

## CHAPTER 4

# Food safety management system EN ISO 22000:2005



### 4.1 Introduction (Clauses 1–3)



**Figure 4.1** Keywords from Section 4.1.

This international standard defines requirements in terms of food safety applied to organizations in the food chain or organizations that support it (see Fig. 4.1 for relevant keywords). In 2004, 54 experts were registered as members of the working group responsible for the development of ISO 22000:2005, and the decision to publish it was taken unanimously by the participating countries of ISO/TC 34/SC 17.<sup>1</sup>

Despite the high number of participants of this committee, any change to the standard can only be approved when 75% of its voting members are in agreement (ISO 2005a). This fact provides this international standard with a wide range of inputs and, at the same time, stability and credibility. Although the requirements

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<sup>1</sup> Information obtained from ISO/TC 34/SC 17 secretariat.

that organizations must comply with are only stated as of Clause 4, some of the most important concepts are introduced before. Those concepts can be fundamental to a successful implementation of the standard in an organization.

Throughout the food chain, several food safety hazards may occur. Collaboration between all parties involved in the food chain is therefore fundamental, providing confidence that, at each step, food safety requirements have been complied with.

The introduction of this standard presents four key elements that are present throughout the norm: interactive communication; system management; prerequisite programs; and HACCP principles. These are fundamental to guarantee food safety in every part of the food chain.

Interactive communication highlights the importance of interaction between each step within the food chain. An accurate and complete transmission of information between the food chain and external stakeholders will ensure, in a more efficient way, the identification and control of all relevant risks to food safety. It is therefore important that each organization understands its role and position in the food chain in order to request and provide the necessary information to guarantee food safety until final consumption.

The standard should be implemented as another tool of the overall organization and not as an isolated element, independent of management functions. The compatibility of this standard with other existing standards, particularly ISO 9001, allows its adaptation and integration when organizations are implementing other management systems.

Hazard analysis is essential in the implementation of an effective food safety management system; this standard integrates the HACCP principles and application steps developed by the *Codex Alimentarius*. In addition, it associates HACCP with prerequisite programs. This combination helps to organize the necessary knowledge to establish an effective range of control measures.

In the scope of the standard it is stated that ‘this International Standard specifies requirements for a food safety management system where an organization in the food chain needs to demonstrate its ability to control food safety hazards in order to ensure that food is safe at the time of human consumption.’ The scope is generic in terms of the type of organization that can implement it; ‘It is applicable to all organizations, regardless of size, which are involved in any aspect of the food chain...’ but specific for the type of food safety hazards that need to be controlled. However, organizations may find it useful to use the same approach to respond to other situations nonspecific to food safety.<sup>2</sup> Furthermore, the standard also mentions the possibility of organizations using external resources to meet the requirements

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<sup>2</sup> Although the standard clearly states that it ‘is intended to address aspects of food safety concerns only,’ several of the procedures presented can be used in other aspects. The procedures established for employee training or the definition of responsibilities and authorities or communication with customers (e.g., enquiries, complaints) are some examples of situations in which the organization may use the same approach, and even the same documents/records, to address issues beyond food safety.

or, in the case of a small and/or less-developed organizations, the possibility of implementing a combination of control measures established externally.

ISO 22004:2014 clarifies that organizations may appeal to external assistance (e.g., generic guidelines or models, individuals, or organizations acting as consultants). However, the organization must guarantee that when using guidelines or models developed externally they are suitable, adjusted, and appropriate to the organization. This option seems particularly interesting for small and low-complex-activity businesses, since it will allow less use of resources in the implementation of the standard.

## 4.2 Food safety management system (Clause 4)

For keywords, please see Figure 4.2.



Figure 4.2 Keywords from Section 4.2.

### 4.2.1 General requirements (Clause 4.1)

This clause provides general requirements that the organization must fulfill and materializes some of the principles mentioned in Section 4.1. From the communication point of view, the organizations are compelled to share information about food safety throughout the food chain and within the organization. Even with different objectives, they share the same purpose: deliver safe products at the time of consumption. The principle of continuous improvement is also present in the requirement, since it is stated that the system should be periodically evaluated and updated with the most recent information available.

The standard also requires the definition of a scope that ‘shall specify the products or product categories, processes and production sites that are addressed by the food safety management system.’ The scope is very important because it clearly identifies the boundaries within which the organization must comply with the requirements of this standard. When this standard is applied as part of the FSSC 22000 the scope has to comply with what is defined in the scheme, as described in Section 5.2.1.

The possibility to ‘outsource any process that may affect end product conformity’ is also foreseen. When this is the case, the organization must identify and document how those processes are controlled. The organization must guarantee the same level of control as if the process was performed in-house.

## 4.2.2 Documentation requirements (Clause 4.2)

Documentation control is one of the foundations on which an organization must support its operating activities and is clearly a key element in the success of any management system. This control allows the organization to keep its documentation constantly available and updated at the appropriate locations in order to be used or consulted whenever necessary. In the application guide of the standard (ISO 22004:2014) it is specified that the documentation can be supported in any kind of media. ISO 22000:2005 divides the documentation in three main groups:

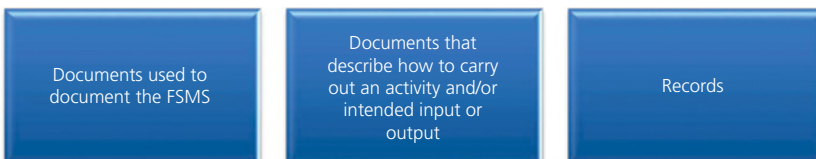
1. statement of the food safety policy and its objectives;
2. procedures and records required by the system; and
3. support documents for development, implementation, and update of the standard.

The statement of policy and related objectives is a particular type of document that the top management shall define, as described below in Section 4.3.2. The system procedures describe the activities that implement food safety and document the actions that need to be developed and respective responsibilities. The records provide evidence that the procedures established in the FSMS are implemented as described and in accordance with the ISO 22000 requirements. Both result directly from the need to comply implicitly or explicitly with the requirements that are presented throughout the scheme.

Support documentation consists of any document that, although not required or explicitly mentioned in the standard, is necessary for its development, implementation, and update (e.g., legislation, good practice guides, fact sheets).

The complexity and amount of documentation required varies depending on the dimension and complexity of the organization. However, there is documentation that must be present independently of these constraints (e.g., policy and objectives, prerequisite programs (PRPs), operational prerequisite programs (OPRPs), HACCP plans). Support documentation and the number of records are, on the other hand, examples of documentation that vary more from one organization to another.

ISO 22004:2014 divides the documentation into three main groups (Fig. 4.3) and presents for each one a comprehensive list of the documents necessary to comply with ISO 22000:2005 requirements. Appendix 1 contains the list of documents mentioned in the guide for each of the three groups. Activities that can be outsourced (e.g., laboratory analyses, transportation, storage, and pest control) should also be documented as part of the system.



**Figure 4.3** The three main groups in which documentation is divided, according to ISO 22004:2014.

The information required for implementation, maintenance, and update of the standard, particularly in bigger or more complex companies, can produce a large number of documents, leading to greater complexity and even discouraging management and other workers. There is therefore a tendency for the increasingly widespread use of computer support to provide and file documentation. This option can be very helpful because it allows a faster update and distribution of new documentation, while providing practical and automatic evidence of these activities. It also facilitates the internal/external communication. The use of dedicated software incurs costs that cannot always be supported by organizations. However, there are some tools which are available for free that can facilitate the implementation of FSMS, making document management a more user-friendly and less time-consuming process (see Box 4.1; Figs 4.4, 4.5). However, this alternative requires the application of measures to ensure protection, recovery, and retention of documents and information. The use of back-ups, databases, and antivirus tools and the definition of passwords and access restrictions are important to allow the creation of conditions for safe use of computer storage media.

After having identified the documentation required to be part of the FSMS (Clause 4.2.1), the following two clauses define the means to control it: Clause 4.2.2 and Clause 4.2.3.

Table 4.1 lists the requirements defined by the standard as mandatory to be included in the documented procedure for the control of documents and examples of how to implement them. A record is considered a special type of document with specific requirements for its control. Records are essential as evidence of the performance of the food safety management system. In order to attain this objective, records must be complete, legible, clearly identifiable and easily retrievable,

#### **Box 4.1** Online surveys

It is possible to find online tools to develop surveys that can be used to reduce the amount of documents, while also providing easier ways to access and analyze the information obtained. Two examples where these tools can be used with great advantage are when the organization uses surveys to obtain information from suppliers and (adapting a survey) to make internal audits or checklists.

In the first case (Fig. 4.4), an online survey not only benefits the organization (it reduces the paper work, the time to prepare the survey and to reach the supplier, and is less time/paper consuming) but also benefits the supplier who has an easier and quicker way to comply with the customer requisite. In the second example (Fig. 4.5), the adaptation of a survey to complete audits or other checklists is hugely convenience, especially when a tablet computer with internet access can be used.

In both cases, the information obtained can be read by anyone granted access and at any location with access to the internet. The information is commonly saved in a spreadsheet or similar tool, enabling easy statistical evaluation of the results.

Box 4.2 explains how to use QR codes to provide access to food safety information but also as an example of using available online tools to minimize bureaucracy and increase interactive communication.

## General Criteria

	Yes	No	In progress
1 - Does the supplier has license for its activities?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2 - Is the supplier certified?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you answered positively to question 2, which standard(s) is the supplier certified to?

## Specific Criteria

	Yes	No	In progress	n/a
1 - Does the supplier have the HACCP system implemented?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2 - Does the supplier have a code for good hygiene and manufacturing practices?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Figure 4.4 Example of an online survey (partial).

## Storage, Handling and Processing

### 7. Check metal detector.

- Ok
- Not Ok

### 8. Correct assignment of the lot and the expiration date on labels.

- Ok
- Not Ok
- Not applicable

## Final classification

Overall, how would you rate the storage and cleaning of the factory?

1 2 3 4 5 6 7 8 9 10

Bad           Excellent

Figure 4.5 Example of an online check (partial).

**Table 4.1** Procedure requirements and examples of methods of implementation

Procedure requirements	Examples
Approve documents before use	Identify the designated personnel that have the knowledge and authority to verify adequacy and approve documentation. It is common that the food safety team leader (FSTL) or top management are responsible for this function, since it requires global knowledge of the standard, food safety, and organization processes.
Identify the need for a new version and update of documents	Suggestions for improving the documentation should be encouraged, although it is common that approval remains the responsibility of the FSTL or top management. A maximum period of time to verify that the document remains adequate can also be stated.
Identify the modifications made in the documents and the current version	Describe the methods of documenting each modification and identify the newest version.
Ensure that the latest version is available at the required location	Identify the location(s) where each document should be used and by whom, so that where to replace a document at each new version is clearly known. The process of changing the old documents for the new documents is described.
Ensure that the documents are identified and legible	A description of how each type of document is identified must be made. It is common to establish a 'template' for each document of the system, including information such as the document name, the version number, and the person responsible for development and approval.
Ensure the identification of the external documentation and the control of its distribution	Identify the process/responsibility to obtain/seek external information. According to each type of information it is important to define the periodicity of this research, ensuring that a routine is created within the organization.
Ensure that obsolete documents are identified and not used	Describe the procedures for the substitution of obsolete documents from the locations/personnel of use and define how to identify them clearly to avoid using them by mistake.

have a defined and documented retention time, and be stored in safe locations which are protected from deterioration.

Table 4.2 lists the instructions that the standard provides to control records and examples of how they can be described in a procedure. To better understand how to control documents and records according to the standard requirements, an example of the contents of a record that can be created for that purpose is as follows.

- *Designation and/or code*: Clearly identify the document.
- *Revision*: Identifies the current version that is being used. If the organization wants to have documentation in paper support, it should consider the size of the documents that are codified under the same version since any change requires the alteration of the version for the entire document and a new print.
- *Date of approval*: Identifies the date of approval of the latest version.

**Table 4.2** Instructions to control records and examples of how can they be described in a procedure

Instructions	Examples
Identification	It must be described how each type of record is identified. It is common to establish a 'template' for each record of the system including information such as the record name, its version, and person responsible for development and approval.
Storage	Identify the location of and the person responsible for the records storage.
Protection	The method implemented to guarantee the security and confidentiality of records during the retention time must be described.
Retrieval	Describe the process of removal of complete or obsolete records from their location of use.
Retention time	Establish the retention time considering the expected usage of the products and shelf life along the food chain.
Disposition	Identify the personnel involved, locations, and methods of discarding records.

- *Responsible for approval:* Identifies the person or persons responsible for approving the documents and records.
- *Distribution:* Identifies the place where documents/records are stored and used. In the case of records, information regarding the person(s) (or their function) responsible for its completion can be included.
- *Changes:* Identifies the modifications that were made in the old version.
- *Retention time:* Identifies the records storage time until their destruction.
- *Disposal:* Identifies the method to destroy the records.

### 4.3 Management responsibility (Clause 5)

For relevant keywords, please see Figure 4.6.



**Figure 4.6** Keywords from Section 4.3.



### 4.3.1 Management commitment (Clause 5.1)

Top management is defined according to the standard ISO 9000:2005 as a group constituted by the person or group of people who directs and controls an organization at the highest level, that is, those who occupy higher hierarchical positions (administration/management/general direction) and therefore have the autonomy to make decisions regarding the availability of resources necessary to achieve food safety (both in terms of material resources and human resources) (ISO 2005b). Workers who exercise functions of direction or department management may be considered top management in case they enjoy that autonomy.

The standard identifies methods of how top management should demonstrate its commitment to the development, implementation, and update of the food safety system (see Table 4.3). However, the documented evidence is not an absolute guarantee of compliance. The real commitment comes from the way in which top management is involved in the development of the system, in which is itself an example of compliance with established procedures while embodying the food safety system and its policy (see Section 5.2). Without a proactive approach of the top management, all efforts made by the rest of the organization may be insignificant and eventually disappear with time. It is essential that top management create a culture where employees know they are valued and recognized as much as for fulfilling the requirements/objectives of food safety as for accomplishing other objectives of the organization (e.g., commercial objectives).

**Table 4.3** Evidence of the top management's commitment

Requirements	Examples
Show that food safety is supported by the business objectives.	Evidence that the strategic vision of the organization and its corporate objectives incorporate and respect the principles of food safety.
Communicate the importance of meeting the requirements of ISO 22000, any statutory and regulatory requirements, and customer food safety requirements.	Minutes of meetings and records of the employees' training about statutory and regulatory requirements and customer food safety requirements.
Establish the food safety policy.	Evidence of knowledge about the food safety policy and objectives (see Section 4.3.2).
Conduct management reviews.	Minutes of the review meetings in accordance with Section 4.3.8 where top management participation (collaborating in the FSMS performance evaluation and its continuous improvement) is demonstrated.
Ensure availability of resources.	Guarantee that the food safety system is operational and not compromised by lack of human and material resources (Section 4.4.).

### 4.3.2 Food safety policy (Clause 5.2)

As referred to in ISO 22004:2014, the food safety policy is defined by the top management as 'the basis of any organization's food safety management system.' The food safety policy is defined in Clause 3.4 of ISO 22000:2005 as 'overall intentions and direction of an organization related to food safety.' This standard identifies six requirements for the policy that the top management must enforce.

1. *It is appropriate to the role of the organization in the food chain:* the activity that the organization carries out, its complexity, and its relative location in the food chain should be considered in the policy. It is easy understandable that the objectives and policies from a primary production, food retail, or manufacturing organization are different.
2. *It demonstrates the organization's commitment to comply with statutory, regulatory, and customer requirements.*
3. *It is implemented, communicated and maintained at all levels of the organization:* management must use means to communicate the food safety policy to all levels of the organization, such as training or printing and displaying the information in places where it can be seen by all employees. Even if the policy is not too extensive (as recommended) it should be communicated in order to identify key points (particularly those designed to meet these requirements) that can be easily recognized and retained by personnel. Top management must guarantee that the policy is comprehended and adopted.
4. *It should be periodically reviewed to ensure its suitability:* the review is usually performed at least once a year or at a time that the management review is made (Section 4.3.8).
5. *It highlights the importance of communication* in order to guarantee food safety.
6. *It is supported by measurable objectives:* in order to define the food safety objectives, the organization must take into consideration the fact that they must be rigorous but achievable. Another important aspect is that they have to be easy to monitor and regularly evaluated. If during the period established for the achievement of objectives (this period should not be longer than the period of policy revision) it is clear that an objective will not be fulfilled, its immediate revision should be considered. It is common to define objectives regarding the number of recalls/withdrawals, occurrence of foreign bodies, number of complaints, analytical plan and internal audit results, number of training activities, and effectiveness of corrective actions.

### 4.3.3 Food Safety Management System planning (Clause 5.3)

The standard establishes the obligation of top management to ensure that the planning of the FSMS is carried out in order to fulfill the general requirements of Clause 4.1 and the food safety objectives. Top management should also ensure the constant integrity of the FSMS whenever updates are implemented.

It is important to emphasize that planning is fundamental to the success of the food safety management system. In fact, the decision to implement it, independently of using external help, should be taken after analyzing the current situation

of the organization in terms of food safety, assessing knowledge of internal resources on the subject, and according to the size and complexity of the organization and the objectives established for the implementation of the FSMS.

No guidance is given for the application of this clause in ISO/TS 2004:2014; there is therefore no formal definition for the content of these plans. An example of application is the establishment of a plan in order to achieve (new) food safety objectives. Another example is the definition of a plan to change a production line or to develop new products. This plan may include:

- identification of the suggested modifications;
- definition of the responsibility for approving/making the alterations;
- definition of the responsibility for analyzing the impact of these modifications on the FSMS;
- identification of the necessary corrections to the system and the person who supervises and approves the adjustments; and
- assessment of the integrity of the system.

#### **4.3.4 Responsibility and authority (Clause 5.4)**

Throughout the standard the need to define responsibilities and authorities for the implementation of certain activities/tasks are referred to, as listed in Table 4.4. The identification of these responsibilities and authorities does not imply that top management cannot establish others that may be necessary for the operation and maintenance of the FSMS. It may also be advantageous, particularly for organizations where a management system is not implemented, to use this approach for other purposes (not related to food safety), as mentioned previously in Section 4.1.

For this requirement organizations may develop the organization's chart and job descriptions for example, where the following features should be defined:

1. essential/desirable skills;
2. essential/desirable education or training;
3. responsibilities;
4. authorities; and
5. person to whom problems related to FSMS should be reported.

#### **4.3.5 Food Safety Team leader (Clause 5.5)**

The Food Safety Team leader is the central element of the Food Safety Team (Section 4.5.3) and is elected by the top management. The team leader is critical to the success of the FSMS and, although this role is commonly attributed to the Quality Manager of the organization, it is fundamental to select or prepare someone who, in addition to technical skills, possesses other capabilities of equal or greater importance in order to take food safety to the plant floor and make it part of the company's culture. Examples of such capabilities are organization, leadership, communication, strong interpersonal skills, and the ability to inspire and motivate personnel.

ISO 22004:2014 suggests that the team leader should be a member of the organization with an understanding of the specificity of its hazards and an extensive

**Table 4.4** Identification of the clauses describing the need to define responsibilities and authorities

ISO 22000:2005 Clauses	Transcriptions
5.4 Responsibility and authority	All personnel shall have responsibility to report problems with the food safety management system ... Designated personnel shall have defined responsibility and authority to initiate and record actions.
5.5 Food safety team leader	Top management shall appoint a food safety team leader who, irrespective of other responsibilities, shall have the responsibility and authority ...
5.6.1 External communication	Designated personnel shall have defined responsibility and authority to communicate externally ...
6.2 Human resources	Where the assistance of external experts is required for the development ... records of agreement or contracts defining the responsibility and authority of external experts shall be available.
7.5 Establishing the operational prerequisite program (PRPs)	The operational PRPs shall be documented and shall include ... responsibilities and authorities ...
7.6.1 HACCP plan	The HACCP plan shall be documented and shall include ... responsibilities and authorities ...
7.6.4 System for the monitoring of critical control points	... responsibility and authority related to monitoring and evaluation of monitoring results ...
7.8 Verification planning	Verification planning shall define the purpose, methods, frequencies, and responsibilities for the verification activities.
7.10.1 Corrections	All corrections shall be approved by the responsible person(s) ...
7.10.2 Corrective actions	Data derived from the monitoring of operational PRPs and CCPs shall be evaluated by designated person(s) with sufficient knowledge ... and authority ... to initiate corrective actions.
7.10.4 Withdrawals	... top management shall appoint personnel having the authority to initiate a withdrawal and personnel responsible for executing the withdrawal ...
8.4.1 Internal audit	The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records, shall be defined in a documented procedure.

knowledge of hygiene, food safety management, and application of the HACCP principles.<sup>3</sup> The use of external resources is not rejected and could be considered, particularly in small or low-complex organizations. When this happens, it is recommended that a person from both the Food Safety Team and the organization who is able to maintain a frequent communication with the team leader is identified.

Although the use of external resources to acquire technical knowledge is possible, the task of supervising and motivating is difficult to someone from outside

<sup>3</sup> This has been considered more important throughout the years since the previous version of ISO/TS 22004:2014 (ISO/TS 22004:2005) recommended a basic knowledge of hygiene management and HACCP principles application.

the organization. However, external resources have the advantage of not being conditioned by other responsibilities within the organization. In fact, the importance of avoiding conflicts of interest whenever the team leader assumes other functions in the company, is highlighted in the standard. The standard identifies that the team leader shall at least have the responsibility and authority to:

- organize and manage the work of the Food Safety Team;
- ensure that all elements of the Food Safety Team have the training and relevant knowledge;
- ensure that the FSMS is established, implemented, maintained, and updated; and
- report the effectiveness and suitability of the FSMS to the top management.

Other responsibilities that are commonly assigned to the Food Safety Team leader include:

- communicating with external parties on matters related to food safety;
- planning the management review meeting (Section 4.3.8);
- monitoring audits to the organization and planning and monitoring audits to suppliers;
- coordinating training activities in the context of the FSMS; and
- providing advice to the top management regarding food and safety issues.

#### **4.3.6 Communication (Clause 5.6)**

As mentioned in Section 4.1, the standard considers interactive communication a key element. Communication is also referred in the general requirements (Section 4.2.1), highlighting the importance of maintaining it throughout the food chain and throughout the organization. The standard identifies specific requirements for both external and internal communication.

##### **External communication (Clause 5.6.1)**

With the increasing dimension and complexity of the food chain, food products go through several stages, organizations, and even countries before reaching the consumer. The ISO 22000:2005 defines food safety as a concept which implies that food cannot 'cause harm to the consumer when it is prepared and/or eaten according to its intended use.' To achieve this objective all elements of the food chain must not only take responsibility for ensuring food safety during their processes, but also obtain and transmit to external organizations all relevant information to ensure the safety of products until the moment of consumption.

The standard emphasizes the importance of communication regarding food safety between organizations and with statutory and regulatory authorities and customers. Records that evidence this communication and documents defining the requirements of the statutory and regulatory authorities must be maintained.

Effective external communication implies that the organization provides and obtains relevant information on food safety without ambiguity or possibility of misinterpretation. This can be a challenge to companies operating in several

markets due to language issues. Every time communication is made between two people or organizations that do not share the same native language, actions should be taken in order to ensure mutual understanding. Examples about the kind of information that may be required or made available externally are described in the following sections.

*Suppliers and contractors* When organizations define the suppliers and contractors that have a greater impact on food safety, it is common to emphasize the importance of communication with suppliers of raw material, goods, packaging, and hygiene/cleaning materials. However, there are other organizations whose services also need to be evaluated regarding their impact on food safety (e.g., pest control organizations, maintenance services, or waste collection services). Examples of information that can be exchanged with suppliers and contractors are provided below.

*Suppliers of raw material and goods:*

- Agreement on the food safety level required, such as defining microbiological/physicochemical criteria or other special requirements to be verified at the moment of reception.
- Information about suppliers, such as evidence of compliance with statutory and regulatory requirements, implementation of a food safety management system, or other certifications.
- Technical information about the supplied products, including the information referred to in Section 4.5.3 and the identification of the need to control any particular hazards.
- Results from controls carried out on supplied products at the moment of reception or during processing and from laboratory analyses. Communication of customer complaints. Identification of causes and measures taken by suppliers for the reported nonconformities.
- Information relative to changes in product specifications or to the update of the technical information. Suppliers should notify their customers whenever the need to retain or withdraw products arises.
- Results of audits carried out on suppliers.

*Suppliers of packaging, hygiene and cleaning materials:*

- Information about suppliers, such as evidence of compliance with statutory and regulatory requirements, implementation of a food safety management system, or other certifications.
- Technical information regarding the cleaning and hygiene materials, which should include expected use and evidence of their suitability to the purpose for which they are designed.
- Technical information of packaging materials that includes evidence of their suitability for use in food products and the accomplishment of specific regulatory requirements, including established migration limits. The level of information and requirements established to ingredients should also be applied to direct food contact packaging.

*Contractors:*

- Contract or an equivalent document that identifies the service to be provided, its duration, and/or periodicity and responsibilities assigned to the service provider.
- Information and training on food safety requirements that have to be respected by employees from the services company when attending the organization's facilities (e.g. pest control, maintenance).
- Information from the contractors about detected occurrences that may affect the safety of food products, even if they are not defined in their responsibilities.

Establishing criteria for the assessment of suppliers and evaluating their degree of compliance can be a method of monitoring their performance and identifying those who need to improve, or even be replaced, if incapable of fulfilling the requirements. This subject is addressed in more detail in Section 4.5.1, Prerequisite 6.

*Customers or consumers* The standard introduces several examples of relevant information that can be exchanged with customers or consumers in order to ensure that all appropriate knowledge to guarantee food safety is available throughout the food chain.

1. *Product information:* For customers, the information is generally organized in data sheets of products which should include, among other information, statements regarding the intended use, specific storage requirements, and shelf life. Section 4.5.3 ('Product characteristics') provides a list of finished product characteristics that shall be documented and that could also be considered when defining the information to be transmitted. Labels are the most important vehicles of information about food safety, as part of that information has to be included in the label by legal obligation. However, organizations may resort to other tools to communicate with customers, such as that presented in Box 4.2. In fact, product information/consumer awareness is considered a prerequisite according to ISO/TS 22002-1:2009 (Section 4.5.1, Prerequisite 14).
2. *Enquiries and customer feedback:* customers and consumers are a very important source of information that the organization should promote and use to assess its performance in subjects relating to food safety. Replies to inquiries and complaints from customers and consumers should be analyzed carefully and used as input to improve the FSMS (Section 4.6.5). A complaint management procedure should be implemented and the responsibility to gather and transmit the information to the organization, make the analysis of causes, and define corrective actions and corrections (Section 4.5.10) should be assigned.
3. *Contracts or order handling:* the definition of contracts may be the best way to formalize mutual acceptance levels of food safety. This definition is especially important in subjects where there is no legislation or when it is intended to set more stringent limits.

**Box 4.2** Food safety information at the point of use

The use of IT to share information related to food safety can have a huge impact on customers/consumers. In fact, this must be part of a widespread change in the mindset of organizations, particularly in its top management and/or food safety manager. Food safety information should not be limited to the fielding cabinet or hard drive, but should be available where it is most necessary: at the moment of use or consumption.

Quick response (QR) codes are two-dimensional barcodes that have a greater storage capacity than the standard linear barcodes that were first used in automotive industry in 1994. QR codes can be read by image reader, smartphone, or software applications, and are popular for their large storage capacity and versatility of the information contained (text, URL, location). When a uniform resource locator (URL) is placed inside a QR code, the user can be redirected to relevant information related to food safety, reducing the mishandling and misuse of the product. It is the most efficient and easily updated way to share information about food safety directly with consumers and also to obtain feedback if, for example, a small query is also available.

Since 2012, GS1 (a global organization that manages barcode standards to guarantee that they can be scanned anywhere in the world) introduced the GS1 QR code with the purpose of sharing extended packaging information. Logistics data that are contained in the GS1 QR code (e.g., lot, expiration date, Global Trade Item number or GTIN) can be read by any organization in the global market. Since 2011, GS1 and the Open Mobile Alliance (OMA), recognized for providing open specifications for the creation of services that operate across all geographical borders, have been working together to develop universal code specifications.

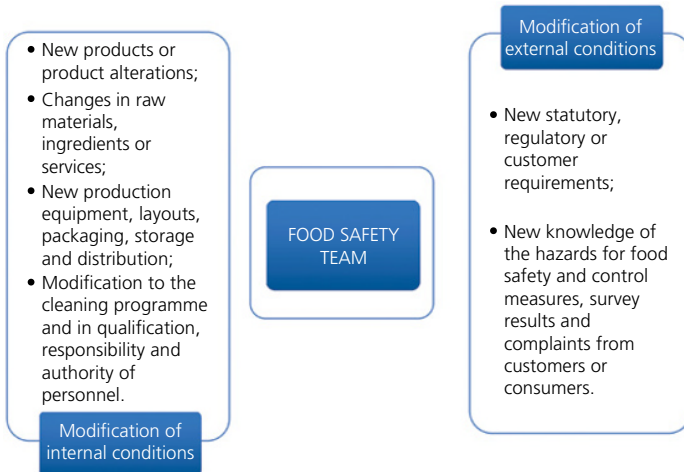


*Statutory and regulatory authorities and other organizations* The standard identifies the importance of establishing channels of communication with the statutory and regulatory authorities, as well as with any other organization relevant to an efficient and up-to-date FSMS. Statutory and regulatory authorities are very important, not only as a source of information about legislation, but also to give assistance to its application. It is also common for these authorities to produce reports of their activities and publish notifications when the activity of an organization or the commercialization of a product is suspended due to food safety issues.

**Internal communication (Clause 5.6.2)**

Internal communication is a fundamental tool to ensure the accomplishment of the food safety principles within the organization. Only the use of a holistic approach to communication allows certain behavior to be permanently modified. As mentioned in Section 4.3.1, one of the most effective methods is to ‘communicate by example,’ especially when it comes from the top management. At the





**Figure 4.7** Modifications that may compromise food safety.

same time the organization should create the means for all employees to access relevant information that will allow them to ensure the safety of food products. The top management and the Food Safety Team must create an internal communication dynamic on issues related to food safety. Besides the use of training sessions or public meetings, the use of audio-visual/electronic supports (e.g., internal television, website, intranet, newsletters) or even conventional methods such as information boards, signs, or slogans are all recommended.

In this clause of the standard, particular emphasis is placed on the obligation of informing the Food Safety Team of any change that may compromise food safety. Such changes can be grouped into two major groups, as shown in Figure 4.7. This information should be used in the FSMS update and included in a management review (Section 4.3.8).

#### **4.3.7 Emergency preparedness and response (Clause 5.7)**

The standard states that the top management should identify the emergencies or accidents likely to occur (considering their role and position in the food chain, geographical location, social stability, and country's politics) that may have an impact on food safety, and the relevant actions to eliminate those negative consequences. This procedure may contain information such as:

1. identification of the emergency or accident;
2. measures to contain or reverse the cause of the event;
3. procedure to identify the affected product;
4. alternative processes that could maintain the safety of affected products;
5. the process to evaluate the safety of affected products; and
6. definition of the responsibility for performing each of the activities above and to communicate with relevant stakeholders.

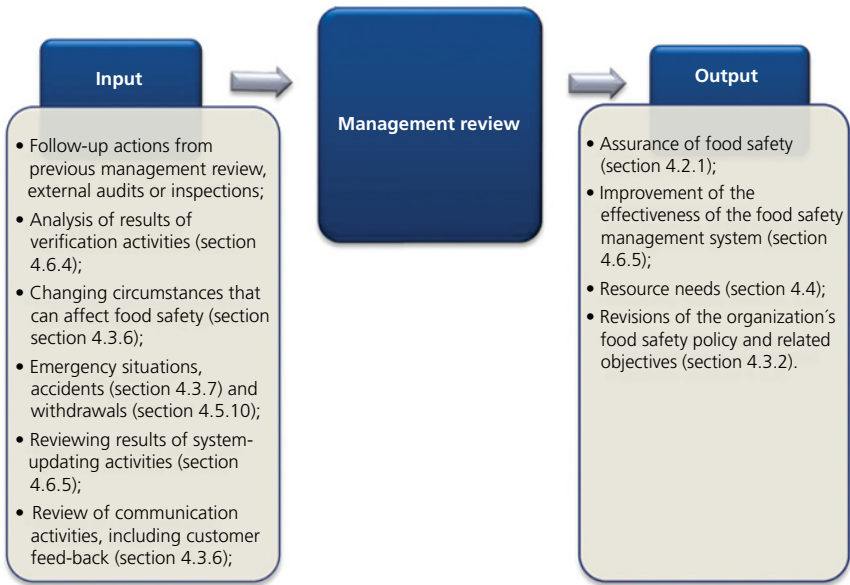
**Table 4.5** Description of procedures for dealing with emergency situations

Task no.	Example 1	Example 2
1	Energy failure (refrigeration system stop)	Vehicle accident (distribution)
2	Trigger the generator and close or limit access to refrigerated or frozen storages.	Identify the actions to take depending on the estimated time that the vehicle will be immobilized. When the safety of the product is at risk, define procedures to send another vehicle in order to collect it or continue distribution.
3	Complete the record which identifies the occurrence and the affected product and place it next to the product or storage.	Complete the record which identifies the occurrence and the affected product. Define the procedure to identify and store the product returned to the organization.
4	Move the product to another defined place where safe conditions can be maintained.	Identify alternative storage facilities when the return of the product is not possible. Hire a company to continue the distribution or collection of the product.
5	Establish the periodicity to check if the product still remains at a temperature that guarantees its safety. Define actions to take when that does not happen.	When the safety of the product is questionable, it must return to the organization. Assessment may consist of microbiological or physical/chemical analysis, sensory evaluation by trained personnel, or by authorization of statutory and regulatory authorities.
6	Name the functions/personnel responsible for each of the above tasks and communicate with stakeholders.	

The interpretive guide ISO 22004:2014 identifies natural disasters, environmental accidents, or bioterrorism<sup>4</sup> as examples of emergency situations. The importance of using test exercises to periodically verify the adequacy of the procedure and the organization's response to a particular situation is also emphasized. One common exercise that organizations should carry out regularly (at least annually) is a product withdrawal/recall (Section 4.5.1, Prerequisite 12 and Section 4.5.10). This process is particularly significant because it can be required whenever any of the emergency situations mentioned above occurs and the affected product reaches the market. It is also a test to traceability (Section 4.5.9).

Table 4.5 lists examples of how each of the six points highlighted above can be described in the procedure in case of energy failure and vehicle accidents.

<sup>4</sup> This topic is considered a prerequisite in ISO/TS 22002-1:2009 (Clause 18) and is developed in Section 4.5.1 of this book.



**Figure 4.8** Management review input information and output decisions.

#### 4.3.8 Management review (Clause 5.8)

Management review is one of the procedures that top management uses to evaluate and ensure the continual improvement of the FSMS (Section 4.6.5). The standard establishes that top management must define a frequency for the review of the system to ensure its continuous suitability, adequacy, and effectiveness. No guidance is given for the maximum or minimum time between management reviews; however, it is not common for this period to be longer than a year (in order to support and promote continuous improvement and assess the food safety objectives and the adequacy of the food safety policy).

The standard identifies the information that is mandatory for discussion during management review and the outputs (decisions) of the meeting (Fig. 4.8). The success of the review is highly dependent on preparatory work, usually performed by the Food Safety Team, to gather relevant information and structure it in a manner that can be easily apprehended and compared with the food safety objectives (Section 4.3.2).

#### 4.4 Resource management (Clause 6)

The nature of the organization's activities and improvement cycles determine the required resources and how often they have to be reviewed (Fig. 4.9 provides topic keywords). The quantity and/or nature of required resources are therefore dynamic within all organizations.



**Figure 4.9** Keywords from Section 4.4.

Although Resource Management is presented in ISO 22000:2005 separately from Management Responsibility, it is clear (Table 4.3) that it is one of the top management obligations. This means that top management must be committed to support the personnel elected to manage human resources, infrastructure, and work environment, in particular by providing the financial resources necessary to satisfy the standard requirements.

ISO 22004:2014 describes the importance of periodically monitoring, evaluating, optimizing, and reviewing the availability and suitability of resources.

#### **4.4.1 Human resources (Clause 6.2)**

The standard requires not only the Food Safety Team, but also all personnel that perform activities with an impact on food safety, to be competent and have appropriate education, training, skills, and experience.

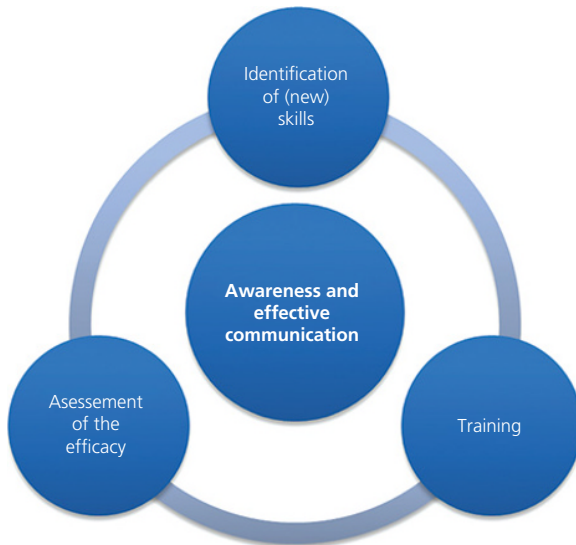
An organization has three alternatives in meeting this requirement, either:

1. providing training to the personnel to achieve the skills defined as necessary for their activities;
2. hiring new personnel who already have the necessary skills; or
3. seeking the assistance of external experts with the necessary skills.

It is usual that organizations employ more than one of the alternatives listed above. In the particular case of using external experts, keeping records of contracts or agreements describing their responsibility and authority is necessary. This requirement is a particular aspect of a principle mentioned in the clause of external communication with contractors (Section 4.3.6).

The standard identifies the need for organizations to use training and effective communication when defining competences and when ensuring personnel are aware of the importance their actions have on food safety (Fig. 4.10).

The first step should be the identification of the necessary competences to perform any activity with an impact on food safety. Section 4.3.4 provides an example of a record in which this identification is defined. After the identification, training activities should be developed in order to ensure that the necessary skills are achieved. The standard gives particular emphasis to the importance of providing training to all those responsible for monitoring, making corrections, and taking corrective actions. It also requires the maintenance of records from training activities and the assessment of their efficacy. Box 4.3 provides an example



**Figure 4.10** Personnel development by training (cycle).

**Box 4.3** 'The hole keeps getting bigger'

Food safety incidents will always occur, but the important consideration is how they are handled. In 1972 Pillsbury rolled out the first HACCP system consisting of three principles: conduct a hazard analysis, determine critical control points (CCP), and establish monitoring procedures. Within a year, it was discovered that Pillsbury's dehydrated potato flakes were contaminated with small pieces of wire. Investigations revealed that the wire pieces came from a broken sifter screen, located just before the packaging machine. At headquarters we could not imagine how this could have happened, as that sifter had been designated as a CCP that required regular inspection. Sure enough, the sifter had indeed been inspected regularly and the inspector had first noted, 'Hole in sifter screen.' For several weeks he had diligently noted: 'Hole getting bigger.' He had done exactly what he had been told to do: inspect and record. It did not occur to him report this matter and there was no formal requirement for him to do so.

of an episode experienced by Dr William H. Sperber in the beginnings of HACCP, when the importance of communicating and reporting problems became clear.

The implementation guide of ISO 22000:2005 details information that should be included in the training record, such as: program content; name and qualifications of the trainer; final assessment of trainees; and establishment of the requirement for retraining. Other relevant information that can be included in that record is: names of the trainees; duration; and objectives of training.

If the organization does not have software for the management of human resources, it can easily develop a computer record where all personnel are identified

(personnel number, name, age, and function) and any attended training recorded. Information about the training or just a code or link that allows access to the training record generated may also be included. Such a computer record can also be used to log and control the periodical medical examination required by the prerequisites (Section 4.5.2).

#### 4.4.2 Infrastructure and work environment (Clauses 6.3 and 6.4)

Infrastructure and the work environment should provide appropriate conditions to produce safe and adequate food for its intended purpose (Box 4.4).

The construction and maintenance of infrastructures should:

- be appropriate to the nature of the available products;
- be preceded by a review of the statutory and regulatory requirements as well as relevant codes or standards for the sector; and
- take into account the organization's relative position in the food chain.

The top management is responsible for ensuring the necessary resources to allow the creation of the conditions described above. A similar approach should be taken by the organization regarding the establishment, management, and maintenance of the work environment. 'Work environment' refers to the set of conditions in which the work is performed, including physical, social, psychological, and environmental factors (e.g., temperature, humidity, composition/circulation of atmospheric air) (ISO 2005b).

##### Box 4.4 'We are entirely without a clue'

*This comprehensive story that Dr William H. Sperber shared shows the importance of prerequisites programs and the consequences of neglecting them.*

Around 1980 I was conducting a due diligence assessment in preparation for the potential acquisition of a frozen foods company. During the inspection of one plant I was taken to the area where frozen foods exited the blast freezer to be packaged, cased, and palletized for frozen storage and distribution. Walking through the area was difficult as the concrete floor was very slippery. I immediately noticed that the entire floor, more than 100 m<sup>2</sup>, was liberally covered with rather small wood splinters. It was immediately obvious to me that the splinters came from stacks of wooden pallets, many in poor condition. I couldn't believe my eyes. Almost as a joke, I asked my tour guide, the facilities quality manager, 'Do you ever receive consumer complaints about wood splinters in your products?' 'Yes,' he replied. 'We get quite a few complaints like that.' 'Do you have any idea where the wood splinters are coming from?' I asked in exasperation. Incredibly, he answered, 'We've never been able to figure it out.' It was about this time that the US Food and Drug Administration had developed and promulgated Good Manufacturing Practices for food operations. The need for such educational training and operation requirements was obvious.

To this day GMPs are a major prerequisite program that supports the HACCP system of food safety management, along with Good Agricultural Practices, Good Distribution Practices, and Good Consumer Practices. The last of these is currently under development by several food safety leaders in the global food industry, with major educational support from many governmental and consumer advocacy organizations.

The construction and management of infrastructure and the work environment is also described in detail in the prerequisites presented in ISO/TS 22002-1, particularly in clauses 4 (Construction and layout of buildings) and 5 (Layout of premises and workspace), which are discussed in Section 4.5.2.

## 4.5 Planning and realization of safe products (Clause 7)

Figure 4.11 provides keywords relevant to this clause.



Figure 4.11 Word cloud for Section 4.5.

### 4.5.1 General (Clause 7.1)

Organizations should plan and develop processes that ensure the effectiveness of their activities in order to obtain safe products. The standard ISO 22000:2005 identifies the need to implement prerequisite programs, the HACCP plan, and the operational prerequisite programs to achieve this goal.

Prerequisite programs aim to control the general hygiene and ensure good manufacturing practices. They establish conditions for obtaining a hygienic environment throughout the food chain, without implying the control of specific hazards (ISO 2014). The HACCP plan manages the control measures identified by the organization as necessary to control the critical control points (ISO 2014). The operational prerequisite programs are designed to control the likelihood of introducing dangers to the food safety or their proliferation in products or work environments (ISO 2005c).

### 4.5.2 Prerequisite program (PRPs) (Clause 7.2)

An implemented prerequisite program helps to reduce the likelihood of introducing hazards in the product through microbiological, physical, or chemical contamination and the hazard levels in the product or work environment. These programs should be appropriate to the needs of the organization, including the size, type of operation, and the nature of the products that are produced or handled. The approval of the prerequisites should be the responsibility of the Food Safety Team and should be implemented throughout the entire production system.

The ISO/TS 22002 series was created with the purpose of assisting in the implementation of ISO 22000:2005. This standard was designed in order to be applied to any organization in the food chain, therefore presenting a general prerequisites program. This limitation was identified by a group of large companies in the food industry, including Kraft, Danone, Nestlé, Unilever, General Mills, and McDonalds who, in collaboration with the British Standards Institution (BSI) and other food manufacturing stakeholders, developed a prerequisite program on food manufacturing, namely PAS 220:2008. This specification was later adapted and replaced by ISO/TS 22002-1.

ISO/TS 22002-1:2009: Food manufacturing is applicable to all organizations that are involved in the manufacturing step of the food chain, regardless of their size or complexity. The standard specifies conditions for the establishment, implementation, and maintenance of prerequisite programs (PRPs) in order to control food safety hazards as specified in Clause 7.2 of ISO 22000:2005. This technical specification was the first (2009) of many with the purpose of reaching different sectors of the food industry (Fig. 4.12).

ISO/TS 22002-1 has 18 clauses, but it is only after the fourth (inclusive) that the standard defines specific requirements for prerequisites. The prerequisites are described in the following sections according to the structure of ISO/TS 22002-1:2009; Prerequisite 1 corresponds to Clause 4 of the technical specification, Prerequisite 2 corresponds to Clause 5, and so on.<sup>5</sup>

The following documents were also consulted to support the explanation and examples provided:

- *Codex Alimentarius* Commission, General Principles of Food Hygiene (CAC/RCP 1-1969 v.4 2003) (CAC 1969, 2003);



**Figure 4.12** ISO/TS 22002 published and unpublished specifications.

<sup>5</sup> A table listing all prerequisites is provided in Chapter 5 (Table 5.1), showing the correspondence between the clauses of ISO/TS 22002-1:2009 and the prerequisites presented in this chapter.



- Food and Drug Administration, 2013 Food Code (FDA 2013);
- Safe Quality Food Institute, General Guidance for Developing, Documenting, Implementing, Maintaining, and Auditing a SQF System – Module 11: Good Manufacturing Practices for Processing of Food Products (SQF 2014a);
- Clever *et al.* (2015) China – Peoples Republic of China’s General Hygiene Regulation for Food Production (GB14881);
- Food and Drug Administration, Code of Federal Regulations – Title 21: Food and Drugs (FDA 2012b);
- Food and Drug Administration, Fish and Fishery – Products Hazards and Controls Guidance, Fourth Edition (FDA 2011); and
- *Codex Alimentarius* Commission, Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003 rev. 2013) (CAC 2003).

### **Prerequisite 1: Construction and layout of buildings**

Buildings must provide adequate space to the nature of the operations that are carried out there; the flow of materials, products, and personnel must respect a certain logic and a physical separation between materials and waste should be kept in order to avoid cross-contamination by microorganisms.

The facilities of a food establishment should be located away from possible sources of contamination and the site should be cleaned to prevent the existence of objects that could facilitate pest infestation. Site boundaries shall be clearly identified and the access to the site must be controlled. The entries and parking areas must have a draining system to prevent standing water. Outside the building, the floor immediately in front of the doors and entries should be paved in order to minimize dust. At least once a year, the effectiveness of the adopted measures to control possible contaminants should be evaluated and reviewed if necessary. Box 4.5 presents examples for fish units in land and on a ship.

### **Prerequisite 2: Layout of premises and workspace**

#### **Internal design, layout, and traffic patterns**

The facilities shall have a product flow pattern that is designed to prevent cross-contamination between the finished products and raw materials and to minimize delays (which can result in product quality loss or compromise its safety). This flow pattern should be respected and executed continuously so that there is total control of critical factors, such as temperature and time.

Facilities must also be designed so that there is a designated area for the entry and exit of personnel who manipulate food products, as well as a physical separation between the areas for raw materials and processed products. The technical specification states that a sufficient distance should be adopted<sup>6</sup> in order to minimize the risk of contamination between two materials.

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<sup>6</sup> The standard does not ascertain a distance. This option should be used only when no other option is technically possible.

**Box 4.5** Construction and layout of buildings (example of fish unit in land and in ship)

To project a fish unit, the following physical and geographical factors of an appropriate location must be considered:

- size of the land: if it is appropriate to the current needs and future development;
- accessibility: by road and/or railways;
- water quality, energy, and waste removal/treatment services: should be appropriated and available throughout the year;
- waste removal: construction, design, location, and suitability of the space designed for that purpose; and
- pollution of adjacent areas – Evaluate the contamination of future facilities by air, through smoke, dust, ash or unpleasant odours present in the region.

**Particular case: Ships**

To project a ship it is important to be aware of certain aspects in order to minimize product contamination or deterioration.

- A good draining system must be in place to prevent standing water, which may cause the proliferation of microorganisms.
- Construction of interior walls must be avoided in order to facilitate cleaning and sterilization, and to prevent the accumulation of dirt.
- Harmful substances from the ship, including smoke, fuel oil, and water from the ship's hold, must not contaminate the fish.
- The containers for offal and waste material should be clearly identified and be made of a waterproof material.
- The entry of birds, insects, or other pests into the workplace should be prevented.
- Ships designed and equipped to preserve fishery products for more than 24 hours should have holds, tanks, and vessels to freeze or refrigerate the products, respecting the temperatures established for that purpose.

**Internal structures and fittings**

Within the facility, all surfaces that are in contact with the product must be resistant to corrosion, made of a waterproof material, light colored, flat, and easily cleanable. The ceiling and overhead fixtures must be prepared to minimize the accumulation of dirt and the falling of particles. The internal walls must be easily cleanable and made of nontoxic and corrosion-proof materials.

The floor must be resistant to dropped products, water, and disinfectants and must be nonslip. The facility must have a water draining system that guarantees an appropriate flow. This system should include grids and/or removable drains to allow the easy cleaning of the facility. Corners between walls and floors must be designed to prevent accumulation of dirt.

Windows should be constructed to minimize the accumulation of dirt and must be protected with a mesh to prevent the entry of insects. Meshes must be removable and made of washable materials.

Doors must be flat, made of waterproof and washable materials, and guarantee the effective isolation between areas. They must always be closed when not in

use. The doors and internal openings should be designed to minimize the entry of exterior materials and pests. It is advisable to use doors that close automatically (e.g., roll-up or swinging doors).

### **Location of equipment**

Equipment shall be constructed of removable or easily transportable components to allow its maintenance, cleaning, disinfection, and monitoring. It should be designed in order to minimize corners (prevent the accumulation of dirt).

### **Laboratory facilities**

Laboratory facilities should not have direct access to the production area and must be located and operated in a way that prevents contamination of food products. Their location shall take into account the level of risk that it might pose to the product. For example, if the laboratory manipulates pathogenic microorganisms, it must be located far from the production area.

### **Temporary or mobile premises and vending machines**

Vending machines shall be constructed in such a way as to avoid food contamination and pest harborage. When defining its location, the organization must take into account the risk of product contamination and consider reinforcing pest control (Prerequisite 9).

### **Storage of food, packaging materials, ingredients, and nonfood chemicals**

The facilities used for storage should protect the products from different sources of contamination (e.g., dust, waste, condensation drains). Storage areas shall be well ventilated and guarantee the ideal conditions of temperature and humidity defined for each food product. They should be designed to allow the separation of raw materials, work in progress, and finished products. The products shall be stored off the floor with easy access to allow the realization of inspection, cleaning, and pest control activities.

The facilities should have a specific area to keep the cleaning products, chemicals, and other hazardous substances. Access to these materials must be controlled in order to prevent their careless use which may constitute not only a risk to the health of personnel but also a risk to the product if, for example, excessive amounts of them are used. It is recommended that access to the storage is prevented or is limited to personnel with specific training.

The storage process should be appropriate to avoid crushing or breaking the product or packaging. The fact that a product can cause damage to other products by putting pressure on them should be considered and avoided. The personnel in charge of these operations should have relevant training, particularly in the use of forklifts or pallet jacks.

### **Prerequisite 3: Utilities: air, water, energy**

#### **General requirements**

The sources of water, air, and energy shall be controlled in order to guarantee their quality and minimize the risk of product contamination.

The distribution routes for these utilities must be designed in order to avoid the risk of cross-contamination and be monitored to avoid water and air contamination.

#### **Water supply**

The quality of the water should be in accordance with the needs of the process. When water is used as an ingredient, to wash food or food contact surfaces, or to manufacture ice or steam that comes into contact with food, it must comply with the chemical, physical, and microbiological requirements specified for potable water and the product in question.

The supply of potable water should be sufficient to meet the needs of the process and be used in all processes that are directly or indirectly in contact with food to avoid contamination. Nonpotable water must have a separate supply system (clearly identified) and the mixing with potable water prevented.

It is common to use chlorine in the treatment of water, especially when the facility has its own water supply system. When this is the case, a procedure must be put in place in order to control the amount of chlorine added to water. Depending on several circumstances (e.g., distance from the injection/addition point to the point of use, temperature, time) the residual chlorine content will vary and must be controlled according to appropriate requirements. Whenever possible, the use of potable water supplied by organizations monitored or controlled by legal authorities is recommended.

It is also recommended to identify all water supply points in the production area as well as in the production plan. This facilitates water quality monitoring (usually performed in alternate points) and the identification of points where the assessment is more critical, requiring more frequent and/or rigorous control.

#### **Boiler chemicals**

When chemical additives are used in the production of steam, they must be authorized by a regulatory authority to ensure that the additive is approved for human consumption (approved as food additive or safe to use in water for human consumption). As described in Prerequisite 2 (Layout of premises and workspace), the chemicals should be stored in a separate and secure area when they are not being used.

#### **Air quality and ventilation**

The air in direct contact with the product or product contact surfaces should not constitute a hazard to the safety of the product. In order to minimize the risk of contamination, the organization must control/monitor air quality (especially in areas where products are exposed) by filtration systems and by setting humidity and/or microbiological parameters.

The ventilation system should be sufficient to remove the excessive steam, smoke, and unpleasant odors and must be constructed to avoid the mechanical flow of air from contaminated to clean areas. These systems must be easily accessible for the purposes of maintenance (e.g., filter replacement).

In addition to assessing air quality against established requirements, it is also relevant to compare it with the outside air and to analyze trends over time. The assessment of the inside air quality when compared with the outside air quality may indicate whether the latter is a source of contamination and to what degree. Analysis of the results allows tendencies to be established and proactive action taken (when necessary) in corrective actions. It is recommended that the comparison of the obtained results be performed at the same time each year in order to minimize the influence of variations in outdoor air quality (resulting from natural climate changes experienced during different seasons) on the results.

### **Compressed air and other gases**

The compression systems of air and other possible gases that are present in production units shall be constructed and maintained in good condition in order to prevent leaks and the contamination of food products. Filtration systems should be located as close as possible to the point of use. The gases that are in contact with products must be approved for that purpose and be free from dust, oil, and water. It is not recommended to use oil in the compressor but, if there is no alternative, the oil used must be of food grade. The level of control of air or other gases depends on the type of product.

### **Lighting**

Adequate lighting shall be provided in all working areas to allow operation in a hygienic manner. Lighting can be natural or artificial and should be appropriate to the nature of the operation. The FDA (2013) gives an example of the level of light intensity in each operation:

- >108 lux at a distance of 75 cm (30 in) from the ground in refrigeration units and storage areas of dry products and other areas during the cleaning period;
- >215 lux at a distance of 75 cm (30 in) from the floor in bathrooms, areas to wash the hands, and in storage areas of equipment and utensils;
- >540 lux in production places where personnel use sharp utensils such as knives, slicers, and saws.

It is possible to find similar values in the Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (CAC/RCP 23-1979; CAC 1979) which defines 540 lux at inspection points, 220 lux in working areas, and 110 lux for the remaining areas.

Light fixtures shall be protected to ensure that the product is not contaminated in case of breakage. The organization should be aware of any lights that are not easily accessible (e.g., inside equipment) and take measures to protect them.

## **Prerequisite 4: Waste disposal**

### **General requirements**

Waste management systems should be implemented to prevent the contamination of products or production areas and ensure its adequate elimination.

### **Containers for waste and inedible or hazardous substances**

Containers for waste help to prevent its accumulation in the production area and shall be: clearly identified for their intended purpose; located in a designated area; constructed of a waterproof and washable material; and closed unless they are being used continuously.

The location established for the containers shall be considered carefully since it implies: tighter control of pests at that location; special attention in the cleaning program; and deterioration of air quality.

The paper bin used for hand hygiene should be located near the place of washing and used appropriately to avoid contamination. Its contents shall be removed regularly, usually at the end of the day.

### **Waste management and removal**

Waste removal frequencies shall be established according to waste category and to avoid accumulation. ISO/TS 20002-1 states that waste must be removed at least daily. When an external organization is responsible for waste collection and destruction, it must be properly approved for it. Records of its service shall be kept for the period legally established or for the period of time relevant for traceability.

All materials that contain trademarks and are considered waste shall be disfigured or destroyed. This destruction must be accompanied by someone from the organization to ensure that these materials cannot be reused in a malicious way (the importance of organizations to be alert to these situations is reinforced in Prerequisite 15). The organization shall retain records describing the destruction.

### **Drains and drainage**

A water drainage system should be implemented throughout the facility allowing an appropriate flow. This system should include grids and/or removable drains, which must always be placed to avoid reflux of unpleasant odors, the entry of pests, and to facilitate the cleaning of the facility. The draining system should be installed to prevent the flow from a contaminated area to a clean area; when it is not possible to have two separate systems it should be ensured at the time of installation that water runs from a clean area to a contaminated area, and not the opposite. Drainage systems shall be properly identified in the installation plan.

## **Prerequisite 5: Equipment suitability, cleaning, and maintenance**

### **General requirements**

The materials in direct or indirect contact with food products should be appropriate and must not represent a risk to the health of consumers (e.g., migration of substances from materials to products) or even cause an unacceptable change in

the organoleptic properties of the products. On the other hand, these same materials should not be affected by products or cleaning agents. All equipment shall have an instruction manual and certificates of conformity that prove compliance with statutory requirements.

### **Hygienic design**

Food contact equipment shall be constructed to be easily cleaned, using durable materials, resistant to multiple washings, and have a self-draining system when used in wet process areas. All equipment must be designed to minimize contact between the hands of operators and products. Piping systems should be constructed and maintained in order to be easily and periodically cleaned and have no dead ends.

### **Product contact surfaces**

Equipment and utensils in contact with food must: be made of washable, water-proof, corrosion-free, and nontoxic materials; be maintained in good condition and be correctly stored to prevent degradation; and have evidence of their suitability for contact with food.

### **Temperature control and monitoring equipment**

When equipment is used for thermal processes it has to be able to meet and maintain the established temperature during the process and to monitor and control the temperature (preferably automatically and continuously).

### **Cleaning plant, utensils, and equipment**

A cleaning program should be documented to ensure that all areas, utensils, and equipment are cleaned correctly and at a defined frequency. In Prerequisite 8 these documents are explained in more detail. When a cleaning-in-place (CIP) system is used (Prerequisite 8), it is particularly important to define responsibilities for the use and management of the system to guarantee its correct functioning. This system can be considered a sensitive area and managed according to Prerequisite 15.

### **Preventive and corrective maintenance**

The facility shall establish a preventive maintenance program that includes, at the least, all devices used to monitor and/or control hazards.<sup>7</sup> This program can include: definition of activities (e.g., mechanical or electrical verification); schedule of the maintenance (and calibration activities); responsibility definition; and calibration and verification activities (planning and procedures).

Preventive or corrective maintenance can be carried out by internal personnel or external specialized technicians. Both must have had previous training on the hazards that maintenance activities can represent for food products.

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<sup>7</sup> The organization should consider extending the program to all equipment. The use of a record to list all equipment could be a good solution to better control maintenance and its schedule.

During maintenance, all risks of contaminating the product or adjacent equipment must be avoided. A person with adequate training and knowledge must be named responsible for verifying whether the equipment is properly sanitized before re-use.

All products used in maintenance or repair of equipment and that may be in contact with food products must be adequate (i.e., food grade).

## **Prerequisite 6: Management of purchased materials**

### **General requirements**

Before the acquisition of materials, an assessment of the suppliers shall be performed in order to ensure that they have the capability to meet specified requirements (i.e., whether the products they commercialize are safe and suitable for the intended use).

### **Selection and management of suppliers**

The standard defines the need to establish a process of selection, approval and monitoring of suppliers. This process should assess the risks and the suppliers' ability to meet food safety expectations, as well as the fulfillment of all requirements and specifications (defined by the organization or imposed by law). It should include a description of how suppliers are assessed and their performance monitored to ensure continued approval status. The organization should maintain an updated record of approved suppliers that includes all the contact information (e.g., address, telephone number, e-mail, name of the person to contact in case of emergency) necessary in cases of withdrawal/recall (Prerequisite 12), and data related to the supplier's ability to fulfill requirements (e.g., information requested, audit results, analytic or organoleptic results, customer complaints).

Selected suppliers should preferably have:

- food safety and/or quality certification (e.g., ISO 9001, ISO 22000, FSSC 22000, BRC, IFS, SQF);
- approval for supplying countries or groups of countries (e.g., the EU, Brazil, USA);
- good results on audits performed or requested by the organization; and
- good references.<sup>8</sup>

### **Incoming material requirements (raw/ingredients/packaging)**

Products must be checked before and during unloading operations to verify that their safety was not compromised during transportation. The tests to be carried out at the time of reception shall be defined and take into account the type of material (and the associated risk), the quantity supplied, the supplier's history and frequency of delivery, and whether the product has already been tested and verified by an external organization. Examples of tests that can be performed during reception

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<sup>8</sup> Gather market information about the supplier: identify the competitors or customers which it supplies and ascertain their level of satisfaction and fulfillment towards that supplier (in particular regarding issues related to food safety).



include: temperature control at the moment of reception and/or during transit; label verification; expiration date and lot control; assessment of hygienic conditions of the vehicle; presence of foreign bodies; sensorial analysis (when applicable); and compliance with other specific requirements established with the supplier.

When the materials are not in conformity with the food safety requirements, they should be treated as potentially unsafe as described in Section 4.5.10.

The control of materials transported in bulk containers is more challenging and requires special attention at the moment of reception. Bulk materials can only be unloaded after control, verification, and approval. When the discharge is performed in piping systems, their access must be covered, closed, and identified.

## **Prerequisite 7: Measures for prevention of cross-contamination**

### **General requirements**

ISO/TS 22002-1:2009 states that a program capable of preventing, controlling, and detecting at least physical, microbiological, and allergen contaminations should be established.

### **Microbiological cross-contamination**

Some areas are especially susceptible to cross-contamination either because they are too close to each other (e.g., no physical barrier between raw and finished products), or because they are located where pathways cross-over (e.g., waste removal and end-product circuits). A hazard assessment shall be carried out to identify potential sources of contamination, the impact they can have on products, and the necessary measures to control them.

Examples of these measures are: build physical barriers; define specific requirements to access certain areas (e.g., definition of specific clothing to be used when handling products ready to eat); set different times frames to avoid cross-over when it is not possible to ensure the separation of movement circuits of raw materials, finished products, waste, and personnel; and create air pressure differentials.

### **Allergen management**

Allergens present in the product shall be declared on the label of finished products.<sup>9</sup> In the case of products intended for further processing, this information must be present on the label or accompanying documentation. The main focus of the organization should be to avoid the occurrence of cross-contamination.

Allergen cross-contamination may have two sources: conveyors or containers used by products with allergens, which are then used for other products without being properly sanitized; or through contact with ingredients or products in separated production lines. The use of water is not enough to avoid cross-contamination, and

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<sup>9</sup> The organization must identify the statutory requirements applicable. Substances that can cause allergies or intolerances can be found in European Regulation (EU) No 1169/2011, in Public Law 108-282-AUG.2, 2004 (US) and in the *Codex Alimentarius* Commission (REV 1-1985 (1991)), for example.

the use of appropriate detergents is recommended for cleaning. One way to avoid accidental transfer of allergens is promoting the systematic cleaning of work surfaces and avoiding contact with other foods. Other techniques may include the handling of products in separate places, the use of specific materials for specific products (e.g., define color patterns to distinguish each material according to its application), a production planning that takes into account those risks (e.g., guarantee that allergenic products are the last product manufactured before cleaning), and the implementation of tests to verify the effectiveness of the elimination of allergens. Staff who handle allergenic material must be trained in the manufacturing practices.

### **Physical contamination**

Possible sources of physical contamination shall be analyzed and procedures to control them must be developed. All equipment used must be resistant and an internal audit to check its state should be carried out regularly. In order to avoid physical contamination, brittle materials, such as glass and plastic, should be avoided.

ISO/TS 22002-1:2009 identifies examples of sources of potential contaminations: wooden pallets, tools, personal protective clothing, and equipment. As examples of measures to prevent, control, and detect physical contaminations, the technical specification suggests the use of covers to protect equipment and containers, magnets, filters or screens, and metal detectors or x-ray detectors.

## **Prerequisite 8: Cleaning and sanitizing**

### **General requirements**

Organizations dealing with food products must implement cleaning and sanitizing programs. Their control and supervision depend on the size of the operation and on the nature of the activities. Programs that ensure monitoring of adequacy and effectiveness of procedures for cleaning and sanitizing should be implemented.

### **Cleaning and sanitizing agents and tools**

Facilities, equipment, and tools should be maintained in good condition to facilitate cleaning and sanitation. Chemicals and cleaning agents shall be clearly identified, stored, and used in accordance with the manufacturer's instructions.

Tools used for cleaning and sanitation should always be stored when not in use to prevent potential contaminations of food products. Tools and cleaning equipment shall be made of strong materials and maintained in a condition which does not represent a potential source of extraneous matter. The use of tools that may project waste or dust is not advised.

### **Cleaning and sanitizing program**

Cleaning and sanitizing programs shall be established and validated by the organization to ensure that all parts of the establishment are cleaned and/or sanitized. These programs (according to ISO/TS 22002-1) shall specify:

- areas and equipment to be sanitized;
- responsibility for the tasks specified;

- sanitizing method and frequency;
- monitoring and verification arrangements; and
- post-clean and pre-start-up inspections.

Other information that may be incorporated in these programs includes: cleaning products to be used; instructions for solution preparation; cleaning agents' contact time; utensils; and items of equipment that must be removed.

As well as having knowledge of the cleaning methods, the personnel responsible for cleaning must have adequate training on the correct and safe use of cleaning agents. The organizations shall provide the workers with mandatory protective clothing and the products safety data sheets (available as close as possible from the point of use).

In certain situations it may be useful to elaborate a schedule with set times for the cleaning of different equipment in order to prevent waste accumulation and/or cross-contamination.

A cleaning and sanitizing process may involve seven steps:

1. *Pre-cleaning*: This stage involves removing food and/or waste of larger dimensions from the area to be sanitized and protecting the parts of equipment that are sensitive to water.
2. *Pre-rinse*: At this stage, water is used to remove any waste that still remains on equipment.
3. *Cleaning*: This stage aims to remove food residues, dirt, grease, or other waste using a cleaning solution.
4. *Rinse*: At this stage all equipment should be rinsed with water to remove all traces of food and detergent.
5. *Disinfection*: The sanitizing agent shall be applied for a specific time. This procedure aims to reduce/eliminate microorganisms that are present on surfaces.
6. *Post-rinse*: At this stage all equipment is rinsed with clean water. This process is repeated until complete elimination of residues of each sanitizing solution.
7. *Cleaning efficiency verification*: The cleaning efficiency shall be controlled as appropriate.

At the end of cleaning, all equipment must be air-dried or dried with disposable/dried towels, and products/cleaning utensils shall be stored appropriately.

### **Cleaning-in-place (CIP) systems**

Cleaning-in-place systems are used to clean contact surfaces without dismantling the equipment and are generally considered to be faster, easier, and cheaper than manual cleaning. Parameters such as type and concentration of detergents, contact time, temperature, and flow shall be defined and monitored. The personnel responsible for controlling and monitoring these parameters shall have appropriate knowledge and training. The system must be monitored, maintained, and validated to guarantee the effectiveness of cleaning. The effectiveness should be regularly verified (e.g., control of detergents residues, analysis of the rinse water or product).

### **Monitoring sanitation effectiveness**

A cleaning and sanitation program shall be monitored at a frequency specified by the organization to ensure their effectiveness.

Apart from qualitative evaluation, which can be performed just after the cleaning processes by a designated person, quantitative tests should also be made periodically. However, these tests do not always provide conclusive and quick results. There are several tests that can be performed, the most important being those that determine whether any organic matter is left on the surfaces and/or assess the microbiological contamination of cleaned surfaces. In the latter case, it is necessary to define which microorganisms shall be investigated and establish limits for compliance. One method of classifying the cleanliness of equipment, utensils, and facilities is the number of microorganisms per cm<sup>2</sup>.

### **Prerequisite 9: Pest control**

#### **General requirements**

Inspection and monitoring procedures shall be implemented to avoid an environment favorable to the attraction and development of pests. For that reason, facilities should be maintained in good hygiene conditions and incoming materials shall be examined.

#### **Pest control program**

Pest control may be managed internally by a nominated person or this service may be provided by an outsourced organization.<sup>10</sup> That person/contractor will be responsible for monitoring, detecting, and eliminating pests according to a program established for this purpose.

A pest management program shall be documented and should identify:

- controlled pests;
- methods and periodicity of controls (the time of year or other factors that may affect the occurrence of pests should be taken into account);
- location of pest control in the plan of the facilities; and
- list of chemicals approved in each area of the establishment.

The following documents must also be obtained:

- copy of service contract (in case of an external service provider) or evidence of the competence of the designated employee and definition of responsibilities;
- updated technical sheets and safety data sheets of chemicals used; and
- pest control records.

#### **Preventing access**

In order to prevent pest access, buildings shall be maintained in a condition of good repair. Holes (e.g., gaps around pipes), drains, and other potential pest access points shall be sealed. External doors, windows, and ventilation openings shall be

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<sup>10</sup> In this case, it is necessary to define a person to deal with the expert from the organization contracted.

designed to minimize the potential entry of pests. Periodically, the effectiveness of established control measures shall be evaluated (e.g., checking the conditions of mosquito nets, bait stations, insect traps, etc.). It is advisable that, as well as these controls, a more thorough inspection of pest activity is performed annually both inside and outside the facilities.

### **Harborage and infestations**

Storage facilities and established procedures should minimize the availability of food and water to pests. Whenever infested materials are detected, they shall be removed and placed in areas which ensure that they do not contaminate other materials, products, or buildings, and identified as potentially unsafe (Section 4.5.10).

The outside area shall be maintained under conditions which minimize the attraction of pests, such as the absence of:

- holes and undergrowth near the facility;
- waste left on the ground (e.g., cloths, paper, plastic films); and
- materials that are not used (to prevent degradation due to climatic factors or from becoming harborage places for pests).

### **Monitoring and detection**

As previously mentioned in 'Pest control program' of this prerequisite, detectors and pest traps shall be identified in the plan of the facilities. Their location shall take into account the type of pest, the activity carried out at that location, and historical information. The type of detector and trap must have the appropriate characteristics for their intended purpose and location.

The results of monitoring activities shall be recorded in order to allow the identification of events and trends, enabling the assessment of the effectiveness of the periodicity and location of detectors or traps.

### **Eradication**

Every time there are suspicions or evidence of infestation, eradication measures shall be put in place. When the use of pesticides to eradicate pests is necessary, it should be restricted to trained personnel and must be controlled to avoid risks to the operator or food products. If the possibility of equipment contamination exists, such equipment should be carefully cleaned before restarting the production activity.

Records of pesticides used shall be maintained to show: date and place of use; application method; target pest; type of pesticide; and quantity and concentrations used.

## **Prerequisite 10: Personnel hygiene and employee facilities**

### **General requirements**

The hygiene and behavior requirements of the personnel belonging to the organization shall be documented and be proportional not only to the type of activity that the organization carries out and to its position in the food chain, but also to

the degree of risk the personnel may pose to the products and production areas. Different degrees of requirements may be considered within the same organization, depending on the probability and severity of contamination (e.g., different clothing or cleaning/changing periods). These requirements should also be respected by visitors and contractors.

### **Personnel hygiene facilities and toilets**

Sanitary facilities and changing rooms should be available and maintained to ensure the degree of personal hygiene required by the organization. These facilities must be clearly identified and located between the access point to the interior of the building and the access point to the production area. The sanitary installations shall not communicate directly with the production or packaging and storage areas.

Establishments must comply with the following requirements.

- Provide sufficient hand washing and drying equipment. Such equipment should supply hot and cold water, soap and disinfectant, wipes for drying hands and paper containers. Lavatories must have taps which are not operated manually.
- Provide a sufficient number of toilets (kept organized and in good condition).
- Provide adequate changing facilities for employees (with lockers for employees' personal objects).
- Ensure that in the path between the dressing rooms and production area the risk of workwear contamination is diminished (e.g., minimizing the distance and using a dedicated access).

### **Staff canteens and designated eating areas**

The canteens and the areas designated for the consumption of food must be located so that they are not a potential source of contamination to the production area. Food storage and preparation should also be conducted under hygienic conditions. When employees bring their own meal, it should be stored and consumed only in designated areas (never in changing facilities).

### **Workwear and protective clothing**

Employees who work in production or are exposed to products and/or materials must wear clean and appropriate work clothes (e.g., light-colored caps and coats without outside pockets above the waist and no buttons, plastic gloves, oversleeves and protective footwear which is nonslip and non-absorbent). Clothing should be appropriate to ensure proper protection of hair, beard, moustache, and sweat so they do not contaminate the product. Gloves should be made of suitable materials for contact with food and kept clean and in good conditions (the technical specification discourages the use of latex gloves). The work clothes must be designed to adapt to the different work areas and must be replaced periodically.

Visitors or others who attend the production area can only do so if adequately equipped in accordance with the organization requirements (the use of visitor's kits or equivalent equipment brought by the visitor is recommended).

## Health status

Employees who for the first time initiate the activity of manipulating food products should undergo a medical examination<sup>11</sup> to assess their ability to handle foodstuffs. This assessment must be renewed periodically as established by the organization or statutory obligation. The organizations shall keep evidence of this aptitude together with the contracts/agreements which establish the examinations made and their periodicity. It is suggested that a file is created to record each worker's medical examination status and plan. This information can be filed together with the worker training record (Section 4.1).

Employees suffering from infectious diseases of the digestive system (e.g., dysentery, typhoid fever, viral hepatitis A, hepatitis E virus), from diseases that affect food safety (e.g., active pulmonary tuberculosis, suppurative dermatitis), or employees with skin lesions that cannot be protected should be transferred to other places or activities that do not affect food safety.

## Illness and injuries

When employees with supervising responsibilities over operators who handle food products detect (or are informed) that an operator suffers from a condition that can constitute a hazard for food safety (e.g., jaundice, diarrhea, vomiting, fever, infected skin lesions, diseases transmissible to food), it must be reported to management and the operator excluded from tasks related to food manipulation, primary packaging materials, or food contact surfaces. Temporary workers, contractors, and visitors should also be made aware that their health status must not pose a risk to food safety.

Any injury, wound, or burn exposed should be protected with appropriate materials (e.g., dressings, bandages), preferably brightly colored, containing a metal detectable strip and, when possible, protected by gloves or clothes.

## Personal cleanliness

Employees who work directly or indirectly with food must maintain a high level of personal hygiene so that contamination of food is minimized. In the production areas the employees must wash and, when necessary, disinfect their hands, at least:

- before beginning any food handling activity or restart after smoking, eating, or drinking;<sup>12</sup>
- before putting on gloves;
- immediately after using the lavatory or blowing the nose;
- after handling any potentially contaminated material;

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<sup>11</sup> The technical specification mentions that medical examinations may not be carried out in some countries due to legal restrictions.

<sup>12</sup> A way to ensure proper sanitation of workers when entering production areas is the installation of sanitary access control systems. These may possess, among other utilities, automatic washing and hand disinfection as well as shoe soles cleaning. It is common that these devices possess a turnstile door that prevents passage before the operator has completed the entire sanitation process.

- after handling waste and/or residues; and
- after change of clothing.

Nails should be kept clean and short. Hair should always have a clean look and be completely covered (e.g., hairnets). It is forbidden to cough, exhale, or spit on the materials, product contact surfaces, and products.

### **Personal behavior**

A policy that describes the behavior required in the areas of processing, packaging, and storage should be documented. This document could lay down rules on the following subjects:

- locations designated for smoking, eating, and drinking;
- use of personal ornaments such as rings, necklaces, earrings, piercings, watches, bracelets, and pins (taking into account the religious, ethnic, medical, and cultural issues);
- locations designed for storage and use of personal items;<sup>13</sup>
- prohibition of the use of nail polish, false nails, false eyelashes, and writing equipment behind the ear;<sup>14</sup> and
- organization and cleaning of personal lockers.<sup>15</sup>

## **Prerequisite 11: Rework**

### **General requirements**

Rework is the reuse of products from previous productions. These products must be stored, handled, and used in a way that maintains their safety, organoleptic characteristics, traceability, and compliance with documented requirements.

### **Storage, identification, and traceability**

Stored rework shall be protected from exposure to microbiological, chemical, and extraneous matter until the time of use. These products must be clearly identified and labeled to allow traceability. Traceability records for rework shall be maintained and ensure information such as: product name; production date; shift; line of origin; shelf life; lot; quantity; and justification (for rework).

### **Rework usage**

When rework is incorporated into a product as an 'in-process' step, its type, conditions of use, and the acceptable amount shall be defined in order to guarantee that those operations do not affect the product food safety requirements or even

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<sup>13</sup> Medicines should be forbidden in food handling areas.

<sup>14</sup> The writing materials used should be appropriate; there are solutions on the market for using pens within the production area with properties that enable them to be detected by metal detectors and x-rays. These pens are impact-resistant so that food safety is not compromised in the event of their loss or damage. They should also be made of materials that meet the established requirements for contact with food and nontoxic paint.

<sup>15</sup> Lockers should be regularly checked to discourage misuse (e.g., storage of dirty clothes, food, or work tools).



organoleptic characteristics. The process step, method of addition and any necessary pre-processing stages shall also be defined. The need to change label content (e.g., new ingredients or allergens) must also be assessed.

When rework activities require the extraction of a product from its recipient, control measures should be established to ensure that packaging materials do not contaminate the product.

## **Prerequisite 12: Product recall procedures**

### **General requirements**

A procedure should be implemented to ensure the identification, location, and removal of products that do not comply with food safety requirements. To this end, the company must have a traceability system that allows it to track the movement of products through the different stages of production, processing and distribution (ISO 2007). More details are given on this subject in Section 4.5.10, including a proposal for the content of the procedure.

### **Product recall requirements**

A list of key contacts shall be maintained by the organization in the case of product withdrawal, including not only the customers but also suppliers and authorities. When products are withdrawn due to food safety hazards, the conditions in which they were produced shall be identified and the safety of other products (produced under the same conditions) should be examined. If food safety is at risk, those products should also be withdrawn. In any situation, the need to make a public warning should be considered.

The products withdrawn for being unsafe for human consumption should be clearly identified for disposal to prevent them from being placed on the market again.

## **Prerequisite 13: Warehousing**

### **General requirements**

The places and conditions in which materials and products are stored shall ensure that they remain clean, dry, well-ventilated, and protected from dust, fumes, odors, and other sources of contamination.

### **Warehousing requirements**

Temperature, humidity, and other environmental conditions should be controlled when required by product or storage specifications.

The storage of products should take into account the expiration date and ensure that the used/delivered product has the shorter expiration date. This way, organizations must manage the stocks according to the FIFO methodology (first-in-first-out) or FEFO (first-expire-first-out).

When the products are stacked, the need for measures to protect the lower layers shall be considered. Products should always be placed on pallets that must be distanced from walls and other pallets to allow cleaning and pest inspection.

Waste materials, chemicals, and nonconforming products should be stored in a separate area of products and materials. The use of forklifts powered by gasoline or diesel in product storage areas should also be prevented.

### **Vehicles, conveyances, and containers**

Vehicles, conveyances and containers shall be maintained in a good state of repair and be safe, innocuous, and cleaned to reduce the risk of food contamination. Prior to loading, it should be guaranteed that these conditions are met.

The organization shall implement procedures and install equipment that ensures temperature and humidity control where required by the characteristics of the products, customers, or regulatory authorities.

During transport, products should be protected from adverse conditions (e.g., direct sunlight, rain, temperature, humidity) and from impacts that may cause damage to the packaging and food. Bulk containers originally intended for use in the transport of food products cannot be used to transport nonfood products. If a vehicle was used to transport nonfood products, it must be cleaned before it is used to transport packaged foods.

### **Prerequisite 14: Product information and consumer awareness**

The organization should provide information relative to the food it produces to ensure a high level of protection of health and consumer interests, allowing consumers to make informed choices and use the food in a safe way.

There are several methods of transmitting this information, including websites, advertising, and labeling. However, the latter method is undoubtedly the leading vehicle to reach the consumer. In addition to the information required (by law or customer agreement), labels may also include storage, preparation, and serving instructions. The use of QR codes as described in Box 4.2 allows organizations to take advantage of so-called 'extended packaging.'

Companies can also promote or participate in actions to increase consumer awareness about the importance of storing, handling, and preparing food properly to ensure its safety. In 2001 WHO introduced the Five Keys to Safer Food poster and later (2006) a manual to spread throughout the world the message that: (1) food should be kept clean; (2) raw and cooked foods should be stored separately; (3) food must be cooked thoroughly; (4) food must be stored at a safe temperature; and (5) food handlers must use safe water and raw materials to guarantee food safety (WHO 2006).

### **Prerequisite 15: Food defense, biovigilance, and bioterrorism**

#### **General requirements**

Each organization shall assess the potential danger of acts of sabotage, vandalism, or terrorism to their products. PAS 96:2014 *Guide to protecting and defending food and drink from deliberate attack* (Anon 2014) proposes a Threat Assessment Critical Control Point (TACCP) approach and the creation of a team to act in these cases. The TACCP team should re-assess every 2 years the probability of a threat

occurring. The HACCP team of the organization shall inform the TACCP team whenever it considers that an abnormal result of laboratory tests on products or services may be caused by acts of sabotage.

### **Access controls**

The organization shall identify, preferably in the facilities plan, the areas considered more sensitive or susceptible to vandalism, sabotage, and terrorism. Access to these places should be denied to unauthorized personnel by using locks or electronic keys.

Employees should always be identified through ID card or working uniforms. The visits should be scheduled and justified, unless visitors belong to a recognized authority. During the visit, visitors must always be accompanied by an employee.

## **4.5.3 Preliminary steps to enable hazard analysis (Clause 7.3)**

### **General**

Prior to making a hazard analysis, some relevant aspects must be taken into account for this process to be carried out comprehensively and properly. These aspects are described in the following sections. All documents regarding the hazard analysis must be collected, maintained, updated, and documented.

### **Food Safety Team**

The Food Safety Team should consist of senior management members and personnel from the organization's key departments (e.g., quality, logistics, production, trading, maintenance, human resources) in order to gather skills not only for food safety but also related to the processes, products, equipment, and human resources management. The composition of the team could be adjusted as and when required, making use of elements from other areas or external organizations. Documentation evidencing the skills of team members and supporting their presence in the team should be kept at all times.

### **Product characteristics**

#### **Raw materials, ingredients, and materials for contact with the product**

This step allows an exhaustive review of the characteristics of such products with the aim of identifying potential hazards to the end-products or manufacturing processes and/or identifying preventative procedures. To conduct a hazard analysis, the standard identifies the following relevant points: biological, chemical, and physical characteristics; composition of formulated ingredients such as additives and processing aids; origin; production method; methods of packaging and distribution; storage conditions; expiration date; preparation and/or handling before use or processing; acceptance criteria related to food safety; and specifications of purchased materials and ingredients appropriate to their intended use.

**Box 4.6** Defining risk associated with seafood products

The specific nature of seafood products, particularly of those that are obtained directly from nature, poses a great challenge in the knowledge and definition of risks associated with these products. As well as the intrinsic factors of the product and environment (e.g., origin, physical, chemical and microbiological characteristics of the aquatic environment, migrations), the safety of the fish product is also conditioned by the handling and transportation from the extraction or growth areas to the manufacturing companies.

In order to perform a successful hazard analysis, the organizations should seek to obtain from their suppliers all the possible information about the mentioned factors and proceed to a rigorous control at reception, not only from the point of view of physical and organoleptic characteristics, but also documental.

To support this analysis a similar approach to that carried out in FAO's Technical Paper 574 can be used, which categorizes the degree of risk of fresh seafood products and processed seafood products. In the particular case of fresh seafood products, fish was divided into six major groups (no terminal heat application; bad safety record; no CCP for identified hazard; harmful re-contamination; abusive handling; growth or accumulation of hazard) that were evaluated against five characteristics and risk factors. Upon the results of the assessment of each of these factors, fish is identified with high, medium or low risk. High-risk examples include live raw molluscan shellfish and tropical reef raw fresh/frozen fish and crustaceans. Low-risk examples include raw fresh/frozen fish and crustaceans other than tropical reef and scombroid fish.

For the organization to comply with this requirement it must keep in its possession the product data sheets containing the information requested and periodically check their update. Alternatively, it can prepare specifications which must define food safety requirements to be fulfilled and send them to suppliers so that they can put in writing a commitment to respect the defined specifications.

It is also necessary to identify the updated statutory and regulatory requirements related to food safety and to verify that they are fulfilled by suppliers (data sheets) or to prepare and update internal specifications. Box 4.6 provides further insights into the challenge of defining risks associated with seafood products.

**Characteristics of finished products**

The characteristics of the products should be specified in documents. These documents may be grouped into categories according to their ingredients, processes, or hazards and may form the basis for the preparation of technical product sheets (ISO 2014). Table 4.6 lists the information that the standard considers mandatory to describe the characteristics of products, and some guidelines for the content of each characteristic.

As mentioned in Table 4.6, shelf life is part of the information required to characterize the end-products. Box 4.7 identifies the main factors to consider by organizations when defining shelf life.

**Table 4.6** Information needed to describe end-products

Information	Description content
Product name	Description that identifies the product or group of products (use photograph when appropriate).
Composition	Identification of product constituents <sup>a</sup> (e.g., raw materials, allergenic substances, food additives).
Biological, chemical and physical characteristics	Description of product or group of products' specific characteristics that may have relevance for food safety. In addition to specifying the physical, chemical, and microbiological parameters (and their limits whenever applicable), the identification of other physical characteristics such as type packaging or physical state may be relevant.
Shelf life	Identification of the shelf life assigned according to the defined storage and storage conditions.
Packaging	Description of the packaging materials and their composition. In the case of printed packaging the type of printing and their constituents must be mentioned.
Labeling	Instructions for handling, preparation, and safe use of product (e.g., temperatures and cooking times, storage temperatures, thawing procedures). <sup>b</sup>
Distribution methods	Description of the methods used for the distribution of finished products and related food safety requirements.

<sup>a</sup>It is advisable that the presentation of the composition of the products in this document complies with specific requirements for labeling;

<sup>b</sup>It is also possible to include other information in the label of the product that, although not related to food safety, is a mandatory statutory/regulatory requirement.

### Intended use

For the hazard analysis to be effective it is essential to make an assessment of the intended use of the manufactured products, whether in the subsequent stages of the food chain or with the final consumer. This review should document not only the intended/expected use but also any improper manipulations of products. A common example in this stage is the consideration of the improper use of products in not complying with the defined preservation temperatures or for insufficient thermal treatment. Another example is the use of the product for consumers intolerant to certain ingredients or with vulnerable immunological system (e.g., infants, elderly). Special attention should also be given to the identification of consumer groups to which the products are intended, particularly if these are especially vulnerable to specific food safety hazards. The information obtained may be displayed alongside the definition of the characteristics of finished products.

The result of these assessments may lead to: the consideration of new hazards; the implementation of new control measures; the changing of processes or product formulas; or communicating instructions for product use/preparation to the customer/consumer.

**Box 4.7** Shelf life determination

Shelf life can be defined as the period during which the product maintains its microbiological safety and sensory qualities at a specific storage temperature. It is based on identified hazards for the product, heat or other preservation treatments, packaging methods, and other hurdles or inhibiting factors that may be used (CAC 1999). This definition describes the two key factors that organizations responsible for defining the shelf life should consider:

- the time until which the product loses organoleptic characteristics and no longer meets the expectations of customers/consumers; and
- the time until which the product becomes unsafe.

The assigned shelf life should be the lowest period of the two. However, this time is very conditioned not only by the characteristics of products, processes, and packaging (usually controlled or known by the organization), but also the circumstances under which the product is transported, stored (in customers or retail), and prepared for consumption (often out of the organization control). In this sense, beyond the communication of the shelf life organizations must define the conditions under which said shelf life is applicable, through information included in the label (especially when destined to the final consumer) or instructions for use and conservation defined in specifications and data sheets. However, it is advisable that the studies for the definition of shelf life also consider scenarios where products are subject to non-ideal conditions. These studies are time-consuming, complex, and costly and, particularly in organizations with fewer resources like small and medium-sized enterprises (SME), it may be advisable to resort to published literature, external experts, or legal authorities for support.

The two most common ways of indicating the shelf life are the 'use by' and the 'best before' dates. When you define the shelf life as 'use by,' it is indicated that after that date the product should not be consumed because it may constitute a danger to human health. In this case, as shelf life commonly corresponds to a short period of time, the loss of organoleptic characteristics is not so relevant. The 'best before' is a minimum durability date set by the manufacturer up to which, if the product is handled and stored in accordance with their instructions, the organoleptic and safety features are guaranteed.

**Flow diagrams, process steps, and control measures****Flow diagrams**

The *Codex Alimentarius* defines flow diagrams as a systematic representation of the sequence of steps or operations used in the production or manufacture of a particular food item (CAC 1969). Flow diagrams shall be prepared for all products covered by the FSMS. The use of flow diagrams allows:

- the visualization of the entire manufacturing process on a graphical form;
- an easier interpretation of particular production processes where these are complex; and
- an actual display of the positioning and sequence of all steps of the production process.

ISO 22000:2005 states how flow diagrams should be grouped by product categories or existing processes in the organization, and must contain:

- the sequence and interaction of all steps of the process;
- any external processes and subcontracted work;
- the steps of reception of raw materials, ingredients, and materials that come into contact with the product as well as the entry locations in the production flow;
- the completion of reprocessing and recycling and entry of intermediate products; and
- the release or removal of the finished products, intermediate products, by-products and waste.

In addition to the above points, flow diagrams may also include:

- existing control measures at every stage;
- identification of the steps defined as CCPs and OPRPs;
- time and temperature conditions whenever there is an intermediate storage step; and
- date and signature of the person responsible for the verification of flow diagrams on site.

The type of information and level of detail of a flow diagram may depend on the type of product, the complexity of the process, or even on the intended use. Organizations may choose to create flow diagrams for a particular step that includes all products, as may be the case for the reception of raw materials or distribution of the final product. Very specific flow diagrams may also be created due to the complexity of the process or product characteristics. It is common to use combinations of these alternatives, where the first and last stages are more generic flow diagrams and the middle stages comprise several (more detailed) flow diagrams, representing the entire operation when combined. It may be necessary and even practical to have flow diagrams with a detail level below what is required to carry out the hazard analysis, to present in nontechnical meetings of the Food Safety Team or even to customers who request them (Wallace *et al.* 2010). Figures 4.13–4.15 provide examples of flow diagrams. These flow diagrams only have illustrative purposes; they are not intended to represent any existing process and should not be considered sufficiently complete and comprehensive to be used in any organization.

### **Description of process steps and control measures**

In order to perform hazards analysis it not only is necessary to know the sequence of the steps required to manufacture the product, but also its function and objective. The standard indicates the need to describe existing control measures and any process parameters relevant to food safety, including those that result from regulatory and customer requirements. In order to facilitate hazard analysis, it is recommended that this information is presented together with the flow diagram (see Figs 4.13–4.15). This allows hazard analysis to be carried out in a more integrated manner, considering the interconnection and interdependence between different control measures.

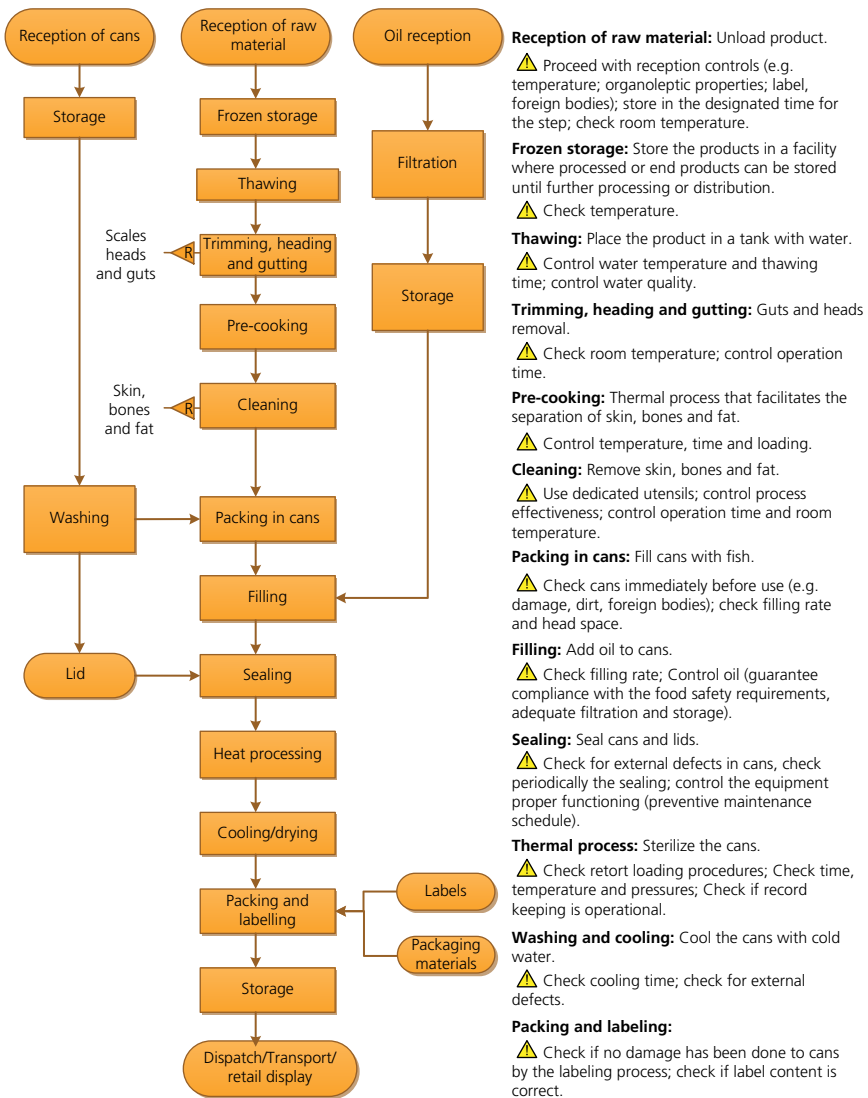


Figure 4.13 Example of canned tuna manufacturing flow diagram.

### 4.5.4 Hazard analysis (Clause 7.4)

#### General

The *Codex Alimentarius* Commission defines a hazard as ‘a biological, chemical or physical agent in food, or the conditions in which they are with the potential to cause an adverse effect on health’ (CAC 1969).

Hazard analysis is a process of collecting and evaluating information about the hazards and the circumstances resulting from their presence in order to decide



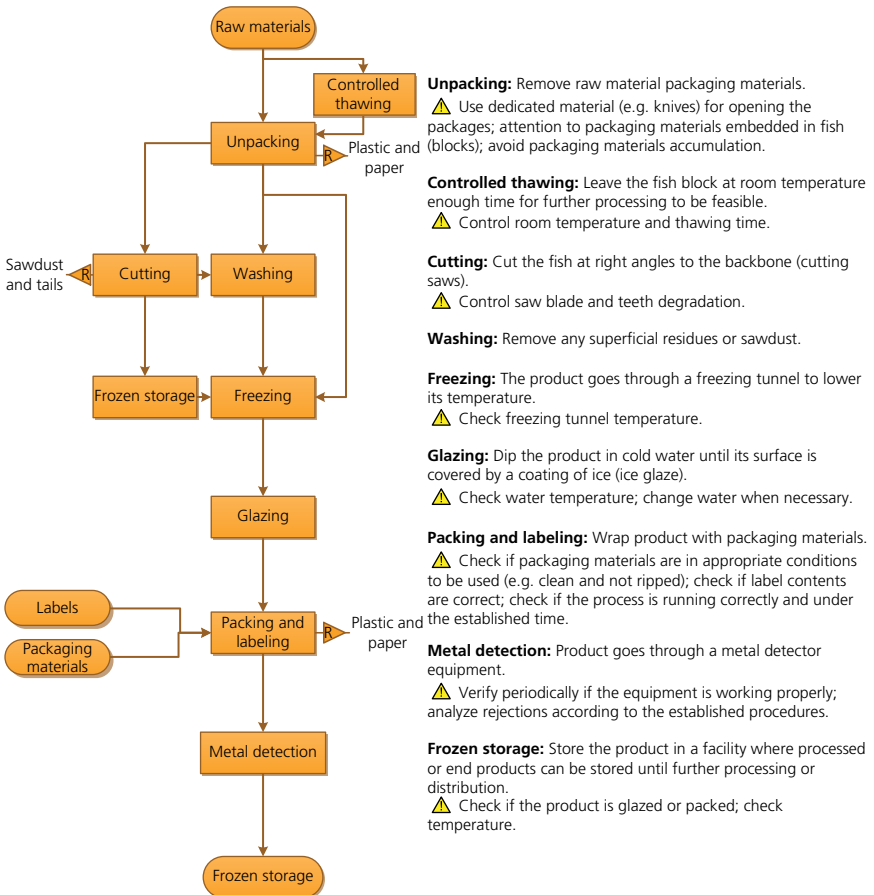


Figure 4.14 Example of frozen fish manufacturing flow diagram.

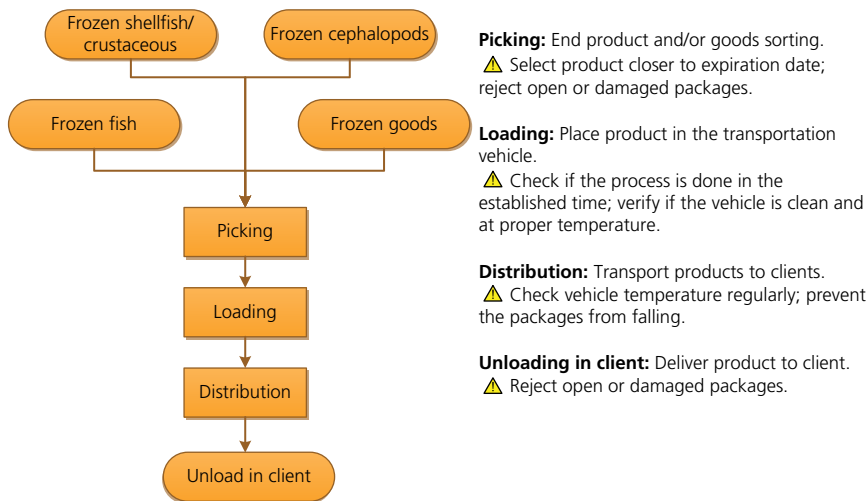
which are significant for food safety. This analysis can be performed for each category of products/processes and should be conducted by the Food Safety Team. All hazards should be considered, namely biological, chemical, and physical.

### Hazard identification and determination of acceptable levels

The Food Safety Team shall conduct a thorough search of all reasonably expected hazards affecting the safety of products. This analysis should cover all ingredients, raw materials, and materials that come into contact with the food product and process stages (preliminary stages, processing, and distribution).

According to the standard, hazard identification should take into account:

- the preliminary information and data collected in Section 4.5.3 ('Product characteristics');



**Figure 4.15** Example of distribution flow diagram.

- experience (e.g., elements of the organization, sector specialists, or statutory and regulatory authorities); and
- external information (e.g., epidemiological data, historical data of the organization or sector, relevant guides or literature, and information from the food chain).

After identifying the hazards, the organization must determine their levels of acceptance. According to ISO 22004:2014 the acceptance level is set to be the permissible level of a hazard in the final product, which cannot be exceeded in order to ensure its safety, and its determination should consider (ISO 2014): established statutory and regulatory requirements; specifications established internally or by customers; and specific hazard information obtained internally or externally (especially considering the intended use of the product by the customer/consumer).

Once the levels of acceptance have been determined, the corresponding result and its justification must be registered.

### Hazard assessment

The hazard assessment step is intended to evaluate the hazards identified in the previous step that require control measures to achieve the level of acceptance defined.<sup>16</sup>

The standard states that each hazard should be evaluated according to its probability of occurrence and the severity of its effects. The probability should be determined taking into account the experience of the Food Safety Team in the

<sup>16</sup> The implementation guide for ISO 22004:2014 states that when a specific hazard is always maintained below the level of acceptance without any intervention from the organization, it must be defined as nonsignificant and does not need to be controlled.

**Box 4.8** Probability of occurrence

The definition of probability of occurrence of a risk and its fitting within levels defined by the food safety team is usually a big challenge during the hazard analysis. In fact, the objective definition of what is very likely or unlikely to occur and the justification for this decision may be controversial, not only within the food safety team but also towards external entities (e.g., customers, certification bodies, regulatory/statutory organizations). The use of historical occurrences within the organization, such as the number of annual incidences of a particular hazard, creates the possibility of making this analysis more objective. At the same time, it is possible to appeal to specialized publications such as reports produced by regulatory authorities or other organizations with information on events regarding such hazards. Appendix 2 contains an example of information that can be obtained from the Rapid Alert System for Food and Feed (RASFF) from the European Commission.

industry, records from previous incidents in the organization, and data obtained from the analysis of reports and studies published by relevant entities (Box 4.8). Severity is an intrinsic characteristic of the hazard related to the effect such hazard may have on consumer health, which reinforces the importance of having well-defined consumer groups (Section 4.5.3, 'Intended use').

The Food Safety Team should gather the necessary information for assessing hazards using scientific literature, databases, regulatory agencies, and industry experts. In this assessment it should also take the following into account (ISO 2014):

- the source of the hazard (its location and how it can be introduced into the product);
- the nature of the hazard (ability to multiply and produce toxins); and
- actions taken in subsequent stages of the food chain and their impact on the hazard acceptance level (organization end product).

According to the FAO, severity is defined as a degree of consequence which may result from the presence of a hazard. This organization classifies the severity in three levels (FAO 1998):

- **High:** serious health effects, life-threatening to the consumer. Examples of bacteria which may cause these effects include *Clostridium botulinum*, *Salmonella typhi*, *Listeria monocytogenes*, *Escherichia coli* 0157:H7, *Vibrio cholerae*, *Vibrio vulnificus*, paralytic shellfish poisoning, and amnesic shellfish poisoning.
- **Moderate:** Severe or chronic hazards to consumers, which may be caused by *Brucella* spp., *Campylobacter* spp., *Salmonella* spp., *Shigella* spp., *Streptococcus* type A, *Yersinia enterocolitica*, hepatitis A virus, mycotoxins, or ciguatera toxin, for example.
- **Low:** minor or moderate hazards to the consumer, such as symptoms caused *Bacillus* spp., *Clostridium perfringens*, *Staphylococcus aureus*, Norwalk virus, most parasites, and histamine-like substances.

It is common for organizations to use a risk matrix in the hazard assessment (Table 4.7). These matrices can range from simple to more complex, depending on the number of established probability and severity levels. However, the definition of many levels does not necessarily make the assessment of the degree of risk more

accurate or correct. The most important is the substantiation used by the Food Safety Team to support their decisions and the definition and maintenance of a consistent methodology throughout the analysis. Box 4.9 contains an interview with Dr Thomas Ross, where the subject of risk assessment in the seafood industry is discussed.

**Table 4.7** Example of matrix used in hazard assessment

<b>Probability</b>	High (3)	0	3	6	9
	Moderate (2)	0	2	4	6
	Low (1)	0	1	2	3
	Negligible(0)	0	0	0	0
			Low (1)	Moderate (2)	High (3)
			<b>Severity</b>		

**Box 4.9** Risk assessment in the seafood industry

Dr Thomas Ross is a microbiologist who has developed expertise in ‘predictive microbiology’ and its application to quantitative microbial food safety risk assessment. He has been involved in numerous FAO/WHO expert panels to develop guidelines for microbiological food safety risk assessment and to use it to answer food safety management questions being considered by the *Codex Alimentarius* Commission, as well preparing microbial food risk assessments for both government and businesses in Australia. He has contributed to risk assessments concerning risk management of histamine in fish, histamine in Asian fish sauces, and risk ranking of hazards in seafood, which led to the development and publication of a simple risk assessment model (now known as ‘Risk Ranger’) that has also found utility in a number of other food safety risk assessments.

**What is the background to risk assessment in the seafood industry?**

The ideas of ‘risk assessment’ have been formally applied to microbial food safety since the late 1980s with impetus from the World Trade Organization (WTO) which mandated that risk to consumer health is one of the only legitimate reasons for restriction of free trade between nations, including seafood. In fact, one of the first international food safety risk assessments concerned seafood in international trade (FAO 1999) and others have been used to change international regulations concerning histamine levels in Asian fish sauces (CAC 2011).

**What are the main challenges and limitations to seafood risk assessment?**

Among the challenges to the widespread implementation of ‘risk assessment’ is the perception that it is labour- and data-intensive, and mathematically complex. But this is not necessarily correct: while the fundamental principles of food safety risk assessment have been articulated (CAC 1999), there is no single method prescribed to assess microbial foodborne risk. Rather, food safety risk assessment is simply a logical, structured and transparent approach to making a decision by systematically combining all the relevant information.

Risk assessment aims to combine data and knowledge about factors that influence a risk (e.g., foodborne illness) to: (1) help to evaluate the magnitude of the risk; (2) identify the factors that most affect the risk; and, potentially (3) identify the most effective way(s) to manage the risk to an acceptable level.

Nonetheless, a limitation to food safety risk assessment currently is the type and quantity of data needed to evaluate food safety risks, particularly for so-called 'boat-to-throat' risk assessments that consider how risks arise and change across all stages of the seafood supply chain, including variation in: (1) pathogen levels in products; (2) pathogen growth rates and limits; (3) handling, processing, and food preparation that affect pathogen inactivation and growth; and (4) amounts eaten by different groups of consumers and the susceptibility of those various consumers to harm from the pathogen.

Another issue in employing formal risk assessment is whether the cost of a fully quantitative risk assessment outweighs the benefits that might be achieved by that approach. For example, imagine a full risk assessment that requires 20 person-years of work to achieve the 'best' answer, and that the risk management strategy would cost US\$ 2 million each year in testing. Imagine also that there is another risk management option based on a simpler risk assessment that achieves the same level of consumer protection and costs producers only US\$ 200,000 per year in testing but a further US\$ 200,000 per year through incorrect rejection of acceptable product. The less precise but more wasteful and 'conservative' strategy, while costing more in lost product, is actually more cost-effective overall, particularly for the initial cost of the risk assessment. Risk assessment methods used should therefore be consistent with the purpose and importance of the decision that needs to be made.

#### **How can HACCP benefit from risk assessment?**

Development of HACCP plans also involves assessment of hazards (Principle 1), that is, 'the things that could go wrong.' The ideas of risk assessment are very apposite in this aspect of HACCP planning because, potentially, there are many hazards. Not all, however, are equally likely to occur and the consequences (e.g., number of people who become ill and how ill they become) of the presence of the hazard can vary enormously. Given the limited resources usually available for food safety management, it makes sense to use those resources to minimize the greatest risks first, that is, those that most need to be controlled through implementation of CCPs. Eminent food microbiologists have considered this in greater detail (Notermans & Mead 1996; Buchanan & Whiting 1998) and in the USDA's Food Safety Modernization Act, introduced in 2011, the concept of risk-based CCPs was formally introduced in USA and termed hazard analysis risk-based preventive controls (HARPC). The idea of HARPC is to assign relative importance (as assessed by risk) to potential hazards and then to assign resources and strategies accordingly to control the most important hazards.

#### **Can you explain better the principles behind 'Risk Ranger'?**

Food safety risk assessment seems to be an idea that will increasingly become a normal part of food safety management, including in the seafood industry. However, regulatory authorities are aware that risk assessment, while a simple concept, is not easily performed, particularly for microbial food safety hazards. That is because the food safety risk can change dramatically over time as microbial hazards grow or, if they are killed, as a result of the storage and handling of the food. For this reason, various organizations are attempting to provide resources to make food safety risk assessment more accessible to a wider range of users. The United Nations' Food and Agriculture Organization (FAO) and World Health Organization (WHO) have, on behalf of the *Codex Alimentarius* Commission, developed guidelines for practical implementation of microbial food safety risk assessment (see the JEMRA website, <http://www.fao.org/food/food-safety-quality/scientific-advice/jemra/en/>). Similarly, FAO's Fisheries Department have developed a practical guide for application of

risk assessment in seafood industries (FAO 2004) that advocates the use of a simple risk assessment tool that has become known as 'Risk Ranger' (Ross & Sumner 2002; Anon 2015).

Risk Ranger is a simple spreadsheet software that guides users through the questions needed to assess risk, and then automates the calculations required to estimate the risk. It is a very useful tool for teaching the ideas of risk assessment but, for it to provide meaningful risk estimates, requires that the user has extensive relevant knowledge of risk-affecting factors. Similarly, iRisk (USFDA/CFSSAN 2015) provides a generic, web-based, risk assessment model that guides users through the risk assessment process. As for Risk Ranger, the data required includes the food and its associated consumption data and processing/preparation methods, the hazard and knowledge of levels normally required to cause human illness, and the anticipated health effects of the hazard when ingested by humans. Clearly, some of this information will not be readily available to nonspecialist users and there are initiatives to establish publicly available web-based databases with relevant information. An example is the FoodRisk.org website ([www.foodrisk.org](http://www.foodrisk.org)) developed and maintained by the US FDA and Food Safety and Inspection Service.

Because so much data are needed to quantify the absolute risk from a particular food/process combination, sometimes a comparative approach is used to quantify the *change* in risk, or relative risk, due to some change in the process or distribution pathway. This simpler approach may be all that is required to make the required risk management decision, but usually requires far less data and perhaps less detailed knowledge and new modeling. Often an existing model can be used to determine relative changes in risk that would be expected from some new intervention (e.g., a change to the critical limits of a CCP).

#### **How do you anticipate the future of risk assessment?**

Risk assessment is a way to use available data and knowledge to make better decisions about risk management needs and priorities. It can clearly be an important aid to HACCP plan design to optimize use of risk management resources, and new HACCP approaches that involve risk assessment (rather than hazard identification only) are being formalized. While some forms of risk assessment are very complex and labor-intensive the principles of Quantitative microbial risk assessment (QMRA) can equally be applied, using simpler approaches, to the benefit of industry. Organizations should realize that food safety risk assessment is not only useful for setting national and global food safety criteria and for international trade negotiations; it can equally be applied using simpler approaches to the benefit of industry. Resources to support a wide range of food, and seafood, risk assessment decisions are already available, and more will continue to be added in the public domain to assist industry develop safer processes and protocols.

### **Selection and assessment of control measures**

For all the control measures defined in Section 4.5.3 ('Flow diagrams, process steps, and control measures') and according to their effectiveness against food safety hazards, the Food Safety Team should select the necessary combination to prevent, eliminate, or reduce food safety hazards to acceptable levels.

The control measures specified should be classified regarding the need to be managed by OPRPs or by the HACCP plan. A systematic approach for this classification is suggested and a flow diagram, such as the one presented in Figure 4.16, can be used by organizations to identify whether the control measures should be managed by PRPs, OPRPs, or CCPs.

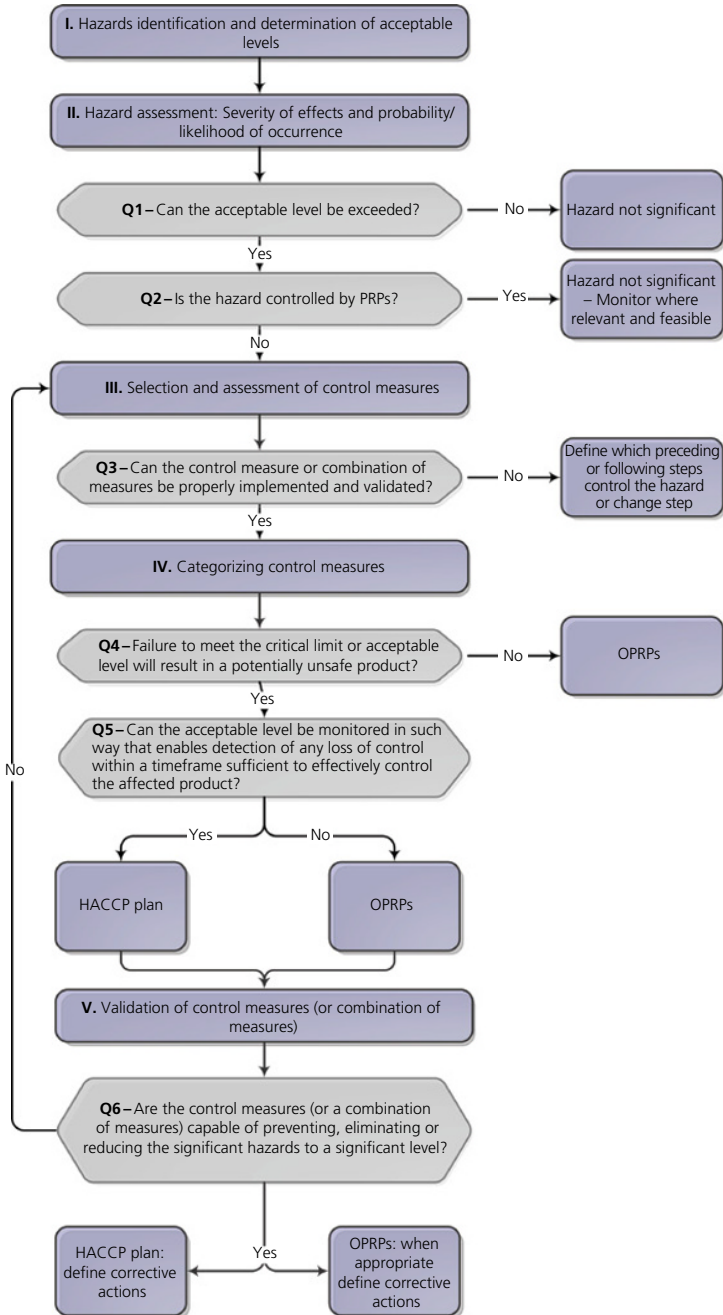


Figure 4.16 Classification of control measures.

### **4.5.5 Establishing the operational prerequisite programs (PRPs) (Clause 7.5)**

ISO 22000:2005 defines an operational PRP as a PRP identified as essential (by hazard analysis) to control the likelihood of introducing food safety hazards or the contamination or proliferation of food safety hazards in the product(s) processing environment (ISO 2005a).

The OPRPs manage control measures in a very similar manner to the HACCP plan. In some cases, OPRPs manage control measures that cannot be controlled by the HACCP plan; in ISO 22004:2014 it is mentioned that the control measures managed by HACCP plan should have critical limits and be monitored so that any loss of control is detected in sufficient time. The control measures identified which do not have these features cannot be managed by HACCP, but may be managed by OPRPs.

The technical specification ISO 22004:2014 introduces the concept of *action limit/action criterion* defined as measurable or observable criterion for monitoring a control measure managed by an operational PRP. An action limit/action criterion determines whether the control measure is under control or not, establishing the distinction between acceptable and unacceptable (depending on whether or not such a limit is met/achieved), thus indicating if the control measure is operating as intended. This concept is equivalent to the critical limit associated with CCPs. The difference is that, in the case of loss of control although the implementation of corrective actions is mandatory it does not result in potentially unsafe products. Operational PRPs shall be documented and include the following information (ISO 2005a).

- Food safety hazards to be controlled: describe the hazard and identify the step (set a numbering system to allow its identification in flowcharts, for example).
- Control measures: describe the measure or combination of control measures established to control the hazard.
- Monitoring procedures: establish the action limits or action criterion for the control measure, determine how often monitoring is performed, and define the person responsible for this task.
- Corrections and corrective actions: describe the actions to take whenever the action limits or action criterion are exceeded and define the person responsible for those actions.
- Monitoring records: identify the record of the food safety management system in which the control of the OPR is performed.

### **4.5.6 Establishing the HACCP plan (Clause 7.6)**

#### **HACCP plan**

According to the *Codex Alimentarius*, the HACCP plan is a document elaborated in accordance with the principles of HACCP to ensure the control of hazards that are significant for food safety (CAC 1969). Its establishment should be performed by the Food Safety Team and its effectiveness is essential to the fulfillment of the



preventive nature of HACCP. In fact, if all CCPs are properly monitored and any deviation from a critical limit is quickly identified, the potentially unsafe product production is reduced and the need to control the final products is significantly restricted. The standard identifies the information that should be included in the document that manages the HACCP plan and, except for the identification of the critical limit, it is the same as described in the previous section for the operational PRPs.<sup>17</sup>

### Identification of critical control points (CCPs)

A critical control point is defined by the standard as a 'step at which a control measure can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level' (ISO 2005a).

The definition of control measures results from the analysis conducted by the Food Safety Team of the steps of the process, which should subsequently be evaluated for the need to be managed by the OPRPs or HACCP plan (Section 4.5.4). This decision is often facilitated by the use of decision trees, as depicted in Figure 4.16. The ISO 22004:2014 establishes criteria to be met by the control measures associated with CCPs: the critical limit should establish the boundary between a safe product and a potentially unsafe product and its monitoring should allow timely actions to be taken to ensure acceptable levels of risk in the final product (ISO 2014).

Failure to comply with the critical limits will result in potentially unsafe products.

### Determination of critical limits for CCPs

Critical limits must be designed to ensure the control of hazards in food safety and should be specific and validated for each CCP. When a CCP controls more than one hazard, the most stringent limit from those determined for each hazard should be applied (ISO 2014).

These limits should be measurable, preferably by the monitoring of objective values such as temperature, time, humidity, water activity, etc. When limits are based on subjective data such as sensory, visual, and textural parameters, they must be supported by instructions or specifications accompanied by images to facilitate the perception (FAO & WHO 2009).

The basis for the definition of a critical limit must be documented in the food safety system. It is frequent for organizations to establish critical limits based on legislation and regulations of the sector but, in certain situations, it may be prudent to establish more stringent limits conditioned by the organization's positioning in the food chain and also by the knowledge of the common practice of manipulation or incorrect use of the products.

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<sup>17</sup> This description also includes the concept *action limit/action criterion* (introduced by the 2014 revision of ISO/TS 22004 and not present in ISO 22000:2005), which should be replaced by the *critical limit* concept when applying the HACCP plan.

### **System for the monitoring of CCPs**

The implementation of a monitoring system is decisive for verifying that critical control limits do not suffer deviations. Whenever possible, this system should allow the monitoring of trends in control loss, thus allowing process adjustments to be performed before the critical limit is exceeded. The information derived from the monitoring systems should be evaluated by a designated person with the authority to take corrective actions when necessary. The frequency of monitoring should be sufficient to guarantee that the CCP is under control and to prevent the affected product from being used or consumed. Physical and chemical measurements (e.g, pH, temperature, relative humidity, time) are preferred since they allow immediate results, whereas microbiological parameters are often more time-consuming and therefore slower to obtain. All equipment essential to food safety must be calibrated. The responsibility and authority for the monitoring and recording of CCPs should be defined and the evidence of these activities should be filed (FAO & WHO 2009).

### **Actions when monitoring results exceed critical limits**

When there is a deviation from a critical limit it means that the product is potentially unsafe. All necessary measures should therefore be taken to ensure that the nonconformity is identified, the CCP put back under control and the reoccurrence of the deviation prevented. In this sense the HACCP team should specify (in the HACCP plan) the corrections and corrective actions that the organization shall take whenever critical limits are exceeded.

ISO 22000:2005 defines correction as an action to eliminate a detected nonconformity. An example of a correction is the reprocessing of a product under conditions that meet the critical limits or the replacement of incomplete or incorrect labels. A corrective action is defined as an action to eliminate the cause of a detected nonconformity or other undesirable situation. This is taken to avoid their repetition and implies a cause analysis. A corrective action is, by nature, more difficult to plan because it depends on the causes that lead to nonconformities. A common corrective action is to carry out training sessions to correct nonconformities resultant from a lack of information or employee training (ISO 2005a).

### **4.5.7 Updating of preliminary information and documents specifying the PRPs and the HACCP plan (Clause 7.7)**

After establishing the OPRP and/or the HACCP plan it is necessary that the organization assesses the need for updated documentation and assumptions used in their elaboration, in particular (ISO 2005a): product features; intended use; flowcharts; process steps; and control measures.

In fact, this need can also arise from the common organization of activities such as changes in products/processes (e.g., creating new products or changing specifications thereof, purchasing equipment) or external changes to the organization (e.g., new statutory and regulatory requirements).

After updating the documentation, the organization shall assess the need to change the procedures and instructions established for the prerequisites, the OPRP, and/or HACCP plan.

#### **4.5.8 Verification planning (Clause 7.8)**

The concept of verification is defined by the ISO 22004:2014 as a confirmation by objective evidence that a specific requirement was satisfied. This confirmation can be accomplished through various activities conducted during or after operations in order to assess whether the control measures are implemented as planned, and should cover the whole food safety management system.

According to a list provided by the standard, verification activities should ensure that (ISO 2005a):

- the PRPs are implemented (e.g., periodic evaluation through audits or checklists);
- inputs for hazard analysis are continuously updated (e.g., assessment of changes in internal and external documents);
- operational PRPs and the elements contained in the HACCP plan are implemented and effective (e.g., verification of records, analysis of nonconformities, and measures implemented);
- hazard levels are within the defined acceptable levels (e.g., review of the results from monitoring acceptable levels); and
- other procedures required by the organization are implemented and effective (e.g., verification of hand-washing procedure through visual control and/or microbiological assessment of effectiveness; verification that equipment is calibrated as planned).

ISO 22004:2014 defines that the established verification plans should include the following information (ISO 2014):

- purpose (e.g., verification of the implementation of PRPs and their effectiveness);
- scope of the verification (e.g., control of documents and implementation);
- verification method (e.g., internal audit and on-site inspection);
- frequency<sup>18</sup> (e.g., twice a year);
- actions to be taken if the results are unsatisfactory (e.g., training on record filling, performing maintenance on equipment, segregating potentially unsafe products); and
- reporting requirements in case verification results are unacceptable (e.g., contact the team leader/Food Safety Team).

The application guide of ISO 22000:2005 places particular emphasis on the verification of the specifications of materials and contracted services, indicating

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<sup>18</sup> The verification should allow the identification of failures in compliance with requirements set by the food safety management system. In this sense, its frequency should consider the history of verification activities, the impact on food safety of the procedure being verified, and the likelihood of the procedure modification.

that they must be defined and available for verification, especially when compliance with the risk levels of ingredients or raw materials is essential to ensure food safety (ISO 2014).

Verification activities shall be recorded and communicated to the Food Safety Team, which should carry out its analysis as described in Section 4.6.4.

#### **4.5.9 Traceability system (Clause 7.9)**

Traceability systems have been used for many years in various sectors. The growing consumer demand for information about the products they consume, as well as the increased size and complexity of the food chain, have created the need for organizations to implement traceability systems that allow the transmission of that information.

ISO 9000 presents a generic concept of traceability, defining it as the ability to trace the history, application, or location of the object in question. The *Codex Alimentarius* Commission, the ISO 22005, and the European Union (Regulation No. 178/2002) have very similar definitions in which they apply this concept to food products (Ryder *et al.* 2014). The standard ISO 22004:2014 considers traceability a basic tool for food safety, defining it as the capability of the organization to accompany their final products, raw materials, packaging materials, and ingredients throughout the food chain (ISO 2014). The fact that ISO has published the international standard ISO 22005:2007 *Traceability in the feed and food chain — General principles and basic requirements for system design and implementation* reveals the importance of the issue for the food industry and also the need to harmonize and guide the implementation of these systems (ISO 2007).

Box 4.10 introduces two examples of organizations that are enhancing confidence in their products by providing traceability information to customers.

The traceability system can be divided into internal and external traceability. The former tracks the transformations of the product inside the organization, while the latter allows the identification of suppliers and customers one step back and one step forward. This system is especially relevant when failures occur (e.g., if there is a food poisoning outbreak, the organization must have the information necessary to remove the product from the market and report to the competent authorities). When the cause of occurrence does not have its origin in the organization, the authorities use the information to try to identify the problem in the previous step of the food chain. A fully implemented traceability system involves the use of organization resources but, on the other hand, in the case of a withdrawal it can minimize the amount of product to recall and reduce the damage to the company's image.

A period for maintaining the records of traceability should be established taking into consideration the characteristics of the product, its expiration date, and the intended use by the customers/consumers (e.g., if it is to be incorporated in another product).

**Box 4.10** Traceability

According to a study by Oceana (Oceana Study Reveals Seafood Fraud Nationwide) where, during 2010–2012, 1215 seafood samples (collected from 21 different states from the United States of America) were genetically identified, 33% of the products tested were considered mislabeled (Warner *et al.* 2013). Another threat to consumer confidence and even health is the illegal, unreported, and unregulated (IUU) fishing. This problem has grown in the last two decades and it is estimated to be of a scale of 11–26 million tons each year (FAO 2014). This fraudulent behavior represent a serious detriment to the consumer and promotes a feeling of distrust in the supply chain. Fish distribution systems are growing more complex and globalized, and it is becoming more costly to obtain information on the origin of and the processes that the fish has been submitted to until it reaches the consumer. The combination of these factors has encouraged the search for solutions to the development of systems that improve the traceability and legitimacy of information that is transmitted to the consumer.

The company Backtracer (Traceability and Verification of Seafood Products) is developing a database that organizations responsible for fish processing can use to record the fish route. This way the consumer can check the origin and stages along the food chain of the fish being consumed. Norpac Fisheries Export implemented a barcode system that allows customers to access a high level of detail about the product. Each fish shipment comes with a label printed with a QR code (see Box 4.2) which, when scanned, opens a link to a webpage of information, such as commander of the ship, when and where the fish was captured, and even the equipment utilized. This technology allows the promotion of fresh fish and offers the consumers a receipt that documents the origin of the fish they are buying. FishPrint® is other traceability program developed by Profish®, allowing information about harvest zone, vessel and fisherman, latin genus, and DNA test results to be accessed via QR codes.

**4.5.10 Control of nonconformity (Clause 7.10)****Corrections**

As already mentioned in Section 4.5.6 ('Actions when monitoring results exceed critical limits'), a correction is an action to eliminate a detected nonconformity and should therefore be carried out immediately after its detection. The greater the elapsed time between the loss of control and the implementation of corrections, the greater the amount of potentially unsafe product. The affected product should be identified and evaluated and handled in accordance with the procedure for handling potentially unsafe products as described in Section 4.5.10 ('Handling of potentially unsafe products') (ISO 2014).

Corrections must be approved by competent personnel previously appointed to this function, and filed together with information on the nature of the nonconformity, the amount and lots of the affected products, and evidence of action taken (e.g., computer records, photographs, records of microbiological or physico-chemical analysis) whenever possible.

**Corrective actions**

Corrective actions (also mentioned in Section 4.5.6, 'Actions when monitoring results exceed critical limits') are actions to eliminate the cause of a detected nonconformity or other undesirable situation in order to prevent its reoccurrence,

and must be initiated when critical limits or (when possible) an action/criterion limit are exceeded. Corrective actions are not only initiated as a result of corrections; any detected nonconformity should generate corrective actions even if a correction has not been made or considered necessary. Following the identification of the causes of nonconformities, and taking into consideration their nature, the possibility of withdrawal of the unsafe product should be considered.

A period to assess the effectiveness of the corrective action should be determined. They should only be considered effective if, during this period, there is no repetition of the nonconformity with origin in the same detected causes.

Standard ISO 22000:2005 requires that a documented procedure is established for the implementation of corrective actions. In addition to the actions described (Fig. 4.17), the documentation must indicate the person responsible for their implementation. It should be demonstrated that the nominated employees have the required skills to perform those actions (ISO 2005a).

The organization must have a record to document the entire process of managing the nonconformity, which can be divided into three main phases as follows.

1. *Problem identification*: Record the source of the problem (e.g., internal/external audit, OPR or CCP), the date of occurrence, and its description.
2. *Identifying the causes*: Register the causes that led to the nonconformity. To facilitate this determination, it is possible to use some methodologies already established for this purpose (Box 4.11 contains examples of such methodologies).
3. *Definition of measures and evaluation of their effectiveness*: Describe the measures identified as necessary to restore conformity (correction) and/or eliminate the causes (corrective action), those responsible for executing them, and the expected date for completion. Identify the period during which the effectiveness of corrective actions is assessed and whether the nonconformity has been corrected; otherwise, restart the process of identification of causes or take further corrective actions.

At all phases it should be clear who is responsible for implementation and/or approval, since nonconformity process can be managed by different persons.

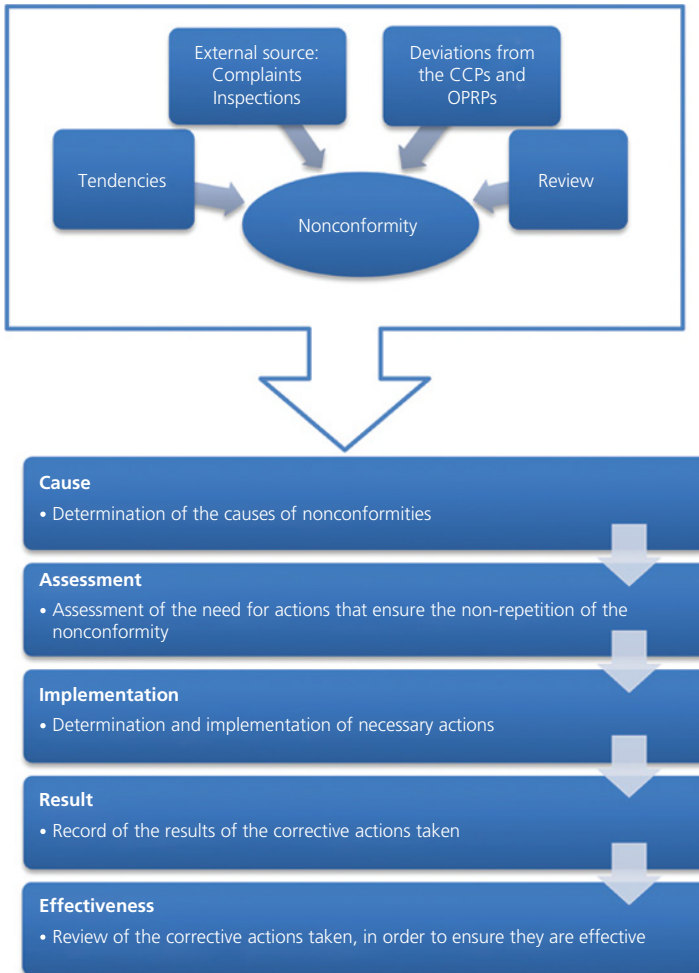
## **Handling of potentially unsafe products**

### **General**

A nonconformity is understood as the failure to meet legal, regulatory, or internal procedures or requirements. This concept is related to the production of unsatisfactory results and potentially unsafe products (e.g., control loss in OPRPs and exceeded critical limits).

The organization shall establish appropriate procedures to prevent the introduction of potentially unsafe products in the food chain, unless (ISO 2005a):

- the organization is able to reduce to acceptable levels the risk to food safety or evidence that these will be reduced before entering the food chain; or
- despite the nonconformity, the product is still within the defined acceptable level.



**Figure 4.17** Nonconformities procedure.

All products that may have been affected by the nonconformity must be clearly identified to prevent them from being used or marketed. If some of these confirmed unsafe products have left the organization, the withdrawal process should be initiated.

**Evaluation for release**

The assessment for release is performed to ensure that a potentially unsafe product is only released to the food chain when it complies with the specified acceptance levels. For this purpose the evaluation must be conclusive and supported by evidence that ensures that the product is safe.

**Box 4.11** Examples of methodologies to identify causes

1. *Cause–effect diagram*: This technique was originally proposed in 1976 in the book *Guide to Quality Control* (Ishikawa 1986). It is a technique that shows the relationship between effect and possible causes. It is schematically organized as a fishbone, allowing the visualization of the possible causes of a problem and analysis of the improvement processes. It uses the brainstorming methodology and classifies the causes in five groups (5M's): machine, material, method, man, and milieu.
2. *Brainstorming*: This is a technique for generating ideas oriented towards solving group problems, stimulating their creativity and the production of innovative ideas. It is divided in two stages. In the first, the goal is to unrestrictedly generate the biggest number of ideas possible to proceed to a second phase in which they are analyzed, discussed and selected. One of the basic rules of the first stage is the prohibition of debate and criticism of the ideas presented so that everyone has an equal opportunity. These rules mean that the parties have the freedom to say what they want without feeling inhibited by criticism.
3. *Tree of whys*: This is a technique which consists of placing a set of questions to the problems and seeking possible solutions. It is considered that the source of the problem is found when is no longer possible to find answers to the questions arisen (i.e., when there is no explanation for the event). An example application of this technique in the case of a nonconformity detected during transportation of products under controlled temperature is included below.

*Tree of whys example*: **Q: Why do products not reach customers at the right temperature?** A: Because the temperature during transport increases. **Q: Why does the temperature increase during transport?** A: Because during transport the doors remain open for too long. **Q: Why do the doors remain open for too long?** A: Because distributors load the vehicle incorrectly (disordered). **Q: Why do distributors perform a disordered load of the vehicle?** A: Because distributors lack training (and time) at the moment of loading.

According to ISO 22000:2005, the products can only be released when there is other evidence, in addition to the monitoring system, that proves that control measures or the combination of them were effective (e.g., able to ensure the desired levels of acceptance) or that the results of verification activities (e.g., laboratory analