

D 20v18

ISO 22000 readiness version 2018

Goal

1 Food safety approach

1.1 Background

1.2 Scope

1.3 Steps

2 Standards, definitions, books

2.1 Standards

2.2 Definitions

2.3 Books

3 Process approach

3.1 Processes

3.2 Process mapping

3.3 Process approach

4 Context

4.1 The organization and its context

4.2 Interested parties

4.3 Scope

4.4 FSMS

5 Leadership

5.1 Commitment

5.2 FS policy

5.3 Roles

6 Planning

6.1 Actions to address risks

6.2 FS objectives

6.3 Changes

7 Support

7.1 Resources

7.2 Competence

7.3 Awareness

7.4 Communication

7.5 Documented information

8a Realization of safe products

8.1 Operational control

8.2 PRPs

8.3 Traceability

8.4 Emergencies

8.5 Hazard control

8b Realization of safe products

8.5.3 Validation

8.6 Update of PRPs

8.7 Control of inspection

8.8 Verification of PRPs

8.9 Control of nonconformities

9 Performance evaluation

9.1 Inspection, analysis and evaluation

9.2 Internal audit

9.3 Management review

10 Improvement

10.1 Nonconformities

10.2 Continual improvement

10.3 Update of the FSMS

Annexes

Goal of the module: Readiness for implementation, certification, maintenance and improvement of your food safety management system (ISO 22000) in order to:

- increase the satisfaction of interested parties
 - guarantee the safety of foodstuffs
- meet customer, statutory and regulatory requirements

1 Food safety approach

1.1 Background

The international standard ISO 22000 (Food safety management systems - Requirements for any organization in the food chain) is recent (first edition in 2005) and allows for the harmonization and simplification of different approaches to the food safety management system (foodstuff) and to obtain certification by an accredited body.

Food: *every product intended for nourishment*

ISO 22000 is based on a global approach to the control of food safety and responds to the crisis of consumer confidence (BSE crisis, dioxin, bird flu).

The ISO 22000 standard has the long-term goal of replacing the many standards on food safety such as the IFS (International Food Standard) and the BRC (British Retail Consortium).

ISO comes from the Greek "isos" (equal).

In contrast to IFS and BRC, the ISO 22000 standard focuses on:

- the result requirements (management system) and not the means requirements (good hygiene practices)
- the entire food chain and
- a system approach (not limited to product categories)

Food hazard: *potential harmful effect of a biological, chemical or physical nature on people's health following the consumption of food*

ISO 22000 is based on (see figure 1-1):

- the requirements of quality management systems (ISO 9001)
- guides to good hygiene practices
- hazard analysis principles (Hazard Analysis and Critical Control Point)
- effective internal and external communication
- an operational traceability system

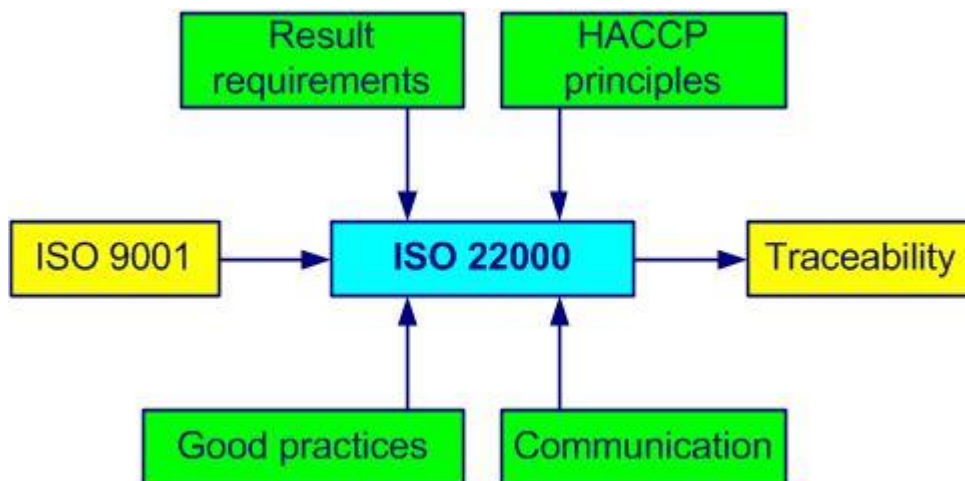


Figure 1-1. ISO 22000 basics

The structures of the ISO 9001 and ISO 22000 standards are very close (high level common structure, annex SL), which facilitates the implementation of an integrated management system.

In the 1950s, Americans Edwards Deming and Joseph Juran contributed to the dissemination and use of methods of statistical quality control and continual improvement approach.

The HACCP concept emerged in the late 1950s when NASA (National Aeronautics and Space Administration) demanded safe food for astronauts. It was with the help of the company Pillsbury that the principles of the prevention of biological, chemical or physical hazards were put in place.

HACCP: *Hazard Analysis Critical Control Point. System for the control of the hazards that threaten food safety*

Food suitability: *ensuring that food when consumed as intended, is acceptable to the consumer*

Hazard analysis (food): *way to determine the hazards and to establish the critical controls so as to guarantee food safety*

These principles, later known as HACCP, significantly increase the safety of end products by controlling and inspecting processes and critical points as early and as efficiently as possible because, as the saying goes:

Prevention is better than cure

In 1993, the HACCP method was internationally recognized through its inclusion as an appendix in the **Codex Alimentarius** (Recommended International Code of Practice - General Principles of Food Hygiene, Rev.4, 2003) under the title Hazard Analysis Critical Control Points (HACCP) system and guidelines for its application. Note that the prerequisite for any HACCP system is the "classic" part of Codex, that is, good manufacturing and hygiene practices.

In 1993, the European Union also published a directive (93/43 / EC) based, among other things, on HACCP principles.

The Codex Alimentarius is a collection of hundreds of (Codex) standards, codes of practice, guidelines, procedure manual, recommendations, guides to good manufacturing and hygiene practices related to food safety and consumer protection. Use without moderation!

The food code (Codex Alimentarius) is the result of cooperation since the 1960s between FAO and WHO and can be found on the website: [codexalimentarius](http://www.codexalimentarius.org)

The requirements for any company in the food chain are mainly focused around:

- the management system
- effective and interactive communication
- prerequisite programs
- HACCP hazard analysis principles
- traceability

1.2 Scope

The ISO 22000 standard is generic as it can be applied to any organization in the food chain, without limitations on size, activity or type. The food chain (cf. figure 1-2) includes:

- the original agricultural producers:
 - animals
 - vegetables
- food processors
- food processors for animals
- distributors (wholesalers and retailers) of food products
- restoration
- providers of services and materials:
 - storage, transportation
 - equipment
 - packaging
 - pesticides, veterinary drugs
 - additives and ingredients
 - hygiene and cleaning products
 - various services

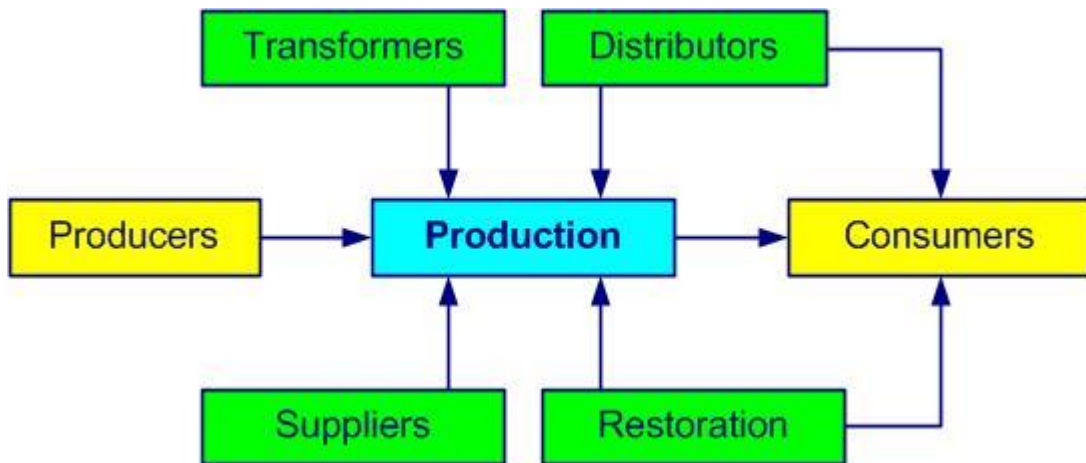


Figure 1-2. The food chain

Some advantages of the ISO 22000 food safety management system:

- a common and complete system for the entire food chain
- greater assurance to:
 - produce and distribute only products that are safe for the consumer
 - comply with statutory and regulatory requirements
 - communicate in full transparency with interested parties
- improved customer satisfaction related with its requirements
- staff awareness of food safety hazards
- staff involvement in the continual improvement approach
- internal decompartmentalization
- an introduction only of useful measures
- a hazard analysis for any control measure
- a focus on essential hazards
- a controlled analysis of hazards
- risk-based thinking (risk-based approach)
- up-to-date documentation
- a guarantee of consistency between the declared food safety policy and the practices in the field

1.3 Steps

A well prepared approach is halfway to success

The approach to implementing a food safety management system (FSMS) goes through several steps. An example of preparation is shown in figure 1-3.

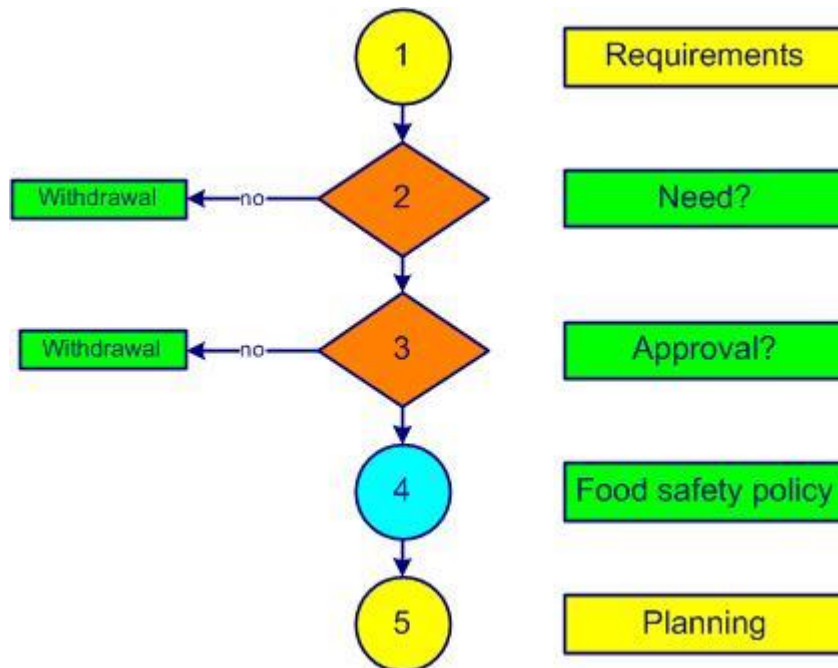


Figure 1-3. FSMS preparation

Step 1 involves identifying the needs and expectations (**requirements**) of customers (internal and external). The involvement of top management at its highest level is truly indispensable. The advice of a consultant is often solicited. Determining the current status of the management system (whole or partial) would be welcome at this stage. An external certification body is chosen.

One of the key questions that comes up quickly (**step 2**) is the **need** for this decision. If this is not really necessary or if the estimated costs of the certification approach exceed the available resources, it is better to reject this idea immediately.

The benefits of implementing a food safety management system are often:

- an improved image of the company
- being one step ahead of the competition
- valued good practices
- prevention of food safety becomes routine
- better economic results
- lower manufacturing costs
- staff who are aware, consulted, motivated and proud
- profitable engagement for all
- formalization of knowledge
- updated legal obligations

The benefits of the certification of a food safety management system are often:

- new customers

- increased market share
- an increase in sales
- better financial performance

More than one and a half million businesses worldwide cannot be wrong!

The internalization of the spirit of the principles and requirements of an ISO standard significantly improves the overall performance of your business, especially when it is not considered as a constraint.

The **third step** shall determine whether this approach receives the **approval** of the staff. A communication campaign is launched in-house on the objectives of a food safety management system (FSMS). The staff is aware and understands that, without their participation, the project cannot succeed.

Have confidence: success will come with the involvement and effort of all!

The vision (what we want to be), the mission (why we exist) and the business plan of the company are determined. The **following step (4)** includes the establishment of an outline of the **food safety policy** and objectives. If you do not have a copy of the ISO 22000 standard, now is the time to get it (cf. section 2.1 of the present course).

Planning is the last **step (5)** of the project preparation for obtaining ISO 22000 certification. A reasonable period is between 5 to 8 months (each company is unique and specific). A top management representative is appointed as food safety project leader. Top management confirms the financial resources and staff. Team training on the requirements of ISO 22000 is planned. Top management commitment is formalized in a document communicated to all staff.

The establishment and implementation of an ISO 22000 food safety management system are shown in figure 1-4 and in [annex 01](#).

