Key points

This chapter explains the new structure (the High Level Structure) applied to MSS, the concept of PDCA in the context of ISO 22000, where it is applied at two levels. It also provides basic information on ‘risk-based thinking’ as applied to ISO 22000.

Objectives of this chapter

This chapter is essential for understanding the structure of ISO 22000 and the relevant implications regarding its requirements.

The “High Level Structure (HLS)” is used for all MSS; the HLS is built around ten common clauses (see **Topic 1**).

ISO 22000 employs the process approach (see **Topic 2**), which incorporates the PDCA cycle at two levels (see **Topic 3**) and the risk-based thinking concept (see **Topic 4**).

- ▶ **Topic 1:** High Level Structure (HLS)
- ▶ **Topic 2:** Process approach
- ▶ **Topic 3:** The two PDCA cycles of ISO 22000
- ▶ **Topic 4:** ‘Risk-based thinking’ in the context of ISO 22000

Topic 1: High Level Structure (HLS)

The ISO 22000:2018 standard was developed to reflect the HLS common to all the ISO MSS. The HLS was an initiative taken by ISO and when revised, all the ISO MSS, including ISO 22000:2005, shall apply this common structure.

The HLS concept is designed to improve alignment across MSS, therefore enabling an organization to apply the process approach (see **Topic 2**), coupled with the PDCA cycle (see **Topic 3**) and risk-based thinking (see **Topic 4**), as well as, where required, to align it with other MSS.

The concept also includes information on the business context and interested parties, risks, opportunities and continual improvement, and leadership and commitment.

The HLS comprises a structure of ten clauses, common terms and definitions, and standard text, making it easier for anyone applying multiple MSS. The illustration below reflects the common clauses shared by all the MSS.



Figure 1: Common clauses shared by all MSS

The text of these clauses was required by ISO to be the same. Where it was specifically needed, allowance was given to modify some of the text addressing the

specific needs of the standard, i.e. ISO 22000 concerning food safety or ISO 9001 concerning quality, etc.

Modified text for ISO 22000 included for example some terms and definitions and information in Subclauses 5.2.1, 5.2.2, 6.3, most of Subclauses 7.1 and 7.4, 9.1.1, 9.1.2, 9.3.1 to 9.3.3 as well as Subclause 10.3. Text unique to ISO 22000 included, for example, the introduction, scope, normative references, Clause 8.

Topic 2: Process approach

The process approach is a tool for managing the identified processes (e.g. food safety management processes, realization processes, supporting processes) of the organization and their interactions in order to achieve the intended results and to avoid unwanted results.

An advantage of the process approach is the ongoing control it provides between the individual processes within the system.

