ISO 22000:2018

Food safety management systems

A PRACTICAL GUIDE

ISO/TC 34/SC 17

ISO

UNIDO

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Published in Switzerland

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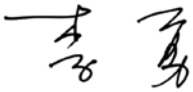
Foreword

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.



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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**.

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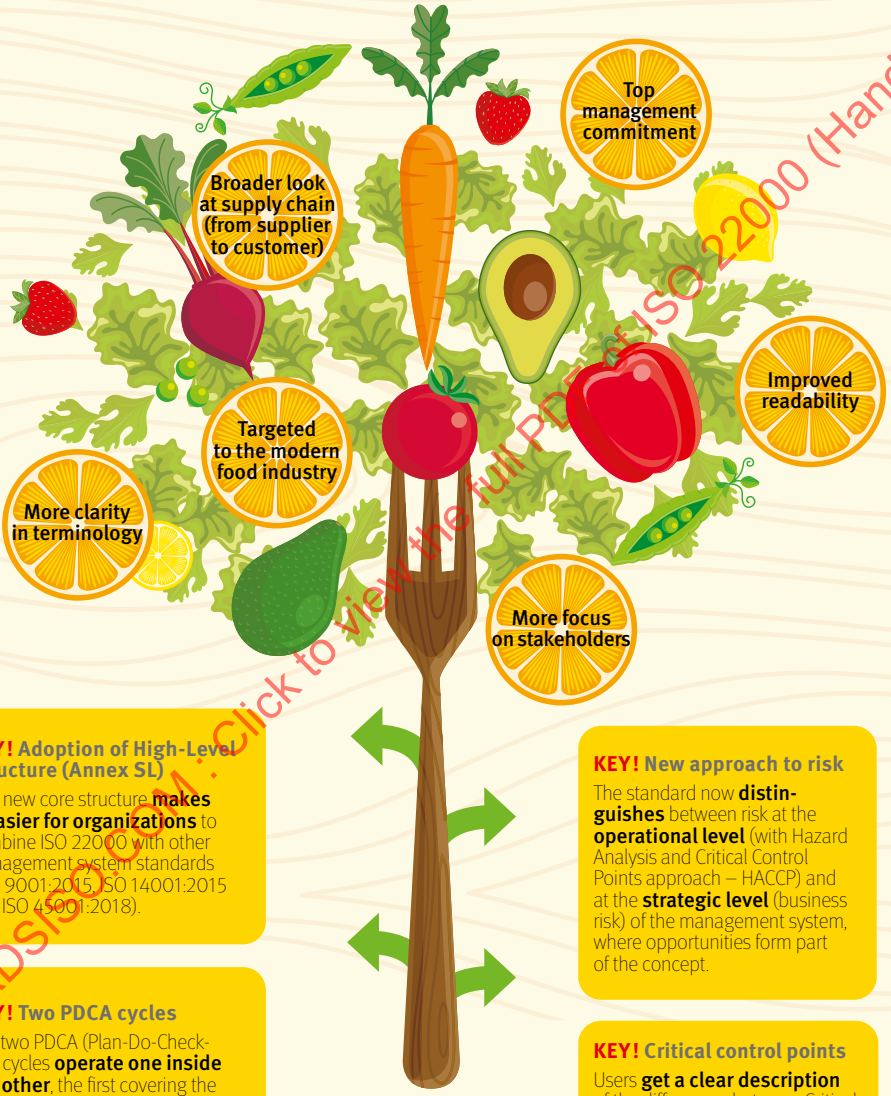

KEY! Adoption of High-Level Structure (Annex SL)

This new core structure **makes it easier for organizations** to combine ISO 22000 with other management system standards (ISO 9001:2015, ISO 14001:2015 and ISO 45001:2018).

KEY! Two PDCA cycles

The two PDCA (Plan-Do-Check-Act) cycles **operate one inside the other**, the first covering the management system, the second the operations (described in Clause 8), which simultaneously cover the HACCP principles.

KEY! New approach to risk

The standard now **distinguishes** between risk at the **operational level** (with Hazard Analysis and Critical Control Points approach – HACCP) and at the **strategic level** (business risk) of the management system, where opportunities form part of the concept.

KEY! Critical control points

Users **get a clear description** of the differences between Critical Control Points (CCPs), Operational Prerequisite Programmes (OPRPs) and Prerequisite Programmes (PRPs).

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.

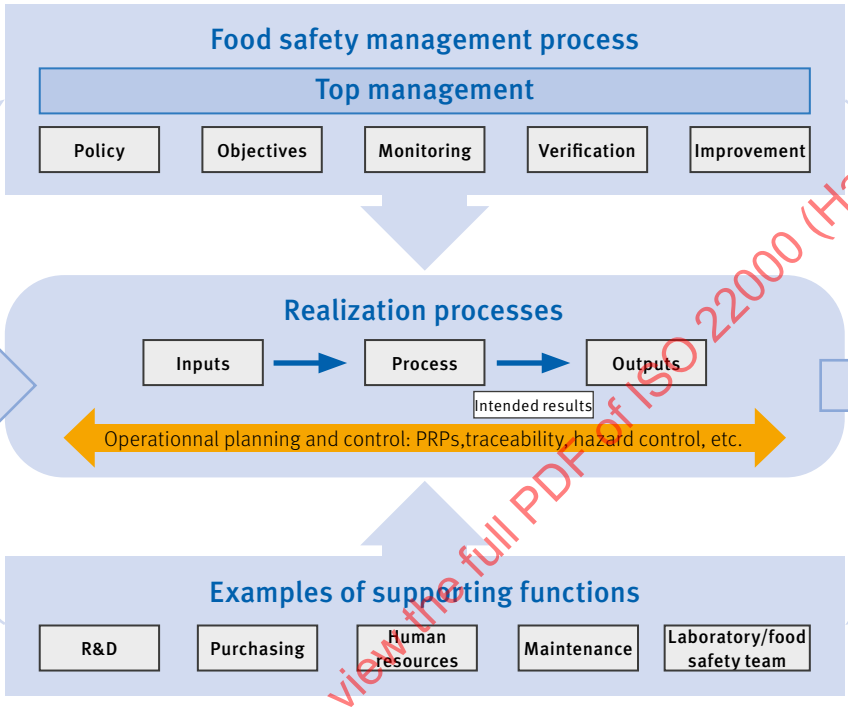

Figure 2 : Generic illustration of the process approach.

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

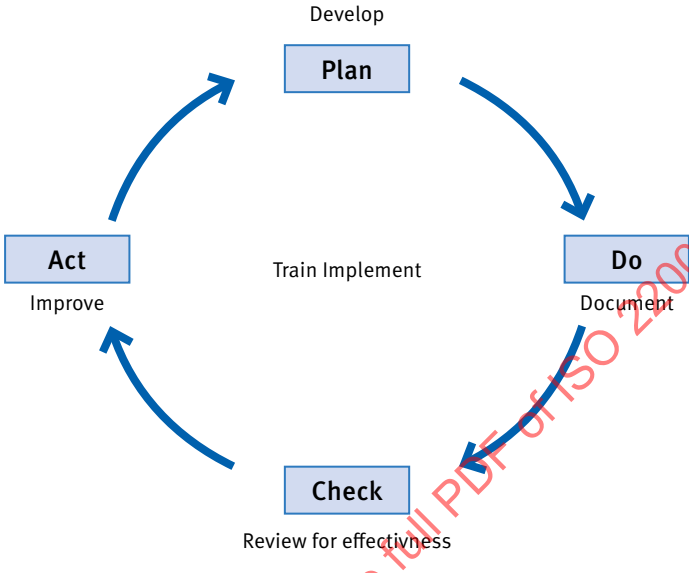

Figure 3 : PDCA cycle

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.

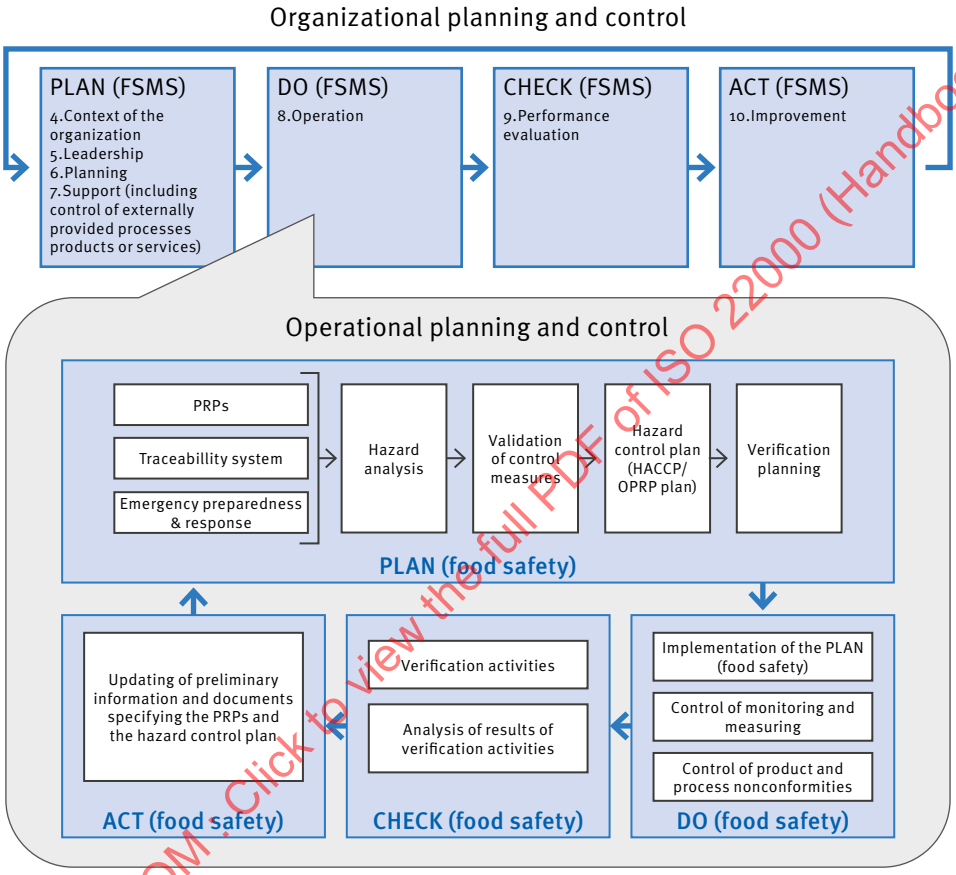

Figure 4: Illustration of the PDCA cycle applied at the two levels

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).

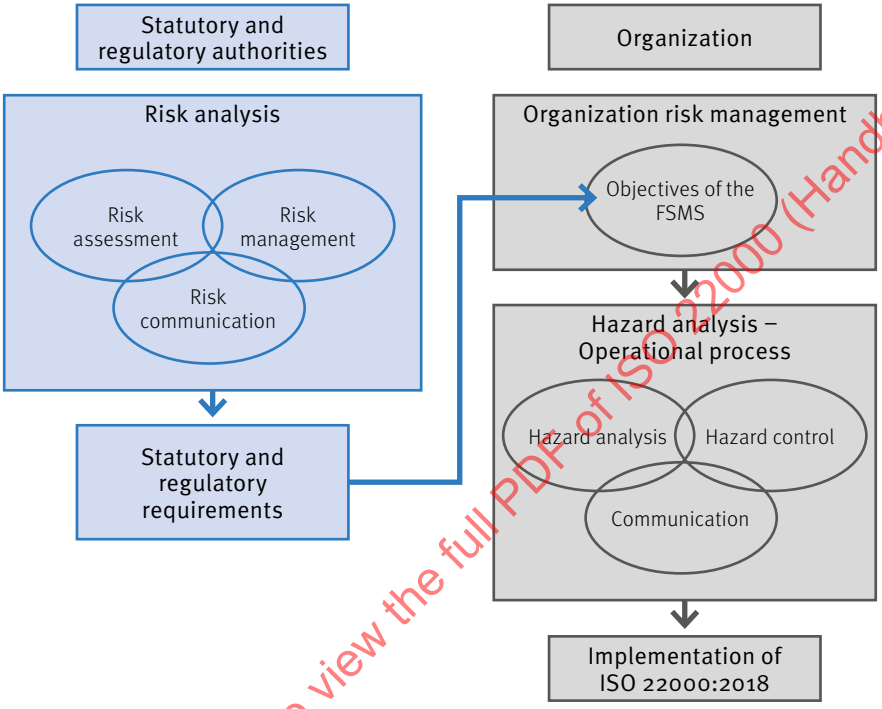

Figure 5 : Conceptual framework of the responsibilities of statutory and regulatory authorities and of the organization

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.