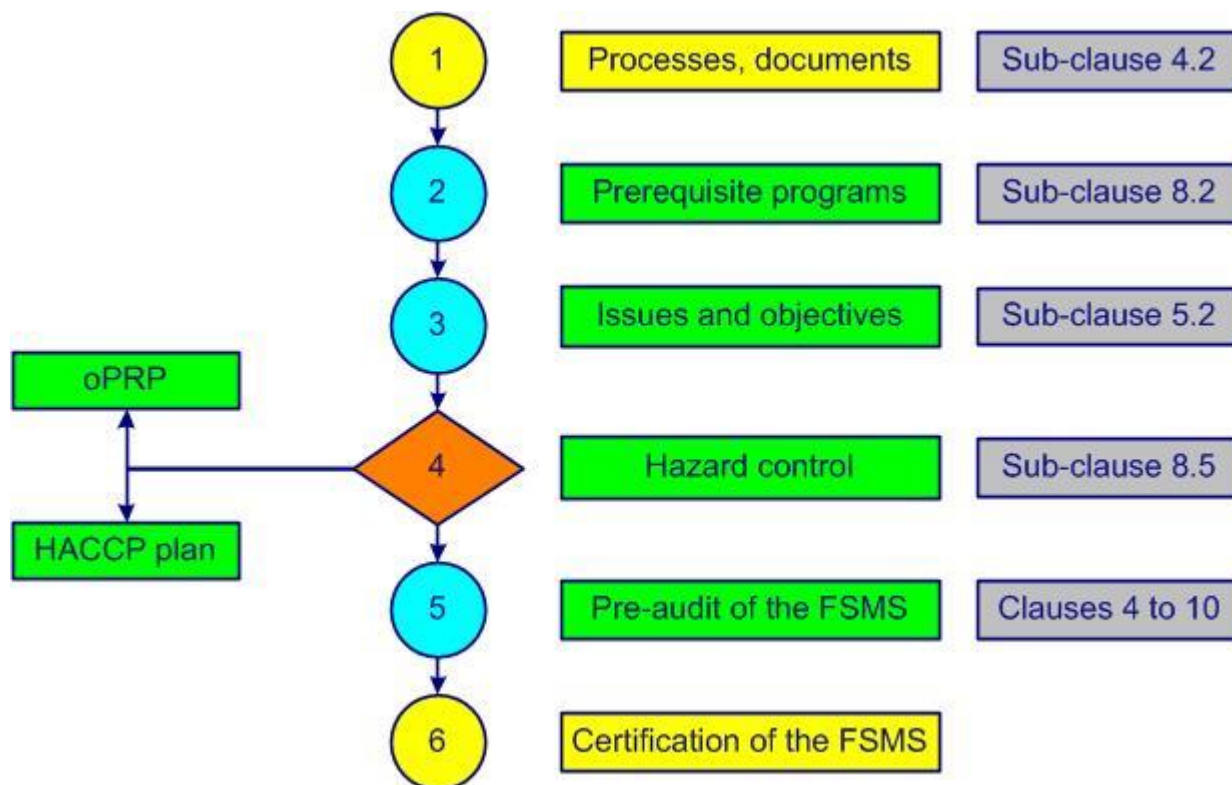


Figure 1-4. FSMS implementation

Step 1 aims to identify and determine the **processes**, interactions, owners, responsibilities and drafts of certain documented information. The first versions of process sheets, job descriptions and work instructions are written with the participation of the maximum number of available persons. The basics of internal and external communication are established.

In **step 2** prerequisite programs are selected as principles and good manufacturing and hygiene practices related to hazards (biological, chemical, physical).

Step 3 identifies the issues and sets objectives from the food safety policy. Control measures are identified and classified. Training of internal auditors is taken into account.

Hazard control is done in **step 4**. The operational prerequisite programs (oPRPs) are established and the HACCP plan is introduced. A traceability system is proposed. Internal audits help to evaluate the degree of implementation of the system.

A first encounter with the tools and application areas of **continual improvement** is made in **step 5**. A table with the main costs of obtaining quality (COQ) is filled in by those with the information at hand. Risks are determined, actions are planned and opportunities for improvement are found. An approach to preventing nonconformities and eliminating causes is established. The internal and external communication is established and formalized.

To conduct the **pre-audit of the FSMS (step 5)**, documented information and best practices are checked and approved by the appropriate people. A management review allows the evaluation of compliance with applicable requirements. The food safety policy and objectives are finalized. A food safety manager from another company or a consultant can provide valuable feedback, suggestions and recommendations. Gaps are corrected.

When the system is accurately implemented and followed, the **certification of the FSMS** by an external body is a breeze, a formality (**step 6**).

An appropriate method for evaluating the performance of your food safety management system is the RADAR logic model of excellence **EFQM** (European Foundation for Quality Management) with its nine criteria and overall score of 1000 points.

The Deming cycle (figure 1-5) is applied to control any process. The PDCA cycles (Plan, Do, Check, Act) are a universal base for continual improvement.

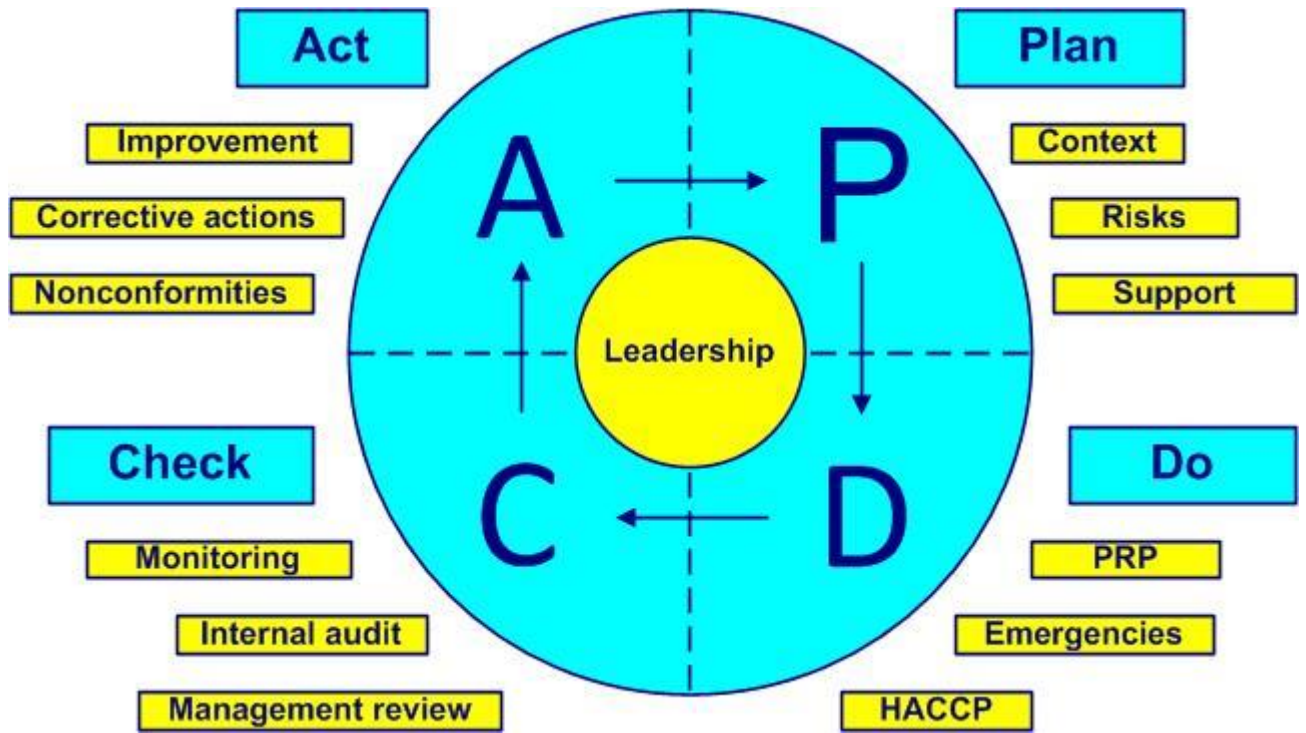


Figure 1-5. The Deming cycle

- Plan – define context, define and establish policy, objectives, resources, documentation, plan actions to address risks and demonstrate leadership (ISO 22000 clauses 4, 5, 6 and 7)
- Do – implement operational control, prerequisites programs, traceability, respond to emergencies, control hazards, inspection, control nonconformities and demonstrate leadership (ISO 22000 clause 8)
- Check – inspect, analyze and evaluate, conduct process audits, audit the HACCP plan, conduct management review and demonstrate leadership (ISO 22000 clause 9)
- Act – adapt, improve, update the FSMS, react with corrective actions, find new improvements (new PDCA cycle) and demonstrate leadership (ISO 22000 clause 10)

For more information on the Deming cycle and its 14 points of management theory, you can consult the classic book "Out of the Crisis", W. Edwards Deming, MIT press, 1982.

2 Standards, definitions, books

2.1 Standards



The ISO 22000 family of standards contains:

- ISO 22000 (2018): [Food safety management systems – Requirements for any organization in the food chain](#)
- ISO/TS 22002-1 (2009): [Prerequisite programs on food safety – Part one: Food manufacturing](#)
- ISO/TS 22002-2 (2013): [Prerequisite programs on food safety – Part two: Catering](#)
- ISO/TS 22002-3 (2011): [Prerequisite programs on food safety – Part three: Farming](#)
- ISO 22004 (2014): [Food safety management systems - Guidance on the application of ISO 22000](#)
- ISO 22005 (2007): [Traceability in the feed and food chain - General principles and basic requirements for system design and implementation](#)

European Union (directly applicable) regulations for a single food and feed hygiene policy can be downloaded from the Internet ("[Hygiene Package](#)"). Some regulations on which the guides of good hygiene practices (GBPH) are based are:

- [REGULATION \(EC\) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL](#) of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures for the safety of foodstuffs
- [REGULATION \(EC\) No 852/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL](#) of 29 April 2004 on the hygiene of foodstuffs
- [REGULATION \(EC\) No 1831/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL](#) of 22 September 2003 on additives for use in animal nutrition
- [REGULATION \(EC\) No 1831/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL](#) of 12 January 2005 laying down requirements for the hygiene of feedstuffs

A free 2001 FAO training is available online under the title "[Food Quality and Safety Systems - A Training Manual on Food Hygiene and the Hazard Analysis and Critical Control Point \(HACCP\) System](#)". It contains a lot of explanations, examples and attached HACCP forms.

All of these standards and many more can be ordered in electronic or paper format on the [ISO](#) site.

More than 28,000 standards (in English and other languages) are available on the [Public.Resource.Org](#) site.

2.2 Definitions

The beginning of wisdom is the definition of terms. Socrates

The definitions of ISO 9000 and ISO 22000 are fully applicable to the food safety management system.

Below are some definitions and specific acronyms:

Accident: *undesired event causing death or health and environmental damages*

CCP: *critical control point*

Conformity: *fulfillment of a specified requirement*

Control measure: activity to prevent, eliminate or reduce a hazard to the safety and suitability of the food or reduce it to an acceptable level

Control plan: document describing the specific provisions for carrying out the control of the product or the process

Documented information: any support allowing the treatment of information

Efficiency: financial relationship between achieved results and used resources

FAO: Food and Agriculture Organization of the United Nations

FS: food safety

Food hygiene: means and conditions to control food hazards and to guarantee the food safety and suitability

Food safety management system: set of processes allowing food safety objectives to be achieved

Foodborne alert: information related to a food whose lack of treatment may have a potential adverse effect on the health of consumers

Foodborne crisis: risk situation, relating to foodstuffs that can create a collective concern

FSMS: food safety management system

Gap: noncompliance with a certain threshold

Good manufacturing practices: all the necessary preventive activities for food manufacturing under acceptable hygienic conditions

HACCP method: tool of reasoning that makes it possible to identify, evaluate and control the food safety hazards

HACCP system: the HACCP plan and the prerequisite programs for the control of food safety

Health quality: ability to satisfy and ensure optimal food safety

Incident: undesired event that can lead to deterioration of health

Stakeholder: person, group or company that can affect or be affected by an organization

oPRP: operational prerequisite program

Organization (company): a structure that satisfies a need

Performance: measurable and expected results of the management system

Problem: gap that must be reduced to get a result

PRP: prerequisite program

Requirement: explicit or implicit need or expectation

Risk: likelihood of occurrence of a threat or an opportunity

WHO: World Health Organization

Examples of stakeholders: investors, customers, employees, suppliers, citizens, social and political organizations

In the terminology of management systems, do not confuse:



- anomaly, defect, dysfunction, failure, nonconformity, reject and waste:
 - anomaly is a deviation from what is expected
 - defect is the non-fulfillment of a requirement related to an intended use
 - dysfunction is a degraded function that can lead to a failure
 - failure is when a function has become unfit
 - nonconformity is the non-fulfillment of a requirement in manufacturing
 - reject is a nonconforming product that will be destroyed
 - waste is when there are added costs but no value
- audit program and audit plan
 - an audit program is the annual planning of the audits
 - an audit plan is the description of the audit activities
- audit, inspection, auditee and auditor
 - an audit is the process of improving the management system
 - an inspection is the conformity verification of a process or product

- an auditee is the one who is audited
 - an auditor is the one who conducts the audit
- calibration and verification
 - the calibration is the confirmation of a value read in relation to a standard
 - verification is the positioning of landmarks
- control and optimize
 - control is meeting the objectives
 - optimize is searching for the best possible results
- customer, external provider and subcontractor
 - a customer receives a product
 - an external provider provides a product on which specific work is done
 - a subcontractor provides a service or product on which specific work is done
- effectiveness and efficiency
 - effectiveness is the level of achievement of planned results
 - efficiency is the ratio between results and resources
- follow-up and review
 - follow-up is the verification of the obtained results of an action
 - review is the analysis of the effectiveness in achieving objectives
- food hazard and risk
 - the hazard is a potential adverse effect coming from a food (contaminated food)
 - the risk is the level of appearance and the severity of the hazard to the consumer (food infection: vomiting, diarrhea)
- food safety and security
 - safety is what is acceptable to the consumer
 - security means no harm to the consumer
- gap and problem
 - the gap is the non-respect of a threshold
 - the problem is a gap that must be reduced (to obtain a result)
- hazard and risk analysis
 - hazard analysis is the responsibility of participants in the food chain
 - risk analysis is in the public health domain
- inform and communicate
 - to inform is to bring information to someone's knowledge
 - to communicate is to pass on a message, to listen to the reaction and discuss
- microorganism (microbe) and contaminant
 - micro-organism: living organism of microscopic size, dangerous or useful (bacterium, virus, yeast)
 - contaminant: substance accidentally or deliberately introduced into the food (cleaning agent residue, disinfectant, pesticide)
- objective and indicator
 - an objective is a sought after commitment
 - an indicator is the information on the difference between the pre-set objective and the achieved result
- organization and enterprise, society, company
 - organization is the term used by the ISO 9001 standard as the entity between the supplier and the customer
 - an enterprise, society and company are examples of organizations
- process, procedure, product, activity and task
 - a process is how we satisfy the customer using people to achieve the objectives
 - a procedure is the description of how we should conform to the rules
 - a product is the result of a process
 - an activity is a set of tasks
 - a task is a sequence of simple operations

- verify and validate
 - to verify is a process to prove compliance
 - to validate is to ensure that a process will be compliant and effective
- withdrawal and recall
 - a withdrawal is the measure to prevent the distribution
 - a recall is the measure to prevent post-distribution consumption

Remark 1: the use of ISO 22000 and ISO 9000 definitions is recommended. The most important thing is to determine a common and unequivocal vocabulary for everyone in the company.

Remark 2: the customer can also be the user, the beneficiary, the trigger, the ordering party or the consumer.

Remark 3: documented information is any information that we must maintain (procedure ) or retain (record ).




For other definitions, comments, explanations and interpretations that you don't find in this module and in [annex 06](#), you can consult: 

- ISO [Online Browsing platform](#) (OBP)
- IEC [Electropedia](#)
- [ISO 9000: 2015](#) - Quality management systems. Fundamentals and vocabulary

2.3 Books



Books for further reading:

-  Bizmanualz, [ISO 22000 Standard Procedures for Food Safety Management Systems](#), Bizmanualz, 2008
-  Sara Mortimore and Carol Wallace, [HACCP: A Practical Approach](#), Springer, 2013
-  Chef Dhir, [FOODSAFE- For Food Handlers and Food Service Managers: International Food Safety and Hygiene Principles](#), Amazon, 2014
-  I. Irshad and M. Khan, [HACCP: A Guide to a Practical Development & Implementation](#) (Food Safety & Quality), Independent, 2017
-  Carlos Hernandez, [GMP Good Manufacturing Practices: Management Systems](#), Individual, 2018



- Vindika Lokunarangodage, [ISO 22000:2018 Generic Model](#): ISO 22000:2018 Food Safety Management System, Amazon, 2018

**When I think of all the books still left for me to read, I am certain of further happiness.
Jules Renard**

3 Process approach

3.1 Processes

If you cannot describe what you are doing as a process, you do not know what you're doing. Edwards Deming

The word process comes from the Latin root *procedere* = go, development, progress (Pro = forward, *cedere* = go). Each process transforms inputs into outputs, creating added value and potential nuisances.

A process has three basic elements: inputs, activities and outputs.



A process can be very complex (launch a rocket) or relatively simple (audit a product). A process is:

- repeatable
- foreseeable
- measurable
- definable
- dependent on its context
- responsible for its external providers

Process: *activities that transform inputs into outputs*

A process is, among other things, determined by its:

- title and type
- purpose (why?)
- beneficiary (for whom?)
- scope and activities
- initiators
- documented information
- inputs
- outputs (intentional and not intentional)
- restraints
- people
- material resources
- objectives and indicators
- person in charge (owner) and actors (participants)
- means of inspection (monitoring, measurement)
- mapping
- interaction with other processes
- risks and potential deviations
- opportunities for continual improvement

A process review is conducted periodically by the process owner (cf. [annex 02](#)).

The components of a process are shown in figure 3-1:



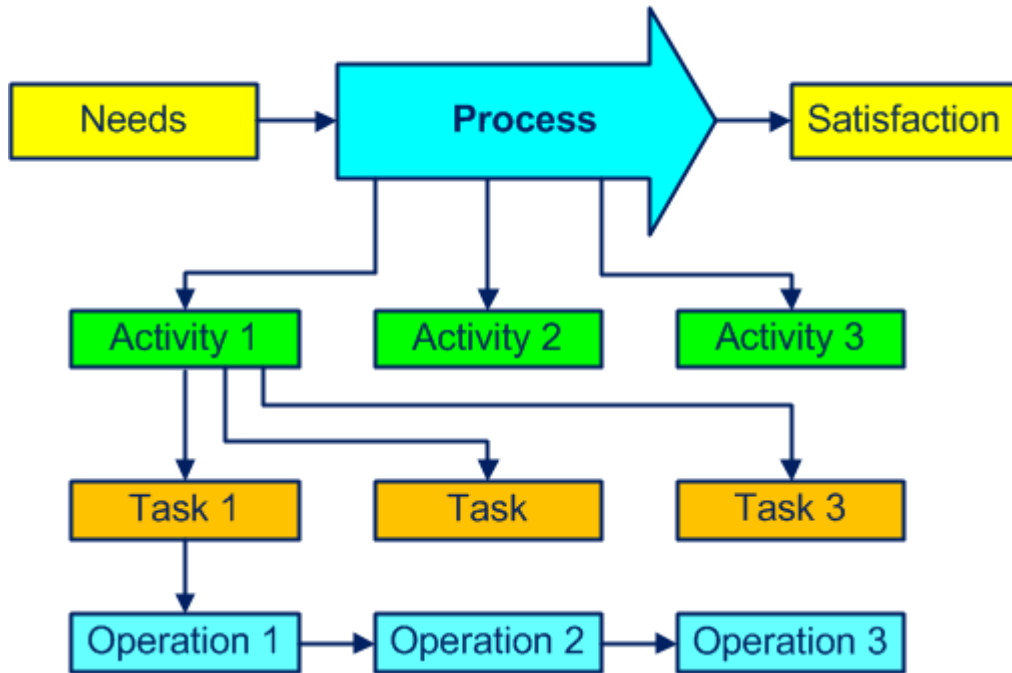


Figure 3-1. Components of a process

Figure 3-2 shows an example that helps to answer some questions:

- which materials, which documents, which tooling? (inputs)
- which title, what objective, which activities, requirements, constraints? (process)
- which products, which documents? (outputs)
- how, which inspections? (methods)
- what is the level of performance? (indicators)
- who, with what competence? (people)
- with what, which machines, which equipment? (material resources)

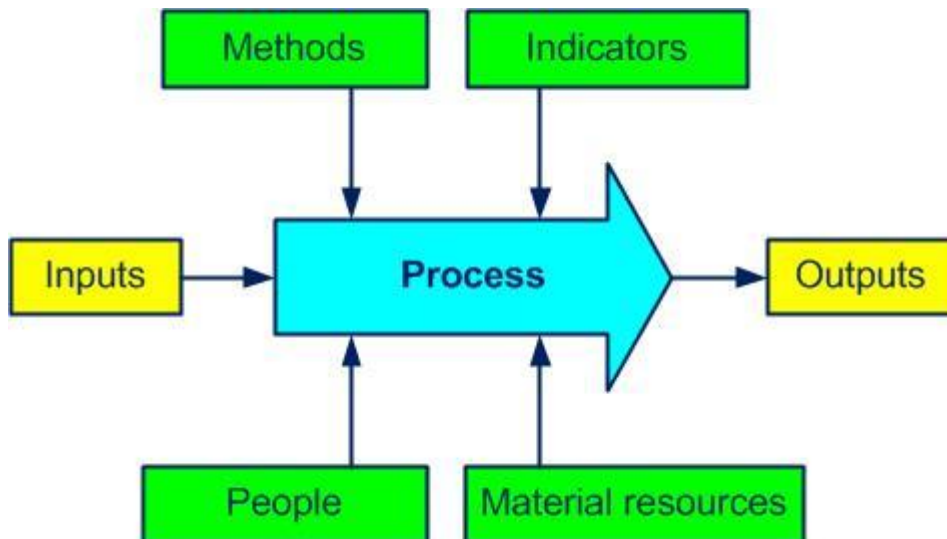


Figure 3-2. Some elements of a process

Often the output of a process is the input of the next process.

You can find some examples of process sheets in the document pack [D 02](#) and a list of processes in [annex 03](#).

Any organization (company) can be considered as a macro process, with its purpose, its inputs (customer needs and expectations) and its outputs (products/services to meet customer requirements).

Our preference is to identify a process using a verb (buy, produce, sell) instead of a noun (purchases, manufacturing, sales) to differentiate the process from the company's department or documented information to maintain and recall the purpose of the process.

The processes are (as we shall see in the following paragraphs) of management, realization and support types. Do not attach too much importance to process categorizing (sometimes it's very relative) but ensure that all the company's activities fall into at least one process.

3.1.1 Management processes

Management processes are also known as piloting, decision, key or major processes. They take part in the overall organization and include elaboration of the policy, deployment of the objectives and all needed checks. They are the glue of all the realization and support processes.

The following processes can be part of this family:

- develop strategy
- develop food safety policy
- plan the FSMS
- address risks
- acquire people
- establish process ownership
- conduct an audit
- conduct management review
- communicate
- improve
- negotiate contract
- measure satisfaction of interested parties

3.1.2 Realization processes

The realization (operational) processes are related to the product, increase the added value and contribute directly to customer satisfaction. Two specific processes are shown in [annex 04](#).

They are mainly:

- design
- implement prerequisite programs
- prevent emergencies
- manage waste
- purchase
- receive, store and deliver
- analyze hazards
- carry out the HACCP plan
- inspect
- verify
- implement traceability (identify and keep history)
- produce

- sell

3.1.3 Support processes

The support processes provide the resources necessary for the proper functioning of all other processes. They are not directly related to a contribution of the product's added value, but are still essential.

The support processes are often:

- control documentation
- provide information
- acquire and maintain infrastructure
- provide training
- manage validation and verification means
- keep updated the regulatory watch
- keep accountability
- manage staff

3.2 Process mapping

Par excellence process “mapping” is a multidisciplinary work. This is not a formal requirement of the ISO 22000 standard but is always welcome.

The three types of processes and some interactions are shown in figure 3-3.

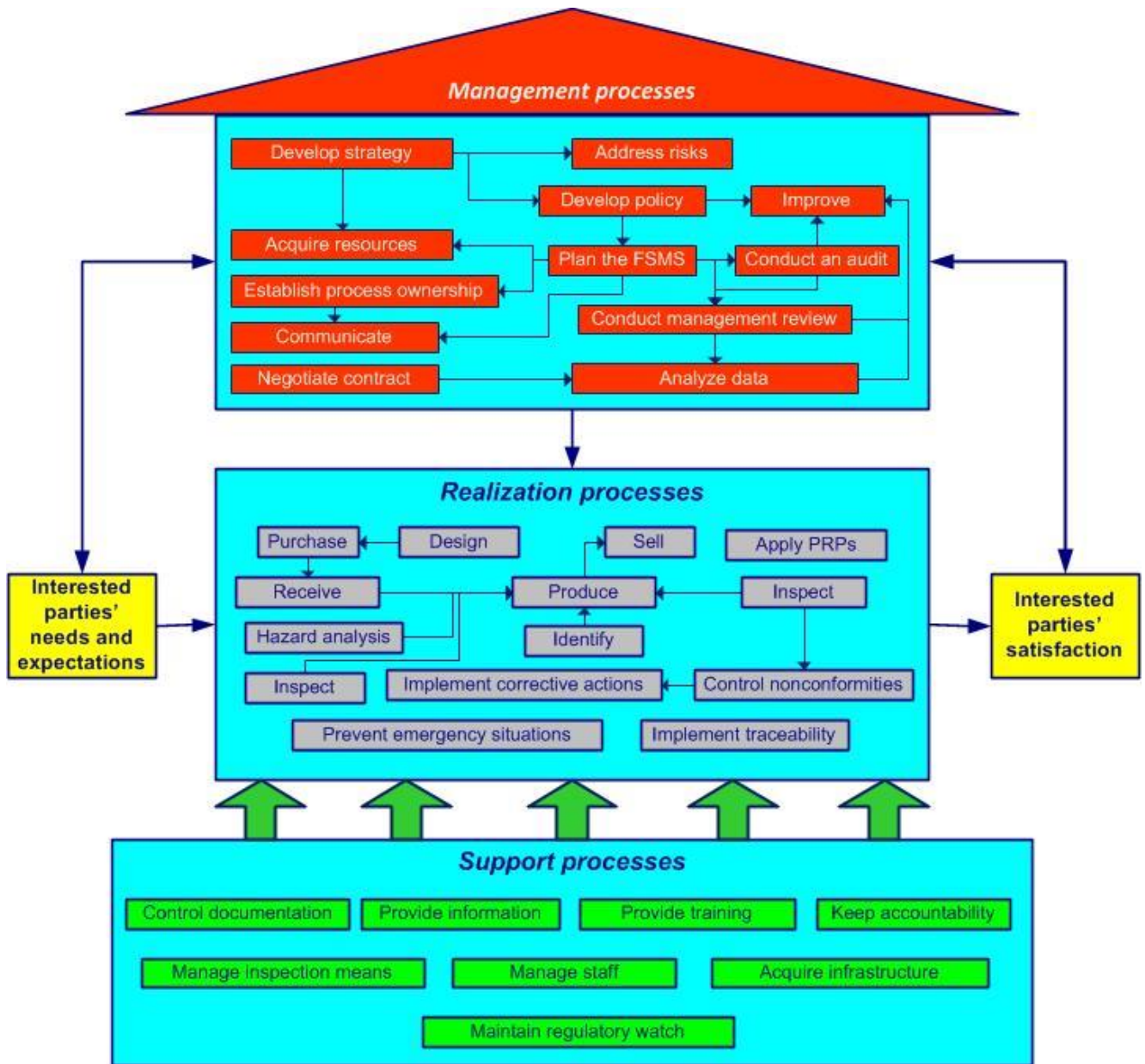


Figure 3-3. The process house


Interested party: person, group or company affected by the impacts of an organization

Examples of interested parties: investors, customers, distributors, consumers, employees, suppliers and society.

Mapping, among other things, allows you to:

- obtain a global vision of the company
- identify the beneficiaries (customers), flows and interactions
- define rules (simple) for communication between processes

To obtain a clearer picture, you can simplify by using a total of about 15 core processes. A core process can contain several sub-processes: for example, the process "develop the

FSMS" can involve: 

- develop strategy
- develop policy

- address risks
- plan the FSMS
- deploy objectives
- acquire resources
- establish process ownership
- improve

An example of the process “produce” is shown in figure 3-4:

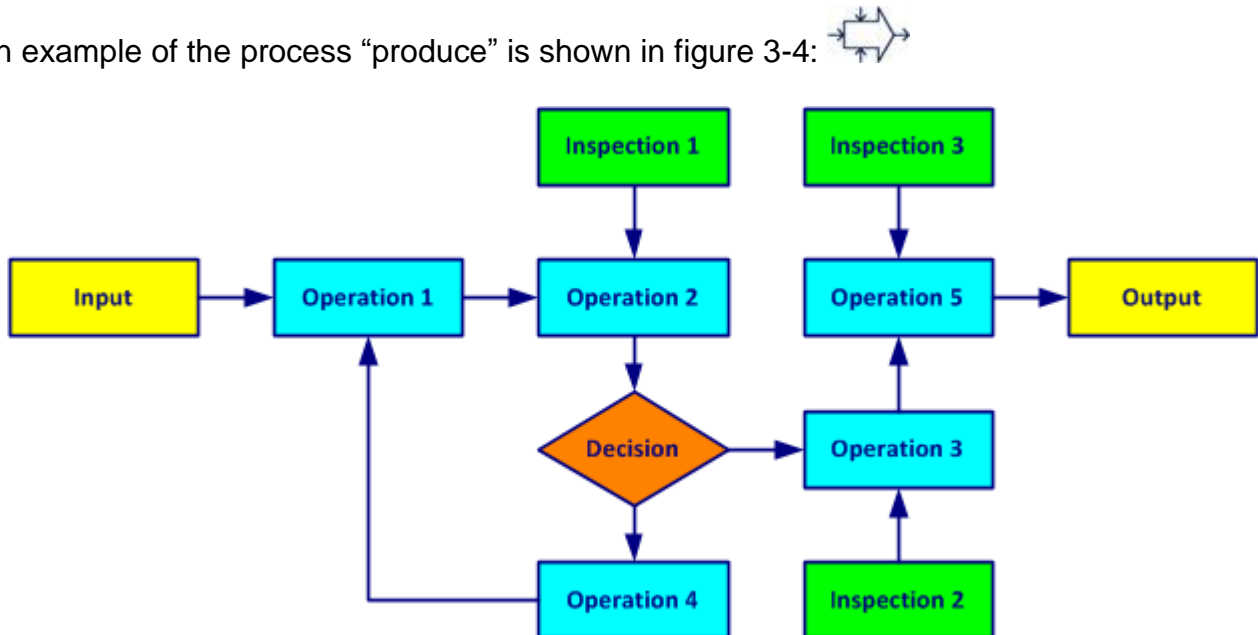


Figure 3-4. Produce process

3.3 Process approach

Simple solutions for now, perfection for later

The process approach contributes enormously to the efficient management of the company.

Process approach: *management by the processes to better satisfy customers, improve the effectiveness of all processes and increase global efficiency*

When the process approach is integrated during the development, implementation and continual improvement of a food safety management system, it allows one to achieve objectives that are related to interested parties' satisfaction, cf. [annex 05](#).

The process approach is based on the PDCA cycle, as shown in figure 3-5 (cf. ISO 22000, sub-clause 0.3.2).

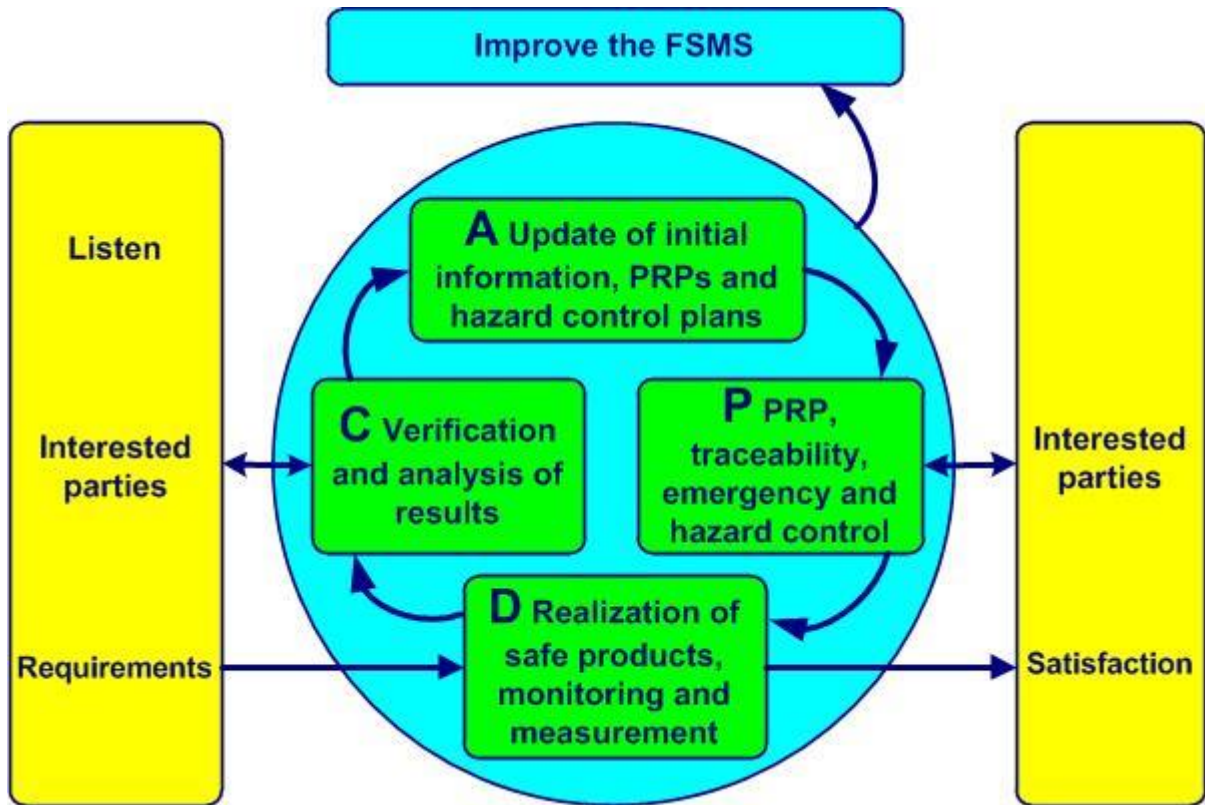


Figure 3-5. Model of a FSMS

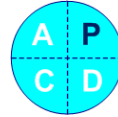
The process approach:

- emphasizes the importance of:
 - understanding and complying with customer requirements
 - prevention so as to react to unwanted elements such as:
 - withdrawals
 - recalls
 - customer returns
 - waste
 - incidents
 - accidents
 - nuisance
 - waste
 - rejects
 - measuring process performance, effectiveness and efficiency
 - permanently improving objectives based on pertinent measurements
 - process added value
- relies on:
 - methodical identification
 - interactions
 - the sequence and
 - process management, which consists of:
 - determining objectives and their indicators
 - piloting related activities
 - analyzing obtained results
 - permanently undertaking improvements
- allows one to:
 - better view inputs and outputs and their relationship
 - clarify roles and responsibilities
 - judiciously assign necessary resources

- break down barriers between departments
- decrease costs, delays and waste
- and ensures in the long run:
 - control
 - monitoring and
 - continual improvement of processes

The process approach **is not**:

- crisis management ("You will not solve the problems by addressing the effects")
- blaming people ("Poor quality is the result of poor management." Masaaki Imai)
- prioritizing investments ("Use your brain, not your money." Taiichi Ohno)




4 Context

4.1 The organization and its context (*requirements 1 to 2*)

The two most important in a company do not appear in its balance sheet: its reputation and its people. Henry Ford

To successfully implement a food safety management system, we must understand and evaluate everything that can influence the reason for being and business performance. You should think carefully about a few key activities:

- develop a thorough diagnosis of the unique context in which your company exists, taking into account these issues:
 - the external environment, such as:
 - social
 - regulatory
 - economic
 - technology
 - the internal environment, such as:
 - specific aspects of the corporate culture:
 - vision
 - rationale, purpose and mission
 - core values
 - staff
 - products and services
 - infrastructure
- monitor and review regularly any information relating to external and internal issues
- analyze the factors that may influence the achievement of business objectives

Documented information on issues are identified, reviewed and updated. 

The SWOT and PESTEL analyses can be useful for relevant analysis of business context (cf. [annex 07](#)).

A list of external and internal issues is carried out by a multidisciplinary team. Each issue is identified by its level of influence and control. Priority is given to issues with great influence and poor control.

Good practices

- *diagnosis of the context includes the main external and internal issues*
- *the core values as part of the corporate culture are taken into account in the context of the company*
- *the results of the context analysis are widely diffused*
- *the SWOT analysis includes many relevant examples*
- *the SWOT analysis is a powerful tool for identifying the main threats and opportunities*

Bad practices

- *the issues of the context of the company, such as the competitive environment, are not taken into account*

- *in some cases, the corporate culture is not taken into account*
- *risk analysis does not take into account strategic issues*
- *no clear link between the SWOT analysis and the actions undertaken*


4.2 Interested parties (requirements [3 to 5](#))

There is only one valid definition of a business purpose: to create a customer. Peter Drucker

To understand the needs and expectations of interested parties, we must begin by determining those who may be affected by the food safety management system, such as:

- employees
- customers
- external providers
- owners
- shareholders
- bankers
- distributors
- competitors
- citizens
- neighbors
- social and political organizations

A list of interested parties is created by a multidisciplinary team.

Documented information on interested parties and their requirements is identified, reviewed and updated. 

Each interested party is determined by its level of influence and control. Priority is given to interested parties with great influence and poor control.

True story

The customer is king but we still can fight against rudeness. This example is taken from the restaurant La petite Syrah in Nice and its coffee prices:



"A coffee" 7 €
 "A coffee, please" 4,25 €
 "Hello, a coffee, please" 1,40 €

Anticipating the reasonable and relevant needs and expectations of interested parties involves:

- meeting the requirements of the product or service offered
- preparing to address risks
- seizing improvement opportunities

When a requirement is accepted, it becomes an internal requirement of the FSMS.

Good practices

- *the list of interested parties is updated*
- *the needs and expectations of interested parties are established through meetings on-site, surveys, roundtables and meetings (monthly or frequent)*
- *the application of statutory and regulatory requirements is a prevention approach and not a constraint*


Bad practices

- *statutory and regulatory requirements are not taken into account*
- *the delivery time is not validated by the customer*
- *the expectations of interested parties are not determined*
- *the list of interested parties does not contain their area of activity*

4.3 Scope (requirements [6 to 11](#))

In many areas, the winner is the one who is best informed. André Muller

The scope (or in other words, the perimeter) of the food safety management system is defined by top management. For this, products, services, processes and manufacturing sites are established.

Documented information is available and maintained on the scope of the FSMS. 

The specific context of the company is taken into account to determine the scope of the FSMS, including:

- issues (cf. sub-clause 4.1)
- products and services
- corporate culture
- environment:
 - social
 - financial
 - technology
 - economic
- requirements of interested parties (cf. sub-clause 4.2)
- outsourced processes

Hazards related to food safety are identified and controlled (HACCP approach).

Food safety: *absence of harm to the consumer when food is prepared or consumed according to its intended use*

Good practices

- *the scope is relevant and available upon request*

- non applicable requirements are justified in writing

Bad practices

- some products are outside the scope of the FSMS without justification
- the washing workshop is not included in the scope of the FSMS
- the requirements of a customer are not accepted and no justification is present
- the scope is obsolete (a new subsidiary is not included)

4.4 FSMS (requirement [12](#))

The requirements of ISO 22000 relate exclusively to the food safety management system. The system is:

- established
- documented
- implemented and
- evaluated and
- continually improved

Specific customer requirements related to food safety are identified and are part of the FSMS.

Answers to the 451 requirements (in the text "shall") of clauses 4 to 10 of ISO 22000 are present in the FSMS documentation.

The requirements of ISO 22000 in the sub-clauses of clauses 4 to 10 are shown in figure 4-1:

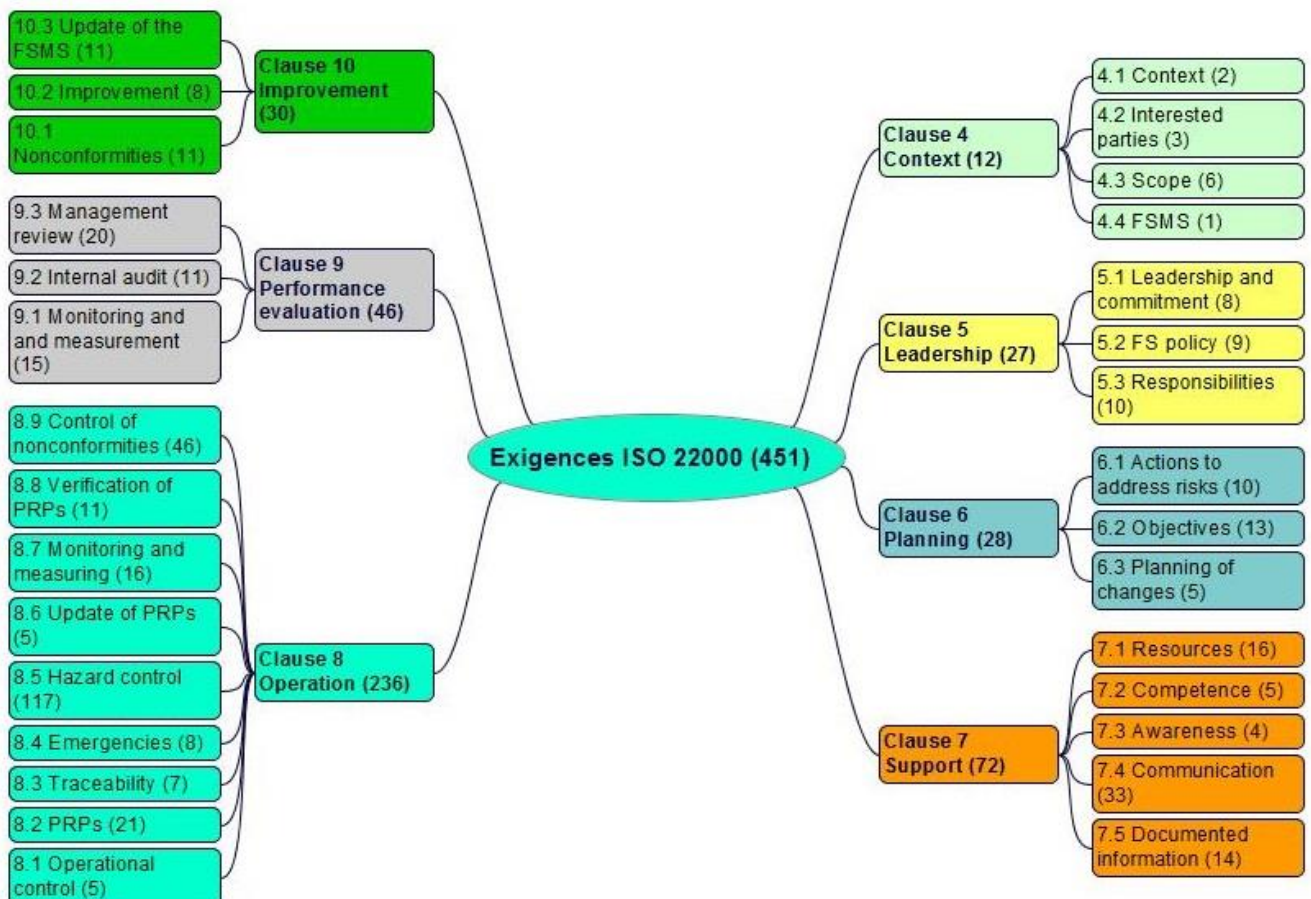


Figure 4-1. Requirements of ISO 22000 version 2018

Relax! If you comply with the food hygiene regulations and you have implemented the HACCP system, you meet a very large part of the requirements of ISO 22000. You simply need to add the oPRPs and the validation of the combinations of control measures.

Never forget that food hygiene always includes food safety and suitability.

When there is insecurity, the consumer is no longer safe from hazards (such as food poisoning). So this can be a very serious situation.




When there is insecurity about food hygiene the consumer often refuses the food because they think they have detected, for example, an unacceptable presence of mold or unpleasant odor. This can have a potentially serious financial impact.

The FS manual is not a requirement of the ISO 22000 version 2018 standard but it is always an opportunity to present the company, its FSMS and its processes (cf. [annex 08](#)).

The ISO guide "[The integrated use of management system standards](#)" of 2018, contains relevant recommendations on the integration of management systems.



Pitfalls to avoid:

- going overboard on quality: 
 - a useless operation is performed without adding value and without the customer asking for it - it is a waste, cf. quality tools [D 12](#)
- having all procedures written by the quality manager: 
 - quality is everybody's business, "the staff is conscious of the relevance and importance of each to the contribution to quality objectives", which is even more true for department heads and process pilots
- forgetting to take into account the specificities related to the corporate culture: 
 - innovation, luxury, secrecy, authoritarian management (Apple)
 - strong culture related to ecology, action and struggle, while cultivating secrecy (Greenpeace)
 - fun and quirky corporate culture (Michel & Augustin)
 - liberated company, the man is good, love your customer, shared dream (Favi)

Good practices

- *the process map has enough arrows to show who the customer (internal or external) is*
- *for a process, it is better to use a lot of arrows (several customers) rather than to forget one*
- *reveal the added value of the process during the process review*
- *the analysis of process performance is an example of continual improvement and evidence of the effectiveness of the FSMS*
- *the purpose of each process is clearly defined*
- *top management regularly monitors the objectives and action plans*
- *innovation potential is confirmed by increased sales of new products*

Bad practices

- *some process outputs are not set correctly (customers not considered)*
- *process efficiency criteria are not established*
- *the process owners are not formalized*
- *outsourced processes are not determined*
- *control of outsourced services is not described*
- *very real activities are not determined in any process*
- *sequences and interactions of certain processes are not determined*
- *methods and criteria to ensure the performance of certain processes are not defined*
- *monitoring the performance of certain processes is not established*
- *the FSMS resources do not allow achievement of objectives*
- *the FSMS is not updated (new processes not determined)*
- *the threats and weaknesses identified in the SWOT analysis remain without actions*