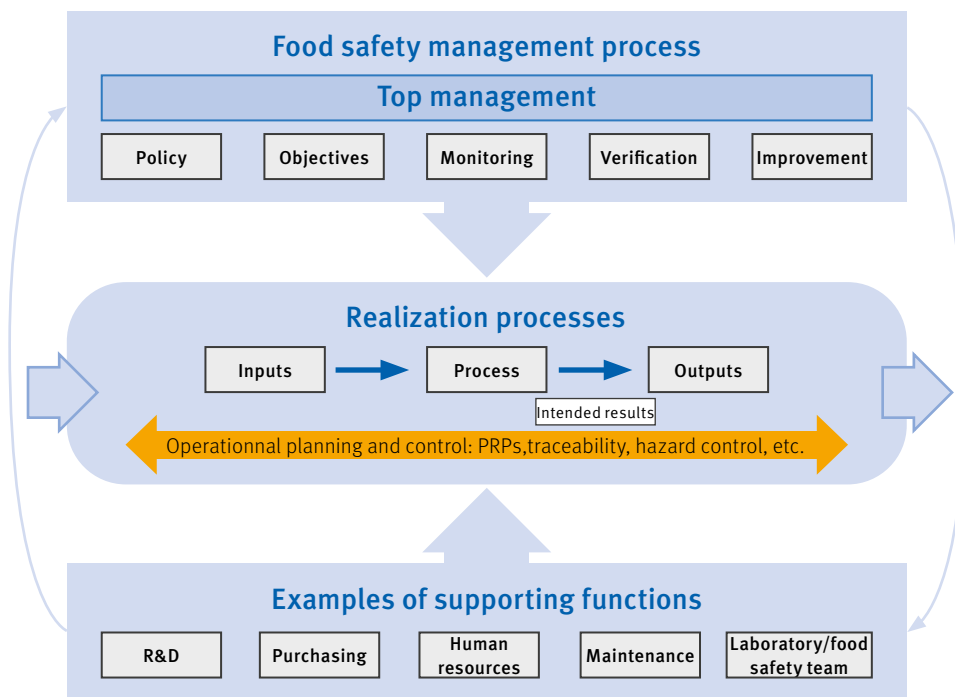


Figure 2 : Generic illustration of the process approach.

ISO 22000 follows the process approach. When used within an FSMS, the process approach emphasizes the importance of:

- ▶ understanding and fulfilling ISO 22000 requirements
- ▶ considering food safety planning as a process
- ▶ considering traceability as a process
- ▶ monitoring of process performance and effectiveness
- ▶ continual improvement of processes based on objective measurement(s)

Any and all parties, as defined by internal and external communication, can play a role in defining process requirements. Evaluating the satisfaction of these entities requires the collection and analysis of information to determine whether or not the organization has been able to meet these demands.

Topic 3: The two PDCA cycles of ISO 22000:2018

ISO 22000 requires the application of a dynamic and systematic process approach to the development, documentation, implementation and maintenance of an FSMS. This is achieved through effective planning, coordination, implementation, verification and updating of activities, and through appropriate actions in the event of a process nonconformity.

The PDCA cycle (see Figure 3) can be described briefly as:

- ▶ Plan: establish the objectives of the system and its processes, provide the resources needed to deliver the results, and identify and address risks and opportunities
- ▶ Do: implement what was planned
- ▶ Check: monitor and (where relevant) measure processes and the resulting products and services, analyse and evaluate information and data from monitoring, measuring and verification activities, and report the results
- ▶ Act: take actions to improve performance, as necessary

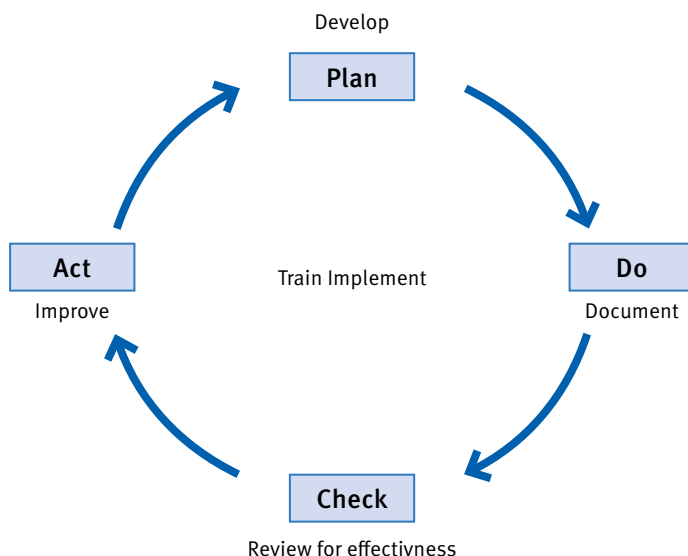


Figure 3: PDCA cycle

The FSMS is developed and implemented through a PDCA approach at two levels, as shown in Figure 4:

- ▶ organizational level (illustrated in Figure 4 by the ‘Organizational planning and control’ part)
- ▶ operational level (illustrated in Figure 4 by the ‘Operational planning and control’ part)

The first level covers the overall framework of the FSMS, including processes directly or indirectly impacting food safety (e.g. resources for engineering and maintenance, product development, top management involvement). The second level covers the operational processes within the food safety system (e.g. hazard analysis, control measures, correction and corrective action). Communication between the two levels is essential.