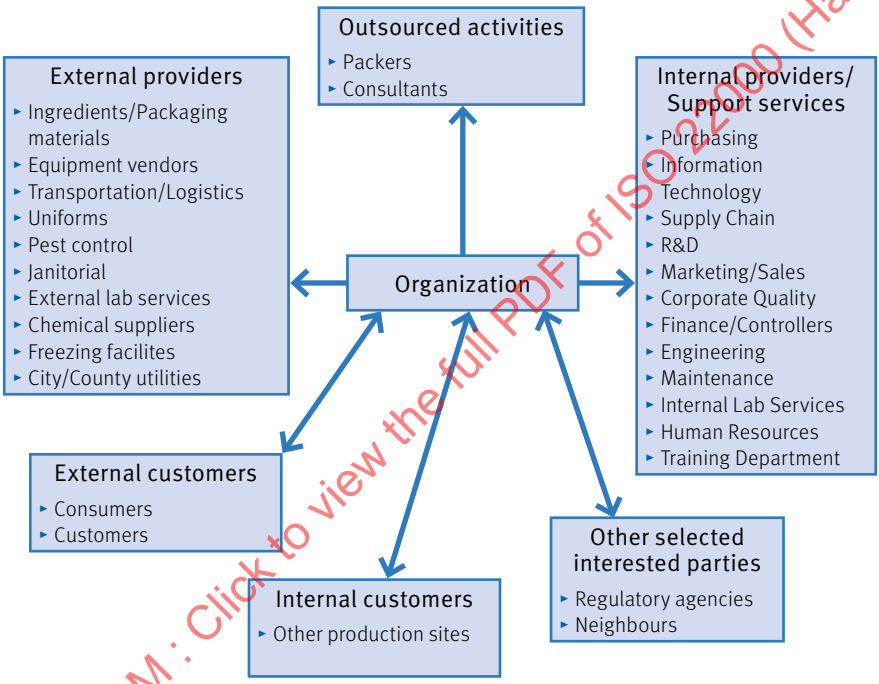

Figure 6: Example of identifying relevant interested parties for an organization

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

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

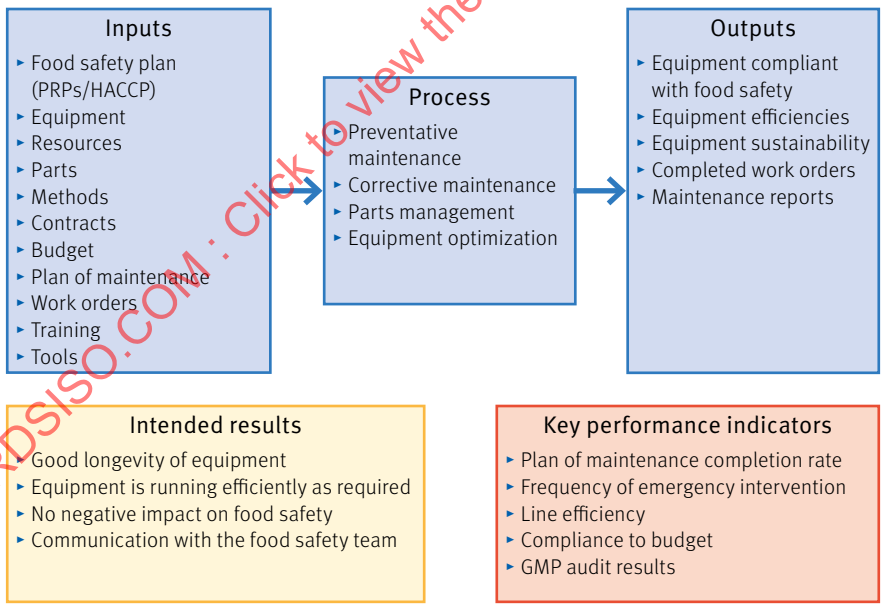

Figure 7: Example of a process (maintenance)

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 supplying

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).

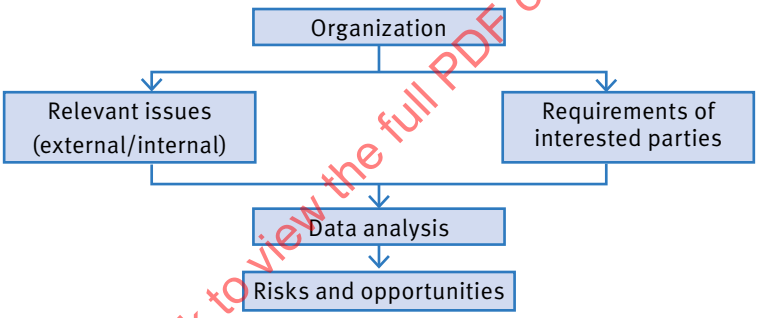

Figure 8 : Typical steps of identifying the risks and opportunities

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.)

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

- Have you documented your organization's food safety policy?
- Do you have objectives that are measurable, using indicators and are in line with the food safety policy?
- Have you planned the implementation of the organization's FSMS?
- Do you plan to use the food safety policy and the objectives of the FSMS to meet customer requirements? If yes, provide the details
- Do you plan to use the food safety policy and the objectives of the FSMS as a tool to make business decisions? If yes, provide the details

Task 3.2: Define and communicate the roles, responsibilities and authorities for personnel who have an impact on food safety

Reference:

ISO 22000:2018, Subclause 5.3

Your main aim should be to:

- Clearly define the roles, responsibilities and the authorities for those individuals who have an impact on food safety
- Communicate these responsibilities and authorities within the organization
- Appoint a person to take charge of the food safety team and define his/her responsibilities and authorities
- Ensure that any person who encounters a problem with the FSMS has the responsibility to report it to identified person(s)

Practical advice:

Top management should lead and play an active role in managing the FSMS, including:

- expressing its awareness of the food safety issues at stake in the business and clearly expressing its commitment through a policy on these issues
- employing and maintaining human resources with an adequate level oynowledge, leadership and expertise to ensure the organization's "food safety commitment" and granting the required financial resources to maintain food safety hazards within the determined acceptable levels
- setting up an appropriate management organization and highly efficient communication channels (internal and external) to achieve the set objectives
- personally chairing management reviews in order to ensure the continuous implementation of the FSMS within the organization and to establish new targets/objectives as necessary (this management step is dealt with in **Chapter 6**)
- ensuring that the food safety team and food safety team leader are appointed, and providing resources to establish, train and maintain the food safety team

This can be expressed as shown in Figure 9.

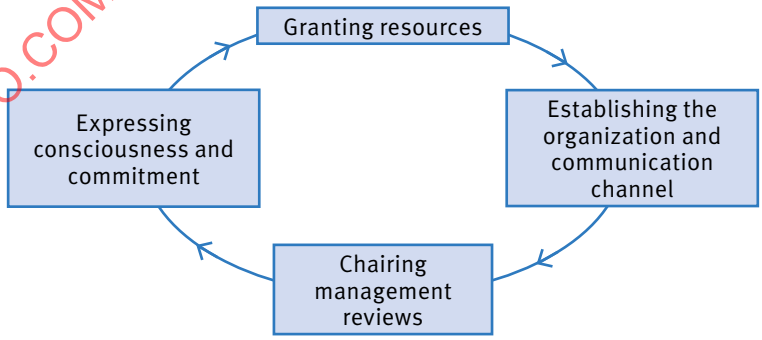

Figure 9 : Illustration of the top management's commitment

The key issue is to make sure responsibility levels are clearly determined, communicated and understood by all levels within the organization, including the food safety team and the food safety team leader.

Make sure that individuals are assigned to manage each of the food safety related roles. Assign deputies as a contingency plan. Ensure all processes/departments that have an impact on food safety are included (e.g. research and development, purchasing, sales, maintenance).

Ensure that the food-safety team is competent on food safety and the application of HACCP principles. In a small business, the manager or the owner may, also be the food safety team leader, provided that he/she has a basic knowledge of hygiene management and the application of HACCP principles.

Job descriptions and responsibilities should be kept up to date.

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

- Organizational chart
- Job definition and/or job description
- Procedures such as documents reflecting roles, responsibilities and authorities of the processes of the FSMS
- Matrix of skills (document indicating people's abilities to perform the tasks related to food safety in different areas)

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

- Do all of the personnel know and understand their responsibilities with regard to food safety?
- Do the individuals responsible for managing each of the food-safety-related functions have the responsibility and authority to take actions, and record them under the FSMS requirements (e.g. communication with authorities, products release, reworking or disposal of failing product, recall/withdraw)?

- Have you defined the responsibilities and the authorities for the team charged with food safety?
- Over time, have the responsibilities with regard to food safety changed, and have the job descriptions been revised accordingly?
- Has a member of the organization (e.g. the person responsible for food safety) been given the responsibility for establishing communication with external organizations for questions about food safety?
- Do you have a mechanism by which everyone can report food safety issues to the management?

Task 3.3: Manage staff skills/competencies

References:

ISO 22000:2018, Subclauses and Clauses 7.1.2, 7.1.6, 7.2 and 7.3

Your main aim should be to:

- Define the roles, responsibilities and authorities of the both internal personnel and external experts used to develop, implement, operate, maintain and evaluate the FSMS
- Identify personnel activities that have an impact on food safety
- Identify required competencies and acquired skills/competencies of persons, including external providers
- Prepare a training plan to eliminate any identified deficiencies in skills
- Evaluate the effectiveness of the training
- Keep contracts/agreements defining the competency, responsibility and authority of external experts

Practical advice:

Skills and competencies comprise combination of knowledge, ability and personal responsibility. Personal responsibility is key in respect of the rules of food safety. Job descriptions should include the skills, competencies and training requirements for each position.

Ensure that any training action is recorded, even if it is an internal session (e.g. tutoring, on the job training, mentoring, shadowing).

Develop a method to assess the competence of employees and external providers, in relation to food safety performance.

Assess the competence of new or temporary employees. In addition, the organization should periodically assess the competencies of existing employees with regards to food safety.

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

- Supporting information for food safety and HACCP training.
- List of resource capabilities and the identification of the need for external providers
- Competency planning, indicating what training on information is required, and to whom training should be given
- Competency scheduling, indicating when to conduct the training, the competency evaluation, and, where required, the re-evaluation
- Training plans and training request forms
- Matrix of skills/competencies
- Training attendance sheets/proof of training
- Curriculum vitae
- Evaluation reports for training effectiveness
- Skills evaluation interview

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

- Have you checked the external experts you are employing are competent and that records detailing the responsibility and the authority of these experts have been kept?
- Have you checked that the employees with activities related to food safety are well aware of their responsibilities and are competent to fulfil them?
- Do those employees with multiple responsibilities clearly understand them, and are they competent to fulfil all responsibilities in an effective and efficient manner?
- Have the employees requiring specialized training (e.g. those responsible for monitoring and corrective actions in the FSMS) received the training? Have you evaluated the effectiveness of the actions taken?
- Have you kept all records related to these skills?
- What actions did you take to acquire the necessary competencies? Have you evaluated the effectiveness of the actions taken?

Task 3.4: Provide resources for the FSMS (beyond personnel)

References:

ISO 22000:2018, Subclauses 7.1.3 and 7.1.4, and links to Subclause 8.2 (PRPs)

Your main aim should be to:

- Define the necessary infrastructure and work environment needed for the proper operation of the organization's FSMS
- Allocate and maintain material and financial resources on a long-term basis to ensure FSMS development and implementation
- Ensure (management) that the infrastructure and resource requirements have been satisfied

Practical advice:

Financial budgets are closely connected to food safety management issues, so it should be made clear that appropriate financial resources are granted when needed.

Financial resources should be allocated in time to build and maintain the system. For instance, understanding the latest food safety trends can be achieved by attending food safety meetings, food safety training and reading technical literature.

The infrastructure (facilities, equipment and services needed for the operation of the organization) will vary according to the specific activities and products of the organization, e.g. concerning open spaces, buildings, manufacturing equipment, vessels (ships), trucks, surrounding areas, pasteurizer, kneading machine, tank, software, water network, maintenance, pest control.

The work environment (conditions under which work is performed) can include physical, social, psychological and environmental factors (such as temperature,

lighting, recognition schemes, occupational stress, ergonomics and atmospheric composition). For example, a badly maintained ventilation system can result in a temperature that is too high and too much humidity.
The organization should have a plan in place when facilities need upgrading to meet food safety requirements.

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

- Financial plan for the organization's expenditures related to the FSMS (budget)
- Operational plans for improving the FSMS

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

- Are the required resources available for the FSMS?
- Is the necessary infrastructure in place to establish or maintain the FSMS?
- Have you supplied the necessary resources for the implementation, management, and maintenance of the work environment as required by the FSMS?

Task 3.5: Using externally developed elements for the organization's FSMS

Reference:

ISO 22000:2018, Subclause 7.1.5

Your main aim should be to:

- Identify elements within the FSMS to be established using externally developed element(s) (e.g. guidance documents, PRPs, hazard analysis, hazard control plan)
- Select the externally developed element(s) to be incorporated into the FSMS
- Determine if the externally developed element(s):
  - is (are) applicable to your site(s), process(es) and product(s)
  - was (were) developed in compliance with ISO 22000:2018 requirements
- Adapt the element(s) to your process(es) or documented information
- Implement, maintain and update the element(s) as part of the FSMS

Practical advice:

The option of using "externally developed combinations of control measures" (PRPs, OPRPs, CCPs) was included in ISO 22000:2005 specifically for small and/or less developed food businesses. ISO 22000:2018 has broadened this concept from "control measures" to any "element" of a FSMS to any food business.

Any element of a FSMS can be sourced externally (e.g. training programme, competence evaluation approach, recall procedure, traceability system, hazard analysis, PRP, hazard control measure). If this is carried out, then the element must be adapted to the organization's specific requirements. Sources for externally developed elements can include industry associations, universities, governments and other relevant sources of knowledge. All externally developed elements must

demonstrate that they were developed in compliance with the requirements of ISO 22000. This is particularly important with respect to externally developed elements associated with the requirements in Clause 8 of ISO 22000.

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

- List of external reference documents consulted
- Communications (e.g. e-mails, letters, notes of telephone calls) with external parties/contributors
- Documents of external origin to support the conformity of the externally developed element(s) of the FSMS
- Documents of internal origin to support the adaptation, maintenance and updating of the externally developed element(s) of the FSMS
- Notes/minutes of internal/food safety team meetings

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

- Have you identified the element(s) within the FSMS that are based on externally developed information?
- Has the external party/contributor provided your organization with enough information to demonstrate that it conforms to the requirements of ISO 22000? For example, has the external party/contributor provided information on the competence of its equivalent function to the food safety team, a detailed hazard analysis, the basis for its determination that the hazard control measures are valid, etc.?
- If you are using externally developed element(s) as a basis for your hazard analysis and/or for establishing PRPs or hazard control measures, have you ensured that your food safety team can access updates to this(these) element(s) if it(they) is(are) provided by the external party/contributor?
- Have you adapted the elements to your specific requirements (e.g. processes, products)?

Task 3.6: Control the externally provided processes, products or services

References:

ISO 22000:2018, Subclauses 7.1.1 to 7.1.6, and links to Subclause 8.1 (operational planning and control)

Your main aim should be to:

- Identify externally provided processes, products or services
- Define the methods for controlling externally provided processes, products or services so that objectives and plans can be met
- Record these methods of control

Practical advice:

There are many externally provided processes, products or services that have an impact on food safety for organizations, e.g. pest control, cleaning and disinfection (sanitization), transportation, storage, packaging and repackaging of products, food safety training, laboratory analysis, calibration of testing equipment, maintenance of infrastructure.

The organization needs to ensure that externally provided processes, products or services are controlled using identified criteria (e.g. specifications, use of certified providers, supplier audits) and will not adversely affect its ability to consistently meet the requirements of the FSMS. It should be noted that the extent of mutually agreed requirements related to the externally provided processes, products or services, will depend on their importance, impact on the FSMS and the competence of the provider.

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

- Documented information, including requirements, for qualifying providers
- Control for externally provided processes, products or services (e.g. trend analysis of data, audits and certification requirements for externally provided processes, products or services)
- Contractual agreements with external providers defining food safety related criteria, which include the roles and responsibilities between the organization and the provider (e.g. who is responsible for supplying raw materials, packaging, testing and release of products, filing production records)
- Warranty statement from the providers
- List of externally provided processes, products or services
- Selection and monitoring criteria for external providers
- Evaluation records of external providers against the set criteria
- List of approved external providers
- Monitoring records of external providers against the set criteria

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

- Have you defined the products, documented information, processes, and production sites covered by the FSMS?
- Have you defined the externally provided processes, products or services and requirements that have an impact on food safety?
- Have you kept records on the control of externally provided processes, products or services?

Task 3.7: Establish and maintain external and internal communications

Reference:

ISO 22000:2018, Subclause 7.4

Your main aim should be to:

- Communicate the pertinent information to the interested parties (see **Task 2.2**) involved in food safety (external and internal)
- Maintain and use records for external and internal communications
- Ensure the team in charge of food safety is informed in a timely manner of modifications that may affect the FSMS

Practical advice:

The purpose of any communication is to distribute information.
Communication should ensure that there is a proper transfer of information between interested parties and within the organization.
Communication should include a feedback mechanism, a review cycle and provisions to proactively address changes in the organization's environment.
The organization's communications process should operate both vertically and horizontally, and should be tailored to the differing needs of its recipients. The communication process should address the issues of:

- ensuring effective two-way communication
- enhancing trust and credibility
- involving, where appropriate, relevant interested parties in the process
- adjusting or modifying the communication programme as needed based on system reviews

The organization shall make sure that channels of external communication and internal communication are identified and managed. Appointed persons shall have defined responsibilities and authorities for the communication of any information regarding food safety.

A communication plan can be used to cover both external and internal communications and should include, at least:

- by whom (the sender)
- who (the addressees)
- what (the message to be delivered)
- how (how the message is sent)
- when (the timing)
- why (the purpose)

Communication methods can include e-mails.

External communication

External communication is an exchange of information related to food safety between the organization and external organizations (e.g. with clients, suppliers, statutory or regulatory authorities). This could be achieved either by contract or by other means. It should concern the level of food safety (information on hazard control along the food chain) and the ability to deliver the product to the agreed requirements.

Internal communication

Internal communication should not be taken for granted. Communication is based on the transmission of information and, as such, it is essential to ensure that the message has been received and fully understood.

The internal communication system of the organization should ensure that sufficient, relevant information and data are available to all personnel involved with the various operations and procedures.

During the development and launch of new products, communication to involved personnel within the organization should be carried out in a clear and timely manner. This also applies to intended changes in raw materials, ingredients, production systems, processes, technologies, suppliers and customer requirements. In particular, attention should be given to the communication of changes in statutory and regulatory requirements, new or emerging food safety hazard(s), and the method of control of these new hazards.

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

- Internal communication methods that allow the food-safety team to be informed of changes (e.g. raw materials, ingredients, services, products, procedures, equipment, cleaning and disinfection products, regulations)
- Documents that describe how communication should be conducted for external and internal communication, including the interfaces between these two groups
- Procedure for handling customer and consumer complaints, and subsequent communications with consumers
- E-mails (which may require storage in specified files for audit purposes)
- Notes/minutes of internal/food safety team meetings
- Records of external communications
- Records of internal communications needed for management review
- Communication plan(s)
- Minutes of the management-review meeting
- An updated record (list) with contact information for internal communication
- An updated record (list) with contact information for external communication

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

- Have you put into place effective arrangements to communicate with external parties about food safety matters?
- Have you put into place effective arrangements to ensure that information on food safety matters (notably concerning changes) is supplied in a timely manner to the team?
- Have you kept records of communications (external and internal) on food safety matters?
- Have you verified the effectiveness of your communications (external and internal)?

Task 3.8: Manage the documentation of the FSMS

Reference:

ISO 22000:2018, Subclause 7.5

Your main aim should be to:

- Identify and implement the relevant documented information required for the effective management of the FSMS:
  - documented information required by ISO 22000
  - documented information needed by the organization
  - documented information required by statutory, regulatory authorities and customers
- Have a system in place to save and back-up electronic data

Practical advice:

"Documented information" means information required to be controlled and maintained by an organization and the medium on which it is contained (e.g. procedures, instructions, specifications, forms for recording information, records, documents arising from regulations, products specifications, the food safety policy). The list should be approved by the food safety team.

The management of documented information must be applied to both internal and external documents.

Documented procedures should clearly define how documented information should be changed, how long and how they should be stored, and how they are to be destroyed. Records of destruction should be documented. A documented procedure for the creation, update and control of documented information, which can include a standardized format for procedures and work instructions, could help the organization in the management of the documentation.

The retention time for documents and records must be defined by the organization and, at least, meet applicable laws and regulations.

A key issue for any management system is to make sure that the type and extent of documented information fits with the organization's size and the complexity of its activities.

All documented information should respect the rule of the 3 U's: useful, useable and utilized.

Sources of external documented information should be identified, e.g. legislation, keeping a list of useful websites or publishing bodies. Organize an identification system for your external documented information, e.g. date of receipt, a simple document code.

When controlled documented information is kept electronically, any printed documents should have a disclaimer that they are not controlled, and the only controlled documents are those kept on the computer server. In any case, the electronic data should be secured (e.g. password protected against alteration, backed-up).

The distribution of documented information needs to be controlled. You need to decide who should receive documents and to define where the master copy is kept.

Keep documented information (documents and records) accessible to the food safety team and other impacted people involved in the organization's FSMS. Regularly review your external documented information to ensure that you have the current versions.
A failure in documented information control and record may lead to a failure in the FSMS.

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

- Documents of external origin sustaining PRP programmes
- Protocol for saving electronic data: organizations must comply with appropriate laws and regulations regarding the saving and storage of electronic data
- Documented information required by ISO 22000
- List of applicable external and internal documents
- Review of internal audits on documented information control and follow up actions regarding any changes to documentation requirements

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

- Have you documented the FSMS?
- Do you have all the documented information required to demonstrate the development, implementation and efficient updating of the FSMS?
- Is the documented information in compliance with appropriate laws and regulations?
- Do you have full control over your documented information (documents and records)?
- Do your designated employees have access to the most recent versions of the documents and record forms?
- Are you sure that people understand and use the current version of documented information and, for records, how they should be completed?

Task 3.9: Plan what to do in case of emergency situations and potential incidents

References:

ISO 22000:2018, Subclause 8.4, and links to Subclause 8.9.4 (handling of potentially unsafe products)

Your main aim should be to:

- Define the actions to be taken to deal with emergency situations or potential incidents that have an impact on food safety
- Ensure that pre-established mechanisms are in place to effectively handle an emergency situation

Practical advice:

Emergency situations and potential incidents can be of very different natures, e.g. a disruption in the supply of raw materials, a break-down or accident, a strike by personnel, natural disasters, and a loss of utilities such as water and energy supplies. In ISO 22000, emergency preparedness addresses situations that could lead to unsafe food (see Subclause 8.4) and how to handle a potentially unsafe product (see subclause 8.9.4).

These mechanisms enable the personnel confronted with emergency situations and potential incidents to be aware of the procedures to be followed, and thereby to avoid improvisation.

The organization should be aware of potential emergency situations, which can include fire, flooding, bioterrorism and sabotage, energy failure, vehicle incidents and contamination of the environment.

In the context of ISO 22000, a minimum emergency response includes:

- communicating to the relevant staff and external organizations (e.g. authorities, fire brigade, media) according to the emergency procedure(s)
- identifying the product/area affected by the emergency situation, including any potential contamination by the first responders, e.g. firefighters, rescue team
- handling product(s) as potentially unsafe products (see Subclause 8.9.4 of ISO 22000)
- evaluating and restoring the affected area through correction and corrective action process (see Subclauses 8.9.2 and 8.9.3 of ISO 22000)
- communicating to customers, if impacted

Simulation (mock) exercises should be used to verify the effectiveness of the emergency procedure response. The complexity of such exercises should be proportional to the complexity and the size of the organization, and the role in the food chain.

The emergency plan may include the possibility to divert production/service to another facility, if feasible.

Product withdrawal/recall is described in **Task 3.10**.

Following all genuine or simulated/mock emergencies, the emergency preparedness team should meet to evaluate performance as part of the continual improvement process.

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

- Emergency preparedness plan (with an up-to-date list of the team responsible for managing possible emergency situations and potential incidents, including the composition, organization and contact details).
- Minutes of the meetings held in relation to the preparation of action plans for diverse types of emergency situations and potential incidents (e.g. roles and missions, simulation exercises, training).

- Records of practice exercises conducted according to the defined planning, and of the implementation and the effectiveness of the emergency preparedness plan

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

- Has the organization appointed an emergency response team and defined the contact details?
- Have you identified emergency situations and potential incidents?
- Have you formally defined the mechanisms (including a contact list) to confront food safety problems arising from emergency situations and potential incidents?
- Is the documented information for emergency response kept up to date?

Task 3.10: Develop, implement and test plans for the withdrawal/recall of products

References:

ISO 22000:2018, Subclause 8.9.5, and links to Subclause 8.3 (traceability)

Your main aim should be to:

- Define mechanisms to ensure an effective and efficient product withdrawal/recall whenever required for food safety issues

Practical advice:

Product withdrawal/recall can be very chaotic. Therefore, organizations should develop a withdrawal/recall plan that addresses all the activities that have to be conducted during the withdrawal/recall.

For example:

- making a decision to initiate a withdrawal/recall
- developing a plan to effectively recover products that have left the control of the organization
- developing a plan to inform customers and the media about the withdrawal/recall
- informing regulatory agencies of the withdrawal/recall
- developing a plan to determine the effectiveness of the withdrawal/recall
- developing a plan to handle and properly dispose of unsafe products

The key steps in conducting a successful withdrawal/recall, which should be also included in the execution of the mock withdrawal/recall, are:

- convening a withdrawal/recall committee
- assessing the hazard
- determining the nature of withdrawal/recall
- determining who should be notified of the withdrawal/recall
- determining the mechanics of notification and recovery
- post-withdrawal/recall reporting

An efficient and effective system of traceability is indispensable when carrying out a product withdrawal/recall.

The organization must be compliant with all regulatory requirements for withdrawal/recall. These requirements may include contacting regulatory authorities, informing customers of the withdrawal/recall, conducting the withdrawal/recall, and keeping records to determine the effectiveness of the withdrawal/recall. If the organization exports food, withdrawal/recall plans should be developed to enable the withdrawal/recall of products in the targeted export countries.

Personnel with the authority to launch a withdrawal/recall should be identified.

The organization should define and maintain a contact list for the withdrawal/recall activities (e.g. distributors, wholesalers, retailers, storage and distribution network, suppliers, authorities, the media).

Personnel executing the withdrawal/recall should be designated, trained and competent.

Establish documented information for handling unsafe products that are impacted by the withdrawal/recall:

- from sources beyond the control of organization (e.g. distributors, wholesalers, retailers, consumers)
- from sources under the control of the organization, including in-stock products (e.g. storage and distribution network)

Ensure that the product does not accidentally re-enter the food chain and does not contaminate other foods during handling.

A simulated/mock withdrawal/recall should be used to verify the effectiveness of the withdrawal/recall mechanism. The organization should identify performance standards to conduct a simulated/mock withdrawal/recall (e.g. the number of hours required determine the location of the product involved in the withdrawal/recall). The organization should ensure that it can conduct a simulated/mock withdrawal/recall by tracing one step backwards to the supplier and one step forward to the customer.

For a mock withdrawal/recall, there is no need to directly involve the customers or authorities, but to test just the interfaces with customers and authorities. Following a genuine or simulated/mock withdrawal/recall, the withdrawal/recall team should meet to evaluate performance as part of the continual improvement process (communication, quantity and location of withdrawn/recalled products, efficiency).

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

- Documented information describing the withdrawal/recall mechanisms (what to do, who, when and how)
- Updated contact information of all members of the withdrawal/recall team
- Updated record (list) of external contacts (both suppliers and customers)
- Documented information for handling unsafe products impacted by the withdrawal/recall
- Records of each withdrawal/recall event (including the cause, extent and success of withdrawal/recall)
- Evaluation at regular intervals of the effectiveness of the withdrawal/recall mechanism
- Meeting minutes from all post-withdrawal/recall reviews
- Copy of media releases, if relevant

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

- Have you defined the mechanism to ensure the withdrawal/recall of products?
- Has the withdrawal/recall procedure been tested for effectiveness?
- Are the contacts for withdrawal/recall valid and up to date?

Chapter 4

The implementation of prerequisites: PRPs and the traceability system

Key points

Before beginning this chapter, you must have implemented the elements from Chapter 3.

After setting the management requirements of the FSMS, the organization now has to focus on the requirements related to implementing the PRPs and the traceability system.

Objectives of this chapter

PRPs constitute the basic conditions and activities necessary to ensure hygienic conditions for the safe production of food. If PRPs are properly implemented, maintained and verified, it is possible to reduce the likelihood of a hazard occurring to the product.

PRPs consist primarily of good practices such as GAP, GHP and GMP. The correct selection of the appropriate good practices depends on where the organization is located in the food chain.

If PRPs are either poorly, or not implemented, the achievement of a safe product is highly unlikely.

In order to ensure the correct implementation of PRPs, you should follow a rigorous method. This chapter provides the main guidelines.

The hazard control plan cannot be developed before PRPs are defined, implemented and a traceability system is established.

- **Task 4.1**: Identify the PRPs required by the organization
- **Task 4.2**: Review the PRPs in place in the organization (applicable to existing organizations)
- **Task 4.3**: Implement the PRPs
- **Task 4.4**: Monitor the PRPs, when relevant
- **Task 4.5**: Verify that established PRPs are applied effectively
- **Task 4.6**: Develop methods or a system for product traceability

Task 4.1: Identify the PRPs required by the organization

Reference:

ISO 22000:2018, Subclause 8.2

Your main aim should be to:

- Establish a justified list of the PRPs required by the organization (see Subclause 8.2.4 of ISO 22000)
- In the context of ISO 22000, the terms 'facilities' and 'utilities' are used
- "facilities" means a group of buildings or equipment to serve a particular function (e.g. lavatories, catering, cloakroom, laboratory) used for specific operations at one geographic location
- "utilities" means ancillary services needed in the operation of a process, such as steam, water, electricity, cooling water, demineralized water, compressed air, refrigeration and effluent disposal

Practical advice:

The list of PRPs required by the organization should be drawn up in a methodical manner, and by consulting identified reference documents relevant to the type of product and/or step in the food chain, such as:

- Codes of Hygiene Practice of the Codex Alimentarius Commission, e.g. General Principles of Food Hygiene (CXC 1-1969)
- applicable regulations, regulatory requirements and rules of the organization's home country and/or export destination(s)
- PRP documents published in the ISO/TS 22002 series, which provide the PRPs required in various parts of the food chain
- published professional guidance documents
- customer requirements, if applicable (e.g. as listed in contracts, specifications and product safety standards, or in the results of customer audits)

Note: The organization shall establish, implement, maintain and update PRPs to facilitate the prevention and/or reduction of contaminants (including food safety hazards) in the products, product processing and work environment. Consideration should also be given to other issues potentially related, but not directly involved in, food safety (e.g. food spoilage).

Note: If an organization is seeking private-sector certification based on ISO 22000, it may have to meet PRP requirements based on the ISO/TS 22002 series, and other requirements of the schemes.

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

- List of external reference documents consulted
- Documents of external origin to support PRPs
- List of identified PRPs

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

- Have you listed the external reference documents that enable the identification of PRPs (e.g. regulations, client/customer requirements, ISO documents, Codex Alimentarius documents, professional guidance documents)?
- Have you made a list of the PRPs that apply to your organization?
- Have you formally documented the PRPs currently applied?

Task 4.2: Review the PRPs in place in the organization (applicable to existing organizations)

Reference:

ISO 22000:2018, Subclause 8.2

Your main aim should be to:

- Conduct a gap analysis in order to identify potential missing PRPs (see **Task 4.1**), e.g. design of the premises, supply of air, water, energy). If there is a gap, complete the list of applicable PRPs with missing (or not adequately implemented) PRPs
- Formulate a what-to-do list or check-list for the implementation of missing or inadequately implemented PRPs
- Communicate the PRPs to be applied to the personnel involved

Effective PRPs are essential for the FSMS. Many recalls/outbreaks are caused by the failure of PRPs.

Practical advice:

The gap analysis should be made by the food safety team in a systematic methodical manner.
Assign the responsibility of managing each of the defined PRPs to relevant personnel (see Subclause 7.3 of ISO 22000).

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

- Documented information of an external origin that supports PRPs
- What-to-do list or check-list to ensure the implementation of selected PRPs
- A document recording the results of the PRP comparison and the action plan (this should be included in the organization's documented information)

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

- Have you identified all the relevant PRP's required within your organization?
- Is there an action plan for implementing the missing PRPs?
- Are all PRPs listed in the organization's documented information and approved by the food safety team?
- Have the relevant PRPs been communicated, and the applicable training provided within the organization?

Task 4.3: Implement the PRPs

References:

ISO 22000:2018, Subclause 8.2, and links to Subclause 8.8.1 (verification)

Your main aim should be to:

- Design or describe the documented information (procedures and instructions) for each of the PRPs identified, then communicate these to the personnel involved
- Implement and maintain PRPs
- Review and update the PRPs, as required
- Ensure communication of the PRPs at appropriate levels
- Assign responsibilities and procedures for corrections and corrective actions in case of non-compliance
- Review and identify gaps in implementation
- Establish verification mechanisms (**Task 4.5**)

Practical advice:

Check all relevant documented information regarding the implemented PRPs exists and is applied.

Examples of documented information include:

- cleaning and sanitizing procedures
- staff hygiene instructions
- pest control programme
- conditions for storage
- site and equipment maintenance plans
- where applicable, assess the efficiency of the PRPs

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

- Documented information (procedures and instructions) specifying the PRPs, including monitoring procedures (see **Task 4.4**), where applicable, and verification plans (see **Task 4.5**)
- List of implemented PRPs
- Records related to the implementation of PRPs

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

- Has the implementation plan been drawn up for all established PRPs?
- Have the applicable PRPs been communicated by the food safety team, and implemented within the organization?
- Has documented information been established for all PRPs?

Task 4.4: Monitor the PRPs, when relevant

Reference:

ISO 22000:2018, Subclause 8.2.4

Your main aim should be to:

- Identify those PRPs where monitoring is feasible and relevant
- Establish procedures that are appropriate and sufficient for monitoring the identified PRPs, i.e. what, how, when and by whom?

Practical advice:

Identify the PRPs that should be monitored. An incorrect implementation of some PRPs may lead to potentially unacceptable products, e.g. cross-contact with allergenic food, insufficient cleaning and sanitation of surfaces in contact with ready-to-eat foods.

Establish appropriate monitoring i.e.:

- monitoring should be based on the parameters established for managing the PRP, if any

- the monitoring parameters should be measurable and/or observable
- when such parameters are exceeded, the process/operation should be adjusted
- the method and frequency of monitoring should be sufficient to enable the detection of an ineffective implementation of the PRPs
- the monitoring results should be kept as documented information

As an example, a PRP monitoring plan could address:

- the PRP
- parameters or characteristics to be controlled
- criteria (when relevant):
  - upper specification
  - lower specification
- control factors (when relevant):
  - upper limit
  - target
  - lower limit
- measurement (when relevant):
  - person responsible
  - sample size
  - sample frequency
  - handling requirements

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

- List of PRPs where monitoring is feasible and relevant
- Procedures that are appropriate and sufficient for monitoring the identified PRPs (what, how, when and by whom)

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

- Have you listed the PRPs where monitoring is feasible and relevant?
- Do you have procedures that are appropriate and sufficient for monitoring the identified PRPs, i.e. what, how, when and by whom?

Task 4.5: Verify that established PRPs are applied effectively

References:

ISO 22000:2018, Subclauses 8.2.4 and 8.8

Your main aim should be to:

- Define suitable methods and frequency for the verification of the applied PRPs
- Verify on-site the effective implementation of the applied PRPs
- In the case of non-compliance of a PRP, define the actions that should be taken to avoid repetition of the non-compliance

Practical advice:

When an organization moves from a GHP/GMP-based system to a FSMS, a hazard analysis is required. In the FSMS, most of the GHP/GMP are likely to continue as PRPs and the organization may be required to implement new PRPs.
The objective of the PRPs' verification is to confirm that all the PRPs are implemented and operating as intended.

The verification should be made on-site by identified trained personnel under all operating conditions. They should be independent of the PRPs being verified, although they may be from the same work area or department.

The assessment of existing PRPs by the organization should be made through:

- interviewing the manager(s) responsible for food safety operations
- examining the available documented information (procedures, instructions and/or other documents)
- examining the application of relevant existing practices

Examples of verification methods:

- visual site inspection
- environmental sampling (followed by testing and review of the results)
- microbiological sampling (followed by testing and review of the results)
- checking monitoring records (e.g. temperature)

Note: Internal audits can also be used.

The frequency of verification can be based on several factors, such as the variability of PRPs, variability and/or stability of the process, impact of correction time needed, feasibility, etc.

The verification results have to be documented.

Depending of the results of verification, it may be necessary to review the PRPs in place in the organization (see **Task 4.2**).

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

- Results of the verification made for each identified PRP
- A report on the food safety audit or the compliance/non-compliance of the application of the PRPs
- Record(s) of actions taken in cases of non-compliance regarding the application of the PRPs

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

- Have you verified the effective application of all identified PRPs?
- Are the PRPs functioning as planned? If yes, how do you know?

Task 4.6: Develop methods or a system for product traceability

References :

ISO 22000:2018, Subclause 8.3

Your main aim should be to:

- Define the mechanisms for ensuring the traceability of the lots/batches of end products (see Subclause 3.15 of ISO 22000)
- Verify the effectiveness of the product identification and product traceability system

Practical advice:

Traceability allows organizations to track their end products forward, and raw materials, packaging or ingredients back through the supply chain. It is considered as a basic element for food safety.

Note: Guidelines on traceability are also provided by ISO 22005:2007, *Traceability in the feed and food chain — General principles and basic requirements for system design and implementation.*

The following terms are associated with a traceability system:

- external traceability: traceability between organizations (one step back, one step forward) providing the ability to identify the immediate, previous supplier of goods/units and the next immediate customer

Note: External traceability requirements do not include the final consumer.

- internal traceability: traceability inside the organization, i.e. the ability to follow the movement within a single organization

Note: Within an organization, the transport or transfer steps are covered by the internal traceability of the organization that has the ownership of the goods/units (e.g. products, materials, reagents).

The size and nature of a lot/batch for each manufactured product is established by the manufacturing organization.

The organization shall have a system for traceability enabling the identification of product lots/batches or logistic units, their relation/link to lots/batches of raw materials/products, processing, delivery records, and shipping information and/or invoices.

Traceability records shall be retained for a defined period, which should be, at minimum, the shelf-life of the product plus any extra time required by the organization, customer, or statutory and regulatory requirements. They should be readily available for system assessment to enable the identification and location of potentially unsafe products in the event of a product withdrawal/recall (see Subclause 8.9.5 of ISO 22000 and **Task 3.10**). Records should be in accordance with the organization's document control programme (see Subclause 7.5.3 of ISO 22000 and **Task 3.8**).

Traceability systems are tested through a traceability test/mock withdrawal/recall. Records of these tests should be retained.

Note: Traceability is essential for conducting an effective withdrawal/recall.

The organization should establish a format for traceability information and its flow (electronic or paper). This information may include:

- identification of organizations involved
- identification of products
- identification of logistics units (e.g. batches/lots, pallets, containers, bulk)

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

- Documented information (procedures) describing the identification system of the product/lot code and traceability
- Results of the evaluation tests for the effectiveness of the traceability system as an input for the management review
- Records/data used for traceability purposes (e.g. production sheets, delivery codes, packing records, lot codes, invoices). These may be hard copies or electronic copies

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

- Have you defined the mechanisms to ensure the traceability of the products (external and internal traceability) and the related documented information (records)?
- Does the traceability system meet regulatory requirements (if applicable)?
- Is verification of the effectiveness of the traceability system by internal audits foreseen:
  - Is your traceability system effective?
  - Is the traceability system efficient?
  - Can the traceability system be sustained?

Chapter 5

Hazard control: control of significant food safety hazards by OPRPs and/or at CCPs

Key points

Refer to the chosen PRPs described in Chapter 4.

While PRPs and hazard control measures are applied simultaneously in organizations, it is optimal to apply them sequentially. Therefore, the chosen PRPs must be considered before proceeding to the hazard analysis. On this basis, control measures targeted at significant food safety hazards that might still need to be controlled are then developed.

Objective of this chapter

This chapter explains how potential hazards are identified and describes how they are evaluated to determine which hazards are significant and must be controlled to ensure food safety. It also gives information on how control measures may be validated and implemented to prevent or reduce the hazards to an acceptable level in the end product.

Since they are not targeted to specified hazards, PRPs minimize the overall load of contaminants. This is achieved by creating an environment for the production of safe food. For example, in the case of microorganisms, a reduction of these affects the load of pathogenic (hazards) and non-pathogenic bacteria. In the case of chemical contaminants, PRPs can minimize those that are toxic and those that only affect organoleptic properties. Thus, PRPs contribute to the safety and suitability of the food.

Examples of potential hazards that can be identified at unacceptable levels are:

- biological hazards: pathogenic microorganisms (bacteria, moulds, viruses, parasites), toxins, etc.
- chemical hazards: natural or acquired toxins, allergens, residues, excess additives, contaminants released by process equipment such as coolants and lubricants, etc.
- physical hazards: foreign bodies: glass, bone or insect debris, metal fragments, hard plastic, etc.
- any other hazards identified by regulatory agencies or customers

CCPs, OPRPs and PRPs are all essential for the safety of the food. If OPRPs and CCPs are not controlled, the resulting food is potentially unsafe, and corrections and corrective actions need to be taken.

When applying this chapter, it must be understood that control measures linked to CCPs are those that can be monitored in a timely manner to allow for an immediate correction and where the result of the measurement can be checked against a critical limit.

Any other control measures identified by hazard analysis shall be categorized as OPRPs.

- **Task 5.1**: Establish the food safety team
- **Task 5.2**: Provide the information needed to conduct the hazard analysis
- **Task 5.3**: Prepare the process flow diagram
- **Task 5.4**: Identify the hazards associated with the food
- **Task 5.5**: Conduct a hazard assessment
- **Task 5.6**: List and select the control measure(s) or combinations of control measures
- **Task 5.7**: Categorize, manage, monitor and document the control measures
- **Task 5.8**: Validate the control measure(s) or combination(s) of control measures
- **Task 5.9**: Establish and apply corrections and corrective actions

- **Task 5.10**: Control monitoring and measuring (operational processes)
- **Task 5.11**: Conduct a verification related to the PRPs and hazard control plan
- **Task 5.12**: Update the preliminary information

Tasks 5.1 to 5.5 and 5.11 to 5.12 are always required.

Task 5.1: Establish the food safety team

References:

ISO 22000:2018, Subclauses 5.3.1 c) and 5.3.2, and links to Subclauses 7.1.2 (people) and 7.2 (competence); *General Principles of Food Hygiene, CXC 1-1969*: HACCP step 1

Your main aim should be to:

- Create or re-establish the food-safety team
- Appoint a person responsible for the team, with the necessary responsibilities and authority (see **Task 3.2**)
- Ensure the food-safety team members are properly trained
- Identify the competencies of the team members (products/processes/equipment and hazards)
- Keep records

Practical advice:

The food safety team is in charge of all the tasks covered in this chapter. Establishing the team is a crucial starting point, since the quality of the work produced will be highly dependent on how it is set up.

The key step is to identify the competences needed in order to involve the appropriate people (see **Task 3.3**). The team should consist of people who have knowledge

of the product, associated hazards, technology and associated equipment (the traditional HACCP team). In addition, the team should know and understand the principles of food safety management and the HACCP approach.

The team should be provided with documented information, including the legislation/regulations of the country of manufacture and, in export countries, guides to GHPs and technical literature. For example, a typical team for a small or medium-sized organization would consist of a production manager, a person skilled in FSMSs including HACCP, and any other personnel possessing sector/product-specific competencies. If external assistance is required, refer to Subclause 7.1.2 in ISO 22000.

Top management shall assign the responsibility and authority for appointing the food safety team and the food safety team leader (see **Task 3.2**). It may be appropriate to issue a formal statement and communicate this statement throughout the organization. Generally, the team will be more effective if it can stay independent of hierarchical pressures. This means that it is rarely appropriate for the organization's chief executive to be a member of the team, except in very small organizations.

The food safety team leader and the food safety team members should attend every meeting. The team organizes how it operates. It may invite people with the competencies needed to contribute and create working groups to help it to complete certain tasks. Depending the organization, it may be necessary to appoint an external consultant/expert with the appropriate competencies (see Subclause 7.2 in ISO 22000). In this case, the organization must clearly define the responsibilities of the consultant.

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

- Statement establishing the food safety team and the appointment of the food safety team leader
- List of members of the food safety team (including internal and external experts)

- Description of the food safety competencies of the team
- Training records for all food safety team members
- Notes/minutes of food safety team meetings
- Contracts with external consultants/experts

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

- Is the list of food safety team members up to date?
- Does the food safety team have the appropriate knowledge and experience?
- If an external consultant/expert is used, does he/she have the appropriate knowledge and experience in the food sector? And how can you prove this?

Task 5.2: Provide the information needed to conduct the hazard analysis

References:

ISO 22000:2018, Subclause 8.5.1 (from Subclauses 8.5.1.2 to 8.5.1.4)
General Principles of Food Hygiene, CXC 1-1969: HACCP steps 2 and 3

Your main aim should be to:

- Gather and organize all relevant data and information to the extent needed to conduct a complete hazard analysis. You should at least:
  - list all the raw materials, ingredients and materials in contact with the product
  - list the end products or categories of end products
  - document the characteristics for raw materials, ingredients and materials in contact with the products
  - document the characteristics for end products

- define the product's intended use, the reasonably expected handling conditions or its improper use
- define the targeted population (particularly vulnerable groups, e.g. infants, the elderly, immune-compromised, pregnant women)
- update all relevant data and information needed to conduct a complete hazard analysis

In order to prepare the flow diagram (see **Task 5.3**), it is advisable to collect information regarding the process.

Practical advice:

This description should help in identifying the hazards to be controlled and the appropriate control measures. This is a pivotal step towards designing and implementing the FSMS. It is a key determinant of the hazard analysis and identification of OPRPs and CCPs.

The team should first describe the product. "The product" includes raw materials (including packaging materials), semi-processed products and end products. The description includes information relevant to the hazard analysis: product composition (physical, chemical and biological characteristics), processing to obtain the end product, shelf-life information, packaging material, packaging conditions, labelling instructions, distribution channels, intended use, and reasonably expected mishandling and/or misuse by consumers.

The team should seek information about the origin* of raw materials to determine:

- if they originate from a region where specific contamination can arise (e.g. aflatoxin in cereals or peanuts, hepatitis virus on berries or in seafood)
- if the region of origin is considered to be free from a specific hazard
- if the transport conditions protect the raw material against contamination, e.g. by allergens
- the previous processing of the product

- if the established product specifications directly or indirectly indicate the hazard levels
- if the supplier has a formal FSMS in place

* The origin refers to a place, a location from where the raw materials, ingredients and materials in contact with the products come. It can be called "provenance".

In cases that could be confusing (e.g. with substitute ingredients), the description also has to include information about the source (animal, mineral, vegetable) from which it has been extracted and that has given it its nature and its special characteristics, including specific hazards.

The team should also describe the conditions for microbiological growth such as pH, water activity α_w (*), the presence of antimicrobial agents or the salt/sugar content of the end product.

(*)α_w = the ratio of the amount of free water in a foodstuff and expressed on a scale of 0 to 1 where 1 represents pure water

Examples of α_w values:

- fresh fruit, meat, milk: 0,95 to 1,0
- salted meat: 0,8 to 0,85
- cookies: 0,3

The team should investigate the transportation and storage conditions used for the determination of shelf-life or durability dates. These are based on the end user (subsequent processor or consumer, including at the consumer's home), and on information about the use of the product (e.g. how the end product is cooked before consumption).

For highly perishable products, the team must ensure that the chill/cold chain is in place from the organization to the consumer.

For food intended for purchase by another organization in the food chain, the team should also describe the expected use by that organization.

For food intended for purchase by the consumer, the team should also describe the expected mode for consumption and consumer categories. Part of this process

is to determine whether consumers could consume the product raw or under-cooked, despite the labelling recommending that it should be well cooked. The team should also determine if the product is intended to be consumed by at-risk groups such as infants, the elderly, pregnant or immuno-compromised people, or animals with specific needs/cares.
Products could be grouped into similar families of products depending on the ingredients, processes and/or hazards.

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

- End product specification: raw material, ingredients, product-contact material, packaging, allergen status
- Identification of statutory and regulatory food safety requirements.
- Supplier specifications
- Technical files of raw materials, ingredients, intermediate/semi-processed products and end products
- Certificates of compliance for packaging
- Certificates of conformity of food contact materials
- Intended use of the end product and the vulnerable consumer groups

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

- Have you described all the product characteristics in sufficient detail, including:
  - raw materials, ingredients?
  - packaging?
  - intermediate/semi-processed products?
  - end products?
- Have the intended use and reasonably expected handling conditions for the end product been documented, taking into account the vulnerable consumer groups?

Task 5.3: Prepare the process flow diagram

References:

ISO 22000:2018, Subclause 8.5.1.5
General Principles of Food Hygiene, CXC 1-1969: HACCP step 6 and principle 1

Your main aim should be to:

- Provide information on the processing steps and an overview of the process flow to assist in the preparation of a complete hazard analysis. Once the design of the FSMS has been completed, the flow diagram constitutes a document suitable for communication (e.g. for presentation to external parties and for staff training)
- Create a diagram for the product or the categories of product:
  - include the entry points of raw materials, ingredients, intermediate/semi-processed products, etc.
  - include the exit points of waste, by-products, intermediate/semi-processed and end products
  - indicate where rework and recycling take place
  - specify the externalized steps and outsourced processes
- Ensure that the food safety team verifies the flow diagram
- Keep the diagram as a record of the FSMS
- Describe the steps of the procedure by using, for example, the 5M method ("methods, machinery, milieu/environment, materials, manpower")
- Describe process parameters that could affect food safety and can assist in choosing hazard-control strategies, control measures and monitoring approaches (time, temperature, pressure, pH, *aw*, concentration, output, etc.)

- Describe the existing control measures (e.g. procedures, instructions, skills, specifications)
- Determine how rigorously these elements have been applied

Practical advice:

All the process steps, from the reception of raw materials to delivery, must be identified. The process flow diagram will be helpful at the hazard identification step. Be sure to indicate where the raw materials, ingredients, intermediate/semi-processed products, rework and end products are held in warehouses and storage facilities. The diagram should be simple, using boxes and arrows. Nevertheless, it should include everything that enters into the product composition or that comes into contact with the product, such as water, air, raw materials, ingredients, intermediate/semi-processed products and packaging materials. It is equally important to examine parallel process flows (with process characteristics) and reworking or recycling. The movement/transport from one process step to the next, should also be included: e.g. any temporary storage, conveyor belt, trolley, etc.

In addition to the flow diagram, it may be useful to depict the flows of ingredients, materials, containers, personnel, air, water, waste, etc. This can be carried out for each processing line. The flow representations frequently reveal that the flow of "clean" matter and/or personnel crosses the flow of "unclean" materials and/or people. This should lead the team to identify areas where contamination may occur, and suggest process improvements. For example, it is often possible to modify the way operations are conducted to minimize the probability of contamination transfer from an "unclean zone" to a "clean zone" by changing the sequence of operations, protecting the "clean zone" with appropriate covers.

Once the flow diagram is established, the team shall confirm on-site that it is accurate and comprehensive. Interviewing staff is useful. The flow diagram shall be updated when a change occurs in the process.

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

- Description of processes and process environment
- On-site confirmation of the flow diagram

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

- Do the flow diagram(s) for each category of product or process contain all the necessary information (e.g. identification of possible cross-contamination)?
- Have all products and steps been documented?
- Have you verified the accuracy of the flow diagram on-site? (This should be carried out during different processing conditions)
- Has the food safety team described and recorded the control measures, or the procedures for food safety, for each step of the process?

Task 5.4: Identify the hazards associated with the food

References:

ISO 22000:2018, Subclauses 8.5.2.1 and 8.5.2.2

General Principles of Food Hygiene CXC 1-1969: HACCP step 6 and principle 1

Your main aim should be to:

- Collect relevant information on all hazards that are reasonably expected to occur, in order to enable hazard assessment

- Collect input data that enables the identification of hazards (regulations, history, guidelines for GHPs, epidemiological studies, etc.)
- Identify all hazards that are reasonably expected to occur
- Define the acceptable level of these hazards in the end product

Practical advice:

The team should rigorously identify all hazards that are reasonably expected to occur for each ingredient and input (air, water, etc.), and for each process step. The hazard list is the basis of the next step.

Where statutory and regulatory authorities have established maximum limits, objectives, targets, or end product and/or process criteria for a specific hazard/product combination, the hazard in question automatically becomes relevant for that product. Other relevant information includes the history, guidelines for GHP, and epidemiological, validation or challenge studies, etc.

Information regarding the "acceptable level" of specific hazards is required. This enables an assessment of a given hazard and whether it needs to be controlled by the organization.

In order to ensure food safety, the "acceptable level" means the level of a specific food safety hazard not to be exceeded in the end product, whether provided by the organization, at a later stage in the food chain or during direct consumption by consumer. Different regulatory agencies may have their own defined acceptable levels of a hazard.

The acceptable level in the end product should be determined through information obtained from one or more of the following sources and should be kept as documented information:

- end product specifications (e.g. maximum levels and other criteria) specified by regulatory authorities in the country of sale
- specifications or other information communicated by the organization constituting the next step in the food chain, in particular for end products intended for further processing or for use other than direct consumption

- maximum acceptable levels established by the food safety team, taking into account the acceptable levels agreed on with the customer and/or established by law and regulations in order to protect the final consumer. In the absence thereof, this should be obtained through scientific literature, professional experience and expert opinion

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

- List of sources or references used to identify the hazards
- List of hazards and justifications for choosing them
- Justification for acceptable levels of hazards in the end product as established by the organization, a competent authority or by the customer

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

- Has your team identified, for each step of the process, all reasonably expected hazards to occur that are related to food safety?
- Has the team determined, documented and justified the acceptable level for each hazard?

Task 5.5: Conduct a hazard assessment

Reference:

ISO 22000:2018, Subclause 8.5.2.3
General Principles of Food Hygiene CXC 1-1969: HACCP step 6 and principle 1

Your main aim should be to:

- Establish a justified list of food safety hazards that need be controlled by OPRPs and/or at CCPs. These hazards can be categorized as significant food safety hazards

Where no such hazards can be identified, the PRPs in place are sufficient to achieve safe products. In this case, **Tasks 5.6** to **5.10** are not applicable. When deviations occur, actions must be taken to prevent the release of a potentially unsafe product.

Practical advice:

The team should assess each individual hazard listed in **Task 5.4**.
The following should be taken into consideration:

- the source of the hazard, where and how it could be introduced into the product, and/or its environment
- the probability of the hazard occurring in the end product before the application of control measures (e.g. qualitative and/or quantitative prevalence, such as frequency of occurrence and typical levels, highest possible levels and/or statistical distribution of levels, the production or persistence of toxins, chemicals or physical debris, impact of the process step)
- the nature of the hazard (e.g. its ability to multiply, deteriorate and produce toxins)
- the severity of the adverse health effects that could be caused by the hazard

When evaluating the probability of a hazard occurring, consideration should be given to both the preceding and following steps of the specified operation. Consideration shall also be given to the process equipment, service activities and surroundings, as well as to the preceding and following links in the food chain. In addition, the organization should consider measures taken at preceding steps in the food chain (e.g. raw material suppliers, subcontractors). The organization should also consider other relevant initiatives (e.g. general environmental protection measures), and measures taken at subsequent steps in the food chain (e.g. further processing, transportation, distribution, consumption).

Finally, the team should identify every significant food safety hazard for which control is essential for the production of a safe food, and establish a control strategy for each of them.

To take into consideration the level that is acceptable in the end product (see **Task 5.4**).

It may be convenient to group hazards. The level of detail regarding hazards should be specified by each organization and be relevant to their needs, including the appropriate choice of control measures.

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

- Description of the methodology used to identify the significant food safety hazards
- A record of the results of the hazard assessment

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

- Has each identified potential significant food safety hazard been assessed to determine if an additional control should be put in place to prevent or reduce it?

- If a remaining significant food safety hazard has to be controlled through a further step in the food chain, has this information been passed on to the relevant interested parties?

Task 5.6: List and select control measure(s) or combination(s) of control measures

Reference:

ISO 22000:2018, Subclause 8.5.2.4

General Principles of Food Hygiene CXC 1-1969: HACCP step 6 and principle 1

Your main aim should be to:

- Select the control measure(s) or combination(s) of control measures, in order to prevent or reduce significant food safety hazards to acceptable levels

Note: The term 'elimination' is not used in ISO 22000 because the elimination of a significant food safety hazard cannot be achieved by control measure(s) or combination(s) of control measures nor can it be proved. Significant food safety hazards can only be reduced to an acceptable level, even if sometimes the achieved level is extremely low.

Practical advice:

For each hazard that has to be controlled (i.e. prevented from occurring, be inhibited, increased, or reduced in extent and/or frequency of occurrence), the team should assess which control measure(s) or combination(s) of control measures (including processing steps) can be effective in ensuring that the identified acceptable levels of significant food safety hazards in the end products are not exceeded. The food safety team shall make a list of the process steps where control measure(s), alone or combined, can be implemented to prevent/reduce contaminants.

- Microbiological contaminants: Control measure(s) to inhibit microbiological growth (e.g. a temperature below 4°C or 40°F), and inactivate or destroy microorganisms (using processes such as chemical disinfection, heating, application of high pressure, filtration, use of visible or UV light, application of electric current, food composition changes such as acidification, reduction of water activity (*aw*)). Control measure(s) that may be used together to control bacteria, include: pH and *aw*, acidification with less-stringent heat treatment, or the application of mild heat treatment combined with a lower storage temperature to achieve a longer shelf-life
- Chemical contaminants: Control measure(s) to prevent/reduce contamination, including allergens (e.g. by rinsing, cleaning or excluding)
- Physical contaminants: Control measure(s) to prevent/reduce contamination (e.g. glass, stone, metal)

Among the listed control measure(s), the food safety team should select only those that are essential to ensure the safety of the end product, and then manage them as OPRP(s) or at CCP(s) (see Appendix A).

The information required to assess the effect of a control measure includes:

- How the significant food safety hazards are affected by the control measure(s) (i.e. through reduction or by controlling increases and/or controlling the frequency of occurrence)
- The extent to which the levels of significant food safety hazards are affected. Very often, the effect depends upon the rigorousness of the control measure (e.g. temperature, time, concentration, frequency). In carrying out the assessment, it can be useful to obtain data on the intensity-effect relationships
- The step or location at which the control measure is intended to be applied. Some control measures are more effective if applied in combination with other control measures (e.g. following control measure(s) that stress micro-organisms)
- The operational parameters, including their operational variability (e.g. fluctuation and/or probability of operational failure)

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

- A list, description and effectiveness of the selected control measure(s) or combination(s) of control measures, in order to prevent or reduce significant food safety hazards to acceptable levels

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

- Has the food safety team selected the required control measure(s) or combination(s) of control measures to prevent or reduce the significant food safety hazards previously identified to an acceptable level?

Task 5.7: Categorize, manage, monitor and document the control measures

References:

ISO 22000:2018, Subclauses 8.5.2.4 and 8.5.4 (from 8.5.4.1 to 8.5.4.3)
General Principles of Food Hygiene, *CXC 1-1969*: HACCP principles 2 and 3, HACCP steps 6, 7, 8, 9 and 12)

Your main aim should be to:

- Determine and apply the methodology to categorize the control measures to be managed as OPRP(s) or at CCP(s)
- Document the hazard control plan (HACCP/OPRP plan)
- Determine and justify the choice of action criteria for the OPRPs and critical limits at CCPs
- Establish monitoring procedures for OPRPs and CCPs

Practical advice:

The significant food safety hazards identified by the hazard analysis in **Task 5.5** have to be controlled using either OPRPs or CCPs. The correct functioning of the hazard control plan (HACCP/OPRP plan) should be included in the verification planning process.

An OPRP is a control measure or combination of control measures applied to prevent or reduce a significant food safety hazard to an acceptable level, and where action criterion and measurement or observation enable effective control of the process and/or product.

For each OPRP, the monitoring method and frequency shall be proportionate to the likelihood of any failure to meet action criterion(a) and the severity of consequences.

A CCP is a step in the process at which control measure(s) is (are) applied to prevent or reduce a significant food safety hazard to an acceptable level, and defined critical limit(s) and measurement enable the application of corrections.

At each CCP, the monitoring method and frequency enable the timely detection of any failure to remain within critical limits, and allow for the timely isolation and handling of potentially unsafe products.

The control measures typically monitor processes through physical measures such as pH, time, temperature and observations by competent personnel.

One approach is to first determine which of the control measures identified in Task 5.6 are to be managed at CCPs. Those remaining must then be categorized as OPRPs. Figure 10 summarizes the relationship between OPRPs and CCPs.

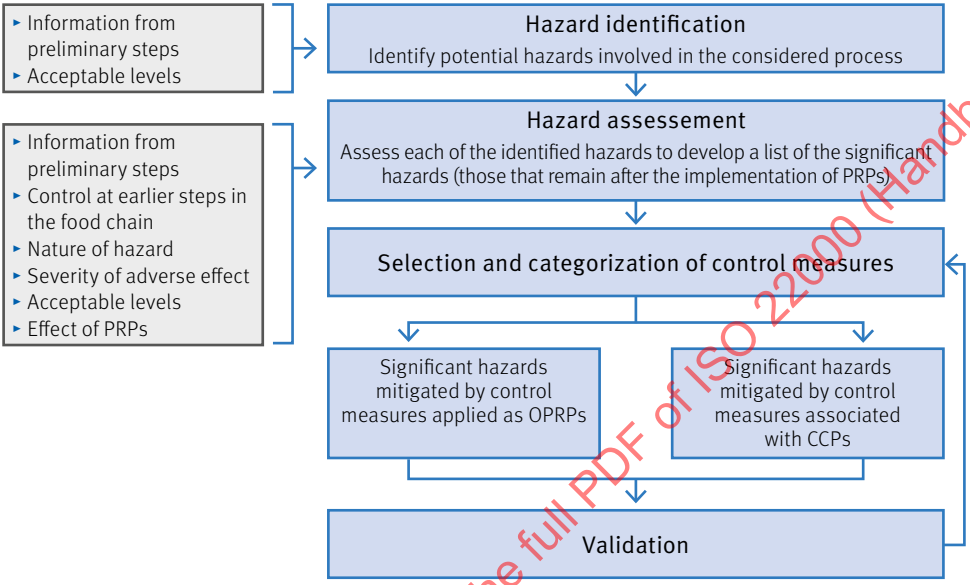

Figure 10 : Illustration of the hazard analysis process

However, the categorization of control measures is not an exact discipline. The method used may vary depending on the organization, processes and products. The next step is implementing the control measures to be managed as OPRP(s) or at CCP(s).

The monitoring of OPRPs should be based on measurable or observable action criteria. Such criteria should correspond to any operational parameters used in the validation (see **Task 5.8**). Where action criterion is only observable (e.g. visual inspection), the observation process must be defined and documented (e.g. instructions, specifications). For each OPRP, the monitoring method and frequency shall be proportionate to the likelihood of any failure to meet action criterion(a) and the severity of consequences, and must be documented in the hazard control plan (see Subclause 8.5.4 of ISO 22000).

The management of CCP control measures is also defined in the hazard control plan. Monitoring of a CCP is based on the monitoring of established critical limits.

The critical limits must be achievable as part of normal process operations and be validated as described earlier (see **Task 5.8**). For CCPs intended to control more than one significant food safety hazard, the critical limit(s) should be determined relative to each significant food safety hazard, and the most stringent limit applied in order to cover the worst-case scenario. At each CCP, the monitoring method and frequency must be capable of timely detection of any failure to remain within critical limits, to allow a timely isolation and evaluation of the product.
All results of monitoring (e.g. action criteria or critical limits) must be recorded by designated trained personnel.

Note: These examples are for illustration purposes only

Example 1: Categorization of control measures throughout the entire food chain

A poultry processor receives chicken. It separates it into parts, which it batters, coats in breadcrumbs, freezes and then packages. The products are sold to a restaurant, which fries and serves them to customers. In the chicken processing factory there is no scientifically based CCP. The CCP will occur in the restaurant when the chicken is cooked at a minimum time and temperature. The cooking process kills the vegetative pathogens. However, there are several points in the factory that can define control measures as OPRPs, such as the receiving temperature of the chicken and the temperature of the product as it leaves the freezer. These two measures control the growth of micro-organisms and subsequently control the growth of pathogens. A final OPRP could be the temperature of the freezer during product storage.

Conclusion: The CCP is not identified at the chicken processing factory, but at the restaurant.

Example 2: Categorization of control measures applied to a typical pasteurization process (plate heat-exchanger)

Pasteurization is a combination of control measures (time and temperature) in order to reduce the level of pathogens in a product (e.g. Brucella in milk).

The control measures are the processing temperature and holding time.

- A minor drop in processing temperature is unacceptable and will most likely result in potentially unsafe end-products. The temperature can be monitored effectively (continuously and in real-time) to enable an immediate correction (flow diversion valve). This control measure must be managed as a CCP.
- Holding time is determined by the size of the holding tube and the flow rate, and these parameters must be validated. The size of the holding tube is determined when installing the equipment and it is not suitable for monitoring. Typically, the flow rate is kept constant, either by a positive displacement pump or a combination of a centrifugal pump and a flow control valve. Thus, the flow rate and the holding time are constant and need only verification.

Conclusion: Pasteurization is a CCP where only the product temperature must be monitored continuously. The holding time must be validated and verified.

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

- Information on the methodology and parameters used to categorize the control measures into OPRPs and CCPs, including the rationale for the categorization shall be recorded
- A hazard control plan (HACCP/OPRP plan), comprising a sequential list of control measures (e.g. following the product flow), each of which includes:
  - the name of the significant food safety hazard(s) that the control measure is intended to control
  - a description of the monitoring procedure (parameter/method, limit(s), frequency)
- Monitoring records

- Information on training of personnel in charge of the monitoring of action criteria for OPRPs and critical limits at each CCP

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

- Has the food safety team selected and documented a specific methodology to categorize control measures to be managed as OPRP(s) or at CCP(s)?
- Has the food safety team categorized each chosen control measure or combination of control measures?
- Has the food safety team established a hazard control plan (HACCP/OPRP plan) as controlled documented information?
- Has the food safety team determined action criterion/criteria for each OPRP and critical limit(s) at each CCP, and has it supplied the necessary instructions and support for its application?
- Do you have the monitoring records for the action criteria for OPRPs and for the critical limits at each CCP?
- Has the person in charge of monitoring been specifically trained for this procedure?

Task 5.8: Validate the control measure(s) or combination(s) of control measures

References:

ISO 22000:2018, Subclause 8.5.3

General Principles of Food Hygiene, CXC 1-1969: HACCP step 7 and principle 2, step 6 and principle 3, step 11 and principle 6

Guidelines for the validation of food safety control measures, CXG 69-2008

Your main aim should be to:

- Conduct validation prior to actual implementation of the control measure(s) or combination(s) of control measures. Validation shall demonstrate that the selected control measures are capable of delivering the intended level of significant food safety hazard control. Failure to demonstrate such capability must result in modification of the combination of control measures

As an example, validation should include the following steps:

- choose a validation method
- define the decision-making parameters and criteria that will demonstrate that the control measure(s) or combination(s) of control measures, if properly implemented, is(are) capable of consistently controlling the significant food-safety hazard to the specified outcome
- collect the pertinent documentation relative to the validation
- undertake validation studies
- analyse validation results
- document, revise the validation (if needed) and communicate any changes

Practical advice:

Validation must be carried out prior to the application of the control measure(s) or combination(s) of control measure(s). The capability of control measure(s) or combination(s) of control measures to achieve the intended level of significant food safety hazard control shall then be measured and assessed.

Different methods can be used to validate the control measure(s) or combination(s) of control measures, such as a reference to the following:

- the literature (scientific or technical), such as previous validation studies
- the historical knowledge of the performance of the control measure(s) or combination(s) of control measures
- the statistically valid experimental data that demonstrate the adequacy of the control measure(s)

Previous studies may have a different set of constraints in sources of variation (ingredients, process, products) than those occurring during current production conditions. These constraints can limit the effectiveness of the validation study.

Note: The equipment used shall be appropriate for the intended purpose.

- Mathematical modelling. This method is increasing in usefulness. For example, predictive microbiology can be used to validate the shelf-life of a product, or to determine alternative time/temperature combinations for heat treatment. However, a mathematical model may not be available for specific products or process conditions

The collection of data during the operation of the entire food production process is not a standalone validation method and should be combined with other validation method(s).

Validation studies shall be conducted before the actual food process is operated for the first time. However, the validation may not show the full extent of variation that can occur during the actual production.

Processes defined in regulatory documents or officially validated guides may be used as is, without re-validation. This is acceptable if the process conditions in the organization are the same as those defined in the guide.

When relying upon validations carried out by others, care should be taken to ensure that the conditions of the intended application are consistent with those of public reference validations.

If the expertise is not available in the organization, it is recommended that the organization utilizes external expertise. Each validation method has limitations, thus it is imperative that the most appropriate validation method be selected.

Validation must be re-established following new scientific or regulatory information, a system failure, or any significant change to the process or product. Changes to the process or product include, for example, changes in raw materials, a process step and organizational management, or changes implemented in response to a critical limit or in the conditions of use by end consumers.

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

- Process of validation of control measure(s), or, combination(s) of control measures
- Reference to the validation method(s) used
- Validation reports

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

- Have the control measure(s) or combination(s) of control measures been validated? If so, then how?
- Is there a validation report or validation documented information?
- Have you demonstrated that the control measure(s) or combination(s) of control measures are capable of controlling the identified significant food safety hazards to acceptable levels (if operated correctly)?

Task 5.9: Establish and apply corrections and corrective actions

References :

ISO 22000:2018, Subclauses 8.5.4.1, 8.5.4.4 and 8.9

General Principles of Food Hygiene, CXC 1-1969: HACCP principle 5, steps 10 and 11

Your main aim should be to:

- Plan corrections and corrective actions, as appropriate, to be carried out when action criteria for OPRPs or critical limits for CCPs are not met
- Develop and draft clear documented information (procedures) that describe the corrective actions that must be taken when there is a deviation for an OPRP or at a CCP
- Train the personnel in charge of applying corrections and corrective actions. These individuals should be competent in applying the established documented information (procedures) for both corrections and corrective actions
- Record the results

Practical advice:

The corrections and corrective actions must be kept as documented information (through the hazard control plan).

When action criteria for OPRPs or critical limits for CCPs are not met, the appropriate corrections and corrective actions should be taken.

For failures to meet action criteria for OPRPs, an evaluation of products will show if they are potentially unsafe or not, but for CCPs they are immediately considered as potentially unsafe.

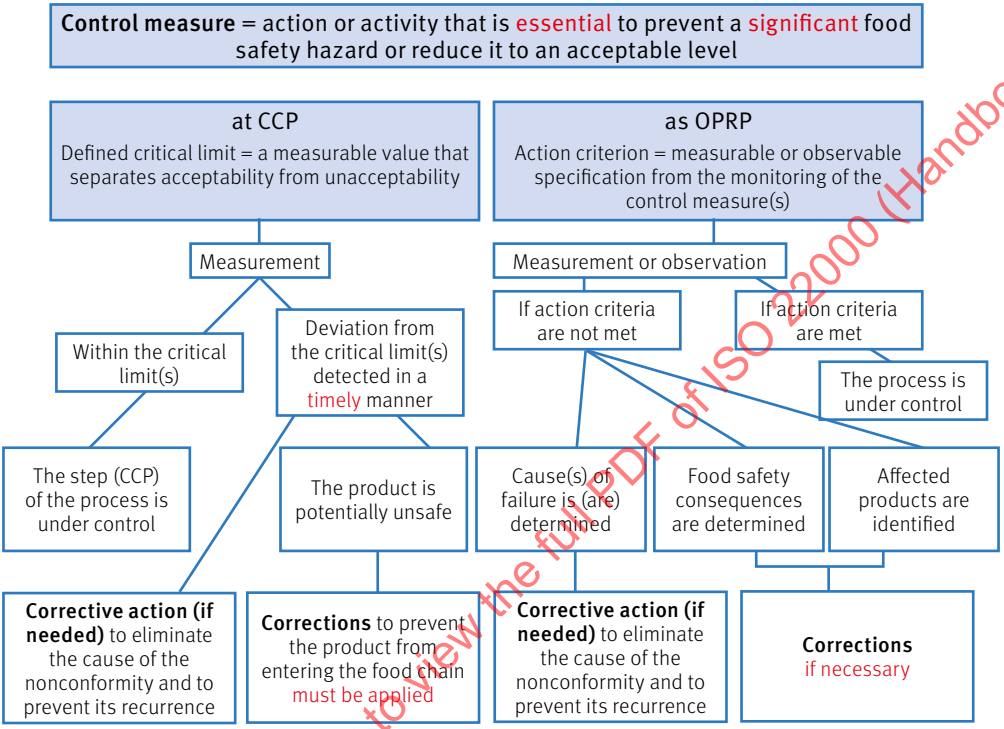

Figure 11: Typical illustration of the difference between OPRPs and CCPs in relation to corrections and corrective actions

Corrections

Corrections are applied to protect the customer/consumer from being exposed to potentially unsafe products. The process of correction has two parts:

- the identification of affected products (e.g. lot/batch numbers) and their control with regard to their use and release
- the handling of affected products, and this may be carried out in different ways (see Subclause 8.9.4 of ISO 22000)
  - For OPRPs, the products affected by the failure to meet action criterion shall only be released if they are safe according to the conditions

described in 8.9.4.2 of ISO 22000. Otherwise, the handling of the affected products may be: reprocessed or further processed within or outside the organization to ensure that the significant food safety hazard is reduced to acceptable levels; redirected for other use provided that food safety in the food chain is not affected, or; destroyed and/or disposed as waste

- For CCPs, the handling of affected products may be: reprocessed or further processed within or outside the organization to ensure that the significant food safety hazard is reduced to acceptable levels; redirected for other use provided that food safety in the food chain is not affected, or; destroyed and/or disposed as waste

Examples of corrections: rework (e.g. flow diversion to a plate heat-exchanger); discard the product; submit the product to reprocessing or further processing inside or outside the organization to reduce the significant food safety hazard to a predetermined, acceptable level.

Corrective actions

The need for corrective actions must be evaluated when action criteria for OPRPs and/or critical limits at CCPs are not met, in order to identify and eliminate the cause of detected nonconformities, to prevent re-occurrence and re-establish control of the process.

After the completion and verification of the effectiveness of a corrective action, the organization should analyse the results of the actions taken. These actions link the corrective action process to the continuous improvement process.

If there are frequent re-occurrences of deviations for an OPRP or at a CCP, the organization shall re-evaluate their processes and its hazard control plan in accordance with Subclauses 8.5.4.4 and 8.9 of ISO 22000.

Examples of corrective actions: fine-tuning the process; fixing defective equipment; reviewing a procedure; training.

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

- Correction and corrective action plans
- Records of correction and corrective action signed-off
- Verification records of the effectiveness of corrective actions
- Records of evaluations of the handling, use and release of affected lots/batches
- Training evidence of personnel in charge of undertaking corrections and corrective actions

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

- Has the food safety team established the corrections and corrective actions for each OPRP and CCP in case of loss of control?
- Has the food safety team verified that the actions taken have been completed as planned?

Task 5.10: Control monitoring and measuring (operational processes)

Reference:

ISO 22000:2018, Subclause 8.7

Your main aim should be to:

- Ensure that the organization uses suitable measuring methods and equipment for internal evaluations of products and processes

Practical advice:

The suitable measuring equipment used for internal evaluations of products and processes requires accuracy and precision. It should be calibrated, and adjusted if necessary, according to Subclause 8.7 of ISO 22000. Equipment must be used by qualified personnel and according to defined methods. This is necessary to guarantee the reliability of internal evaluations.

Some monitoring and verifying activities rely on measurements rather than observations.

The results of the calibration and verification of measuring equipment, the assessment and the resulting actions are kept as documented information.

Software used to monitor and measure activities related to PRPs and the hazard control plan shall be validated prior to its implementation. Commercial off-the-shelf software in general use within its designated application range can be considered to be sufficiently validated.

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

- Documented information specifying monitoring and measuring methods and requirements for equipment used for monitoring and measuring activities related to the PRPs and hazard control plan
- Certificates of calibration (including traceability against international or national measurement standards, if applicable); verification of measuring equipment; equipment logbooks showing results of calibrations and verifications, records evaluating the validity of previous measurements (in the case of equipment found with incorrect results)
- Training records of qualified personnel
- Documented information regarding the assessment and resulting actions of the control of monitoring and measuring

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

- Are the measuring devices used for monitoring the PRPs and hazard control plan verified and/or calibrated? Can you demonstrate this?
- In the case of non-calibrated and/or non-verified equipment, have you kept records evaluating its impact and the associated actions?

Task 5.11: Conduct a verification related to the PRPs and hazard control plan

Reference:

ISO 22000:2018, Subclause 8.8

Your main aim should be to:

- Verify:
  - the implementation of, and the adherence to, the identified PRP (see **Task 4.1**)
  - the effectiveness of the hazard control plan, ensuring that significant food safety hazard levels are within identified acceptable levels (e.g. by laboratory analysis, by analysis of customer complaints)
  - if the inputs to the hazard analysis are kept up to date (see **Tasks 3.8** and **5.2**)
  - the effectiveness of the traceability mechanisms (see **Task 4.6**) and withdrawal/recall of products (see **Task 3.10**)
- Analyse the results of the verification activities and undertake any necessary corrective actions (see **Task 5.9**)

Practical advice:

All the above evidence is reviewed to ascertain if the operational processes system (see **Figure 4** in Topic 3) is functioning as planned and to determine if any updates or improvements are necessary. Notes of the meeting about the review should be kept. The notes should include any decisions made regarding the operational processes system.

There are two steps to the verification activities.

1. Analyse individual verification activities.
   For example, in the case where an organization takes weekly environmental swabs, the results from the environmental monitoring samples should be reviewed to determine if one of more of the results do not meet internal specifications. If so, the organization shall take corrective actions to reduce the environmental contamination in the sample area
2. Analyse the results of verification activities.
   For example, the results of environmental monitoring samples may be plotted on a control chart. If the chart indicates a slow increase in the microbiological count, this could indicate a weakness in the cleaning and sanitizing programme. In this case, the organization may use the data to take corrective action to prevent the occurrence of a food safety incident

Between management reviews, the analysis of results will enable the food safety team to detect any major problems and to implement the necessary actions.
The frequency of verification depends on the degree of uncertainty in a control measure relative to the acceptable level of a significant food safety hazard or predetermined performance. In addition, the organization needs to consider the ability of monitoring documented information (procedures) to detect a loss of control. Hence, the frequency required depends on the uncertainties associated with the result of the validation and the functioning of the control measure (e.g. process variability).
Verifications should be scheduled at regular intervals to check operational compliance with the food safety documented information. This verification must be performed by qualified personnel with the required authority.
If verification activities (operational processes) indicate that there is a potential food safety issue (e.g. hold, recall, training etc.), corrections and corrective actions need to be implemented.
Initial verification must be performed after the first production run, ideally by someone who is not a member of the food safety team. Individuals should not verify their own activities.