Organizational planning and control

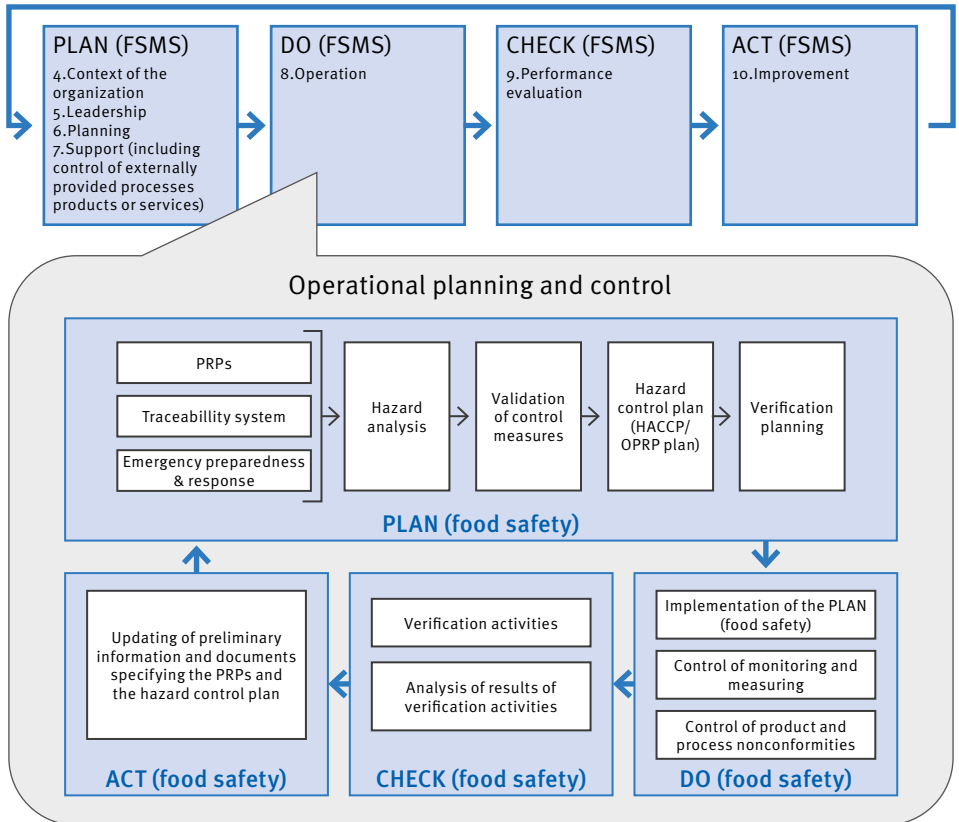


Figure 4: Illustration of the PDCA cycle applied at the two levels

Topic 4: ‘Risk-based thinking’ in the context of ISO 22000

Food safety is ensured through the combined efforts of all the parties participating in the food chain. It is a requirement of ISO 22000 that the organization understands the issues associated with the context in which it operates (see Figure 5). This includes the food safety related needs and expectations of interested parties. The organization should determine the risks and opportunities arising from these issues, and use them as a basis for planning the actions to address them. This action should ensure the FSMS delivers safe products and services from their organization.

The concept of ‘risk-based thinking’ has been introduced explicitly with the HLS (see Topic 1) and therefore has to be applied by food operators wishing to conform to ISO 22000.

‘Risk-based thinking’ is essential for achieving an effective FSMS. In ISO 22000, ‘risk-based thinking’ is addressed at two levels: organizational (in Clause 6) and operational levels (in Clause 8).

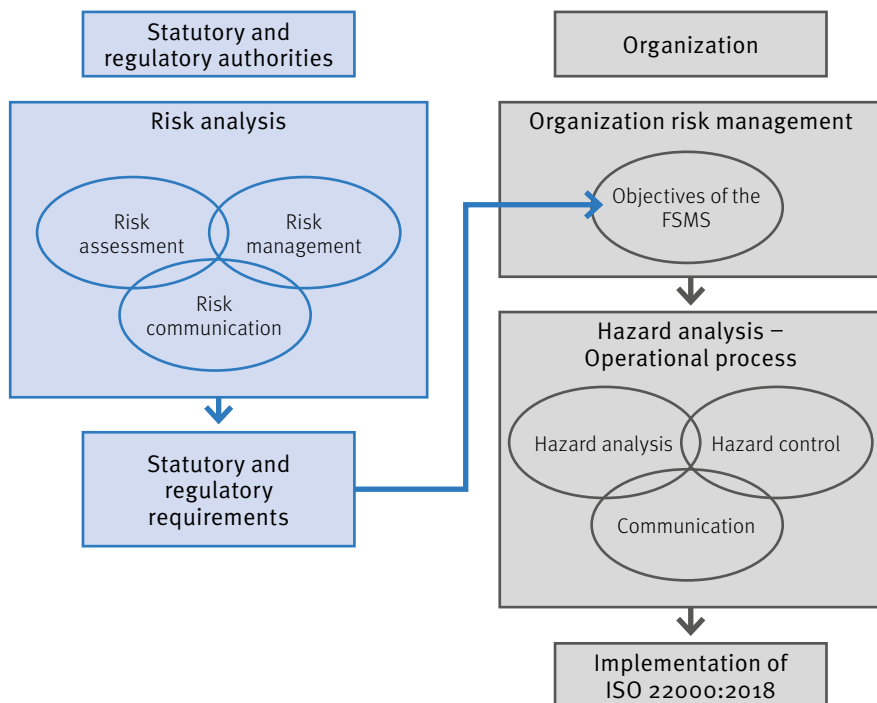


Figure 5: Conceptual framework of the responsibilities of statutory and regulatory authorities and of the organization

Organizational risk management

Risk is the effect of uncertainty. In the context of a FSMS, any such uncertainty can have positive and negative consequences, as opposed to the hazard control plan, where actions are taken to minimize risk with negative effects.

As a concept, risk is used in various ways and it is very important for organizations that work with food to distinguish between the well-known hazard assessment at the operational level, and the concept of business risk, where opportunities also form part of the concept.

Business risks that have an impact on the performance of the FSMS must always be considered when applying ISO 22000.

Consideration should be taken for any decisions that affect the FSMS which may result in potential changes to hazards.

Resources should be available to assess the effects of business decisions that can result in food safety issues. There should be effective communication between top management and the food safety team leader. Personnel involved in assessing management decisions are trained to understand that their decisions may have an impact on hazards, and not only on the FSMS.

In order to conform to the requirements of ISO 22000, an organization must plan to address the organizational risks and opportunities. These risks and opportunities may impact the FSMS and should be mitigated by being proactive.

Example 1: Allergen control

Considering the context of the organization and the needs of the market to reduce the disclaimer 'may contain traces of ...', the organization needs to improve the production-process segregation which may lead to the opportunity to remove the disclaimer 'may contain traces of ...' from product.

Example 2: Recycled water (e.g. sustainability purposes)

The use of recycled water in a facility may limit the use of water and require a review of water used for food safety. The opportunity is to reduce the water use, the risk is that the water is not fit for purpose.

NOTE: Although risks and opportunities need to be determined and addressed, there is no requirement for a formal risk management or a documented risk management process.

Chapter 2

Design of the FSMS framework

Key points

Before beginning this chapter, the elements described in Chapter 1 should be understood in order to facilitate the implementation of ISO 22000.

The organization is not a stand-alone entity. It has to coordinate with the relevant interested parties that may influence and be influenced by the FSMS. To ensure the effectiveness and efficiency of the FSMS, understanding these interested parties is a key element for the organization..

Objectives of this chapter

This chapter provides an understanding of the FSMS framework and identifies the key items to be considered when designing the FSMS. The key items are described in Tasks 2.1 to 2.4.

- ▶ Task 2.1: Understanding the organization and its context
- ▶ Task 2.2: Understanding the needs and expectations of interested parties
- ▶ Task 2.3: Determining the scope of the FSMS
- ▶ Task 2.4: FSMS processes and interactions

Task 2.1: Understanding the organization and its context

Reference:

ISO 22000:2018, Subclause 4.1

Your main aim should be to:

- ▶ Understand the external and internal issues relevant to the organization's purpose and strategic direction that may affect, either positively or negatively, its ability to achieve the intended results of the FSMS
- ▶ Identify, review and update information related to these external and internal issues

It is important to remember, while the organization may perceive little change, its context and surrounding continually change, including the expectations of its interested parties.

Practical advice:

Identify, review and update the relevant information related to external and internal issues which may impact (positive or negative) on the achievement of the intended results of the organization's FSMS (e.g. continual improvement, compliance to statutory and regulatory requirements, customer requirements, producing safe food).

In order to identify the relevant information, you need to ask yourself: what is relevant to your organization, process(es) and products?

Relevant information regarding external and internal issues can be found from various sources, for example:

- ▶ external sources : press (e.g. international, national, local), Websites from relevant governmental agencies, relevant regulations/legal issues

(international, national, local), relevant interested parties, professional associations and meetings

- ▶ internal sources: FSMS-documented information such as product specifications, notice boards, management meetings, verification, internal results

Examples of information to look for: food adulteration, availability of raw materials, food waste reduction, food poisoning outbreaks, availability of potable water, new technologies, educational levels of employees, local unemployment rates, etc. When sources or information have been identified, the action is to evaluate their pertinence to the organization and determine the potential positive or negative impact on the organization's FSMS.

The results of the information evaluation should be considered as an input to the management review (see Subclause 9.3.2 of ISO 22000).

To determine the organization's context and the relevant issues for achieving its intended results, you can use methods such as asking "what if" questions, brainstorming and using a SWOT (strengths, weaknesses, opportunities and threats) analysis or a PESTLE (political, economic, social, technological, legal, environmental) analysis.

Types of documented information supporting the implementation of the FSMS and related task(s): example(s)

- ▶ Statement of the purpose of the organization
- ▶ Statement of the intended result of the FSMS
- ▶ List of external and internal issues derived from the collected information, noting their negative and positive contributions
- ▶ Collected information used to list the external and internal issues

What questions do you need to ask yourself (to which an affirmative reply is required) before continuing?

- ▶ Have you identified any food safety issues that may affect your organization?
- ▶ Have you reviewed and updated information related to external and internal issues that may affect your organization?

Task 2.2: Understanding the needs and expectations of interested parties

References :

ISO 22000:2018, Subclauses 4.2 and 7.4.2

Your main aim should be to:

- ▶ Identify the interested parties and their applicable food safety requirements, needs and expectations
- ▶ Identify, review and update information related to the interested parties and their requirements

Practical advice:

The organization needs to consider interested parties other than just the direct customer (see Figure 6). The focus needs to be on those parties that could have an impact on the ability of the organization to provide safe food. Using, for example, the list of external and internal issues from Task 2.1 may assist the organization to identify their interested parties. A focus needs to be placed on the relevance of their requirements to food safety.

The organization should consider the relevant requirements of relevant interested parties (e.g. statutory, regulatory authorities, suppliers, services providers,

media, customers including charity organizations, financial partners, consumers). The intention is to focus on only those relevant interested parties that can have an impact on the organization’s ability to provide products and services that meet requirements.

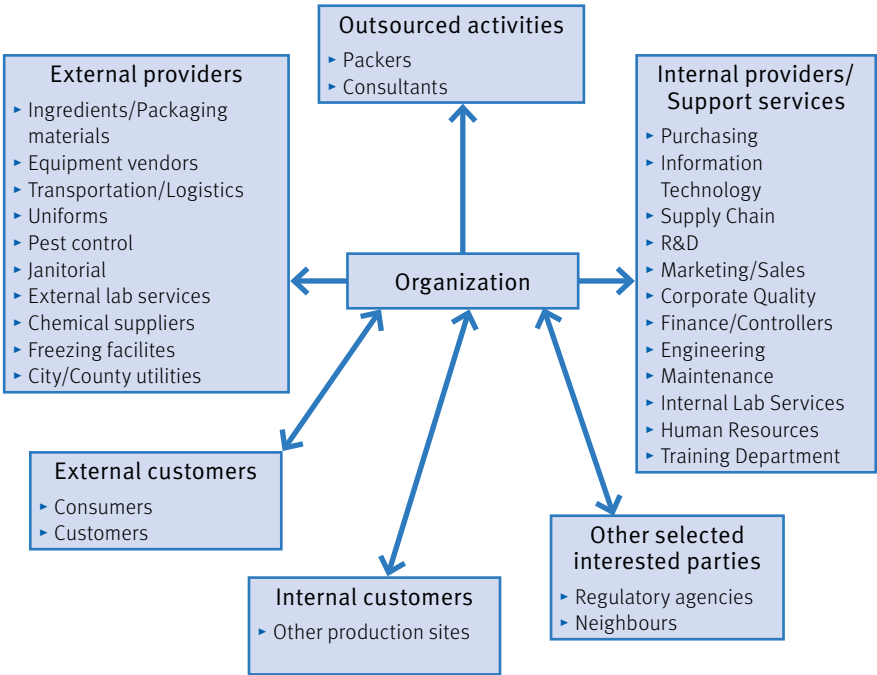


Figure 6: Example of identifying relevant interested parties for an organization

You should gather, analyse, and determine the external and internal information relevant to the organization regarding food safety, in order to satisfy the requirements, needs and expectations of the interested parties.

Communicate with these interested parties to ensure a continual understanding of their food-safety requirements, needs and expectations.

Types of documented information supporting the implementation of the FSMS and related task(s): example(s)

- ▶ An updated list identifying all interested parties and their requirements with an assessment of the relevance of the requirements

What questions do you need to ask yourself (to which an affirmative reply is required) before continuing?

- ▶ Have you identified and prioritized the relevant interested parties?
- ▶ Have you identified the food safety requirements, needs and expectations of the relevant interested parties?

Task 2.3: Determining the scope of the FSMS

Reference :

ISO 22000:2018, Subclause 4.3

Your main aim should be to:

- ▶ Determine the scope, boundaries and applicability of organization's FSMS, taking into consideration its context (see Task 2.1) and the relevant food safety requirements, needs and expectations of identified interested parties (see **Task 2.2**)
- ▶ Decide which markets/consumers the organization should address

Practical advice:

Maintain the scope as documented information.

The scope should include details of the products and services provided, including processes and production site(s) and, when relevant, categories of products. The decision to exclude activities, processes, products or services should be carefully assessed; this is only possible if the exclusion does not influence the food safety of the end products included in the scope.

This documented information can be maintained in any form that the organization chooses, from a handwritten document to a computer file.

Types of documented information supporting the implementation of the FSMS and related task(s): example(s)

- Scope of the organization's FSMS.

What questions do you need to ask yourself (to which an affirmative reply is required) before continuing?

- Do you have a clear and fully documented scope?

Task 2.4: FSMS (processes and interactions)

References :

ISO 22000:2018, Subclause 4.4, and links to Clauses 5, 6, 7, 8, 9 and 10

Your main aim should be to:

- Determine the processes needed for achieving the intended outputs
- Determine how the processes flow in sequence and interaction



Documents

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Practical advice:

The organization should identify the processes needed for the FSMS, their sequence and their interactions. This includes not only the processes for production and service provision, but also the processes that are needed for the effective implementation of the system, such as internal audit, management review and others (including processes that are performed by external providers).

These processes include management, resources, operations, measurement, analysis and improvement in order to establish, implement, maintain, update and continually improve a robust FSMS.

Define and describe the network of processes and their interaction (see Figure 7), considering the following:

- ▶ the inputs and outputs of each process (which may be internal or external)
- ▶ process interactions and interfaces on which processes depend or enable

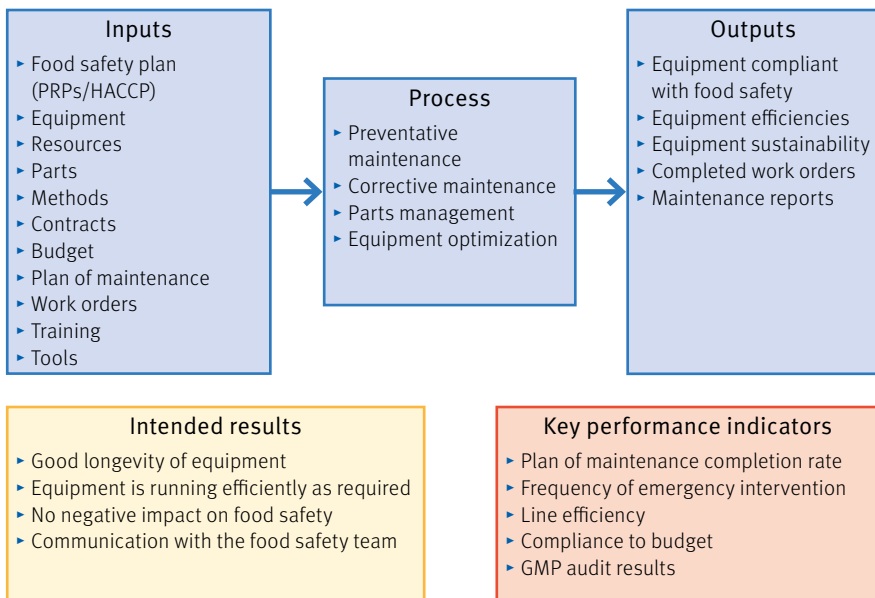


Figure 7: Example of a process (maintenance)

Types of documented information supporting the implementation of the FSMS and related task(s): example(s)

- ▶ List of processes (e.g. business, FSMS, service providers) also indicating their inputs and outputs
- ▶ Process diagram/process map indicating the interaction of the processes

What questions do you need to ask yourself (to which an affirmative reply is required) before continuing?

- ▶ Have you determined the processes needed for achieving the intended outputs?
- ▶ Have you determined how the processes flow in sequence and interaction?

Chapter 3

Leadership and commitment

Key points

Before beginning this chapter, you must have taken into consideration the elements from Chapter 2.

The highest level of the organization's management recognizes the need to implement a FSMS. The management is aware of the main hazards related to the safety of its products, and is prepared to make the necessary investments in human and material resources in order to control these hazards.

Objectives of this chapter

As with any management system, the FSMS can only exist if the top management of the organization is fully convinced that it is needed and is fully committed to its implementation, maintenance and improvement.

This chapter provides guidance to establish and demonstrate leadership and commitment by top management.

- ▶ **Task 3.1:** Draft a food safety policy, a set of objectives of the FSMS and plan to achieve them
- ▶ **Task 3.2:** Define and communicate the roles, responsibilities and authorities for personnel who have an impact on food safety
- ▶ **Task 3.3:** Manage staff skills/competencies
- ▶ **Task 3.4:** Provide resources for the FSMS (beyond personnel)
- ▶ **Task 3.5:** Using externally developed elements for the organization's FSMS

- ▶ **Task 3.6:** Control the externally provided processes, products or services
- ▶ **Task 3.7:** Establish and maintain external and internal communications
- ▶ **Task 3.8:** Manage the documentation of the FSMS
- ▶ **Task 3.9:** Plan what to do in case of emergency situations and potential incidents
- ▶ **Task 3.10:** Develop, implement and test plans for the withdrawal/recall of products

Task 3.1: Draft a food safety policy, a set of objectives of the FSMS and plan to achieve them

References :

ISO 22000:2018, Subclauses 5.1, 5.2, 6.1, 6.2, 6.3 and 7.3

Your main aim should be to:

- ▶ Identify the risks and opportunities for your organization
- ▶ Ensure a very strong leadership and commitment for the FSMS
- ▶ Establish the food safety policy
- ▶ Define measurable objectives for the FSMS
- ▶ Plan the FSMS in order to fulfil this commitment, including change management

Practical advice:

Top management must demonstrate its leadership and commitment to food safety. This is achieved, for example, by establishing the food safety policy and objectives. Management actions need to be based on the food safety policy and objectives of FSMS. This provides evidence of its commitment and leadership, e.g. by

the required resources, formulating the policies and objectives of the FSMS, management reviews, communicating the importance of satisfying the food safety requirements.

The policies and objectives of the FSMS must take into account food safety requirements, including statutory/regulatory and customer requirements. The objectives should be specific to the FSMS, measurable (if practicable) and achievable.

ISO 22000 requires that the objectives of the FSMS be linked to the business objectives.

The organization shall determine its risks and opportunities related to FSMS performance and plan/take appropriate actions to address them (see Topic 4).

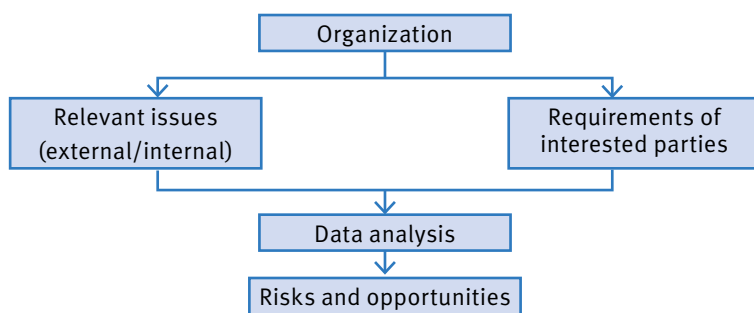


Figure 8 : Typical steps of identifying the risks and opportunities

When identifying the risks and opportunities for the FSMS, consider relevant external and internal issues, as well as relevant interested parties' requirements. Consider both the current situation and the possibilities for change.

Regarding the risks, the organization shall:

- ▶ identify what the risks are (depending on the organization's context)
- ▶ understand them (determine what is acceptable and unacceptable)

Regarding the opportunities, the organization shall:

- ▶ take into consideration the identified risks relevant to the FSMS
- ▶ examine the opportunities, such as ensuring product safety, improving the efficiency of organization, developing new technologies, enhancing customer satisfaction, in compliance with statutory and regulatory requirements

There are various situations where risks and opportunities should be considered, e.g. strategy meetings, management reviews, internal audits, food safety related meetings, the planning stages for the design and development of new products and services, production processes.

For example, the objectives of the FSMS may be derived from the actions noted in 6.1 of ISO 22000, where risks and opportunities are identified (see examples in **Topic 4**) and the organization shall establish how to plan and achieve the actions taken.

Examples of objectives of the FSMS: a maximum of 2 % of deliveries to customers delayed due to food safety issues; an 8 % reduction of customer returns; a 10 % reduction of any waste of raw materials; a food tracing operation completed within 4 hours.

Planning to implement the FSMS can be achieved, for example, by using a simple spread-sheet, including action plans with deadlines, scheduling, resources required to achieve goals and assigned responsibilities.

The food safety policy and objectives of the FSMS shall be communicated, and top management shall decide:

- ▶ when to communicate
- ▶ with whom to communicate
- ▶ how to communicate
- ▶ who should communicate

The organization shall ensure that the food safety policy and objectives of FSMS are understood and applied at all levels within the organization. The food safety policy should be available to interested parties.

The requirement for the food safety policy to be “understood” implies the need for top management to actively facilitate and verify its understanding.

The actions taken by the organization to address risks and opportunities shall be proportionate to the impact on compliance and on food safety. In some cases, the option to address the identified risk could be to accept the risk itself (by informed decision).

Types of documented information supporting the implementation of the FSMS and related task(s): example(s)

- ▶ Strategic direction of the organization (business plans)
- ▶ Food safety policy
- ▶ Objectives of the FSMS
- ▶ Noting of business processes and indicating their integration with the FSMS requirements
- ▶ Provision of resources related to food safety (including personnel and financial)
- ▶ Policy relevant to the role that the organization plays in the food chain
- ▶ Implementation planning of objectives
- ▶ Review of whether the objectives of FSMS have been achieved, to be used as an input for the management review
- ▶ Evidence of communicating the policy and objectives of the FSMS (e.g. posters, e-mails, letters, notice boards, minutes of meetings, training.)
- ▶ Evidence of understanding the policy and objectives of the FSMS (e.g. interviews, internal audits, quizzes, tests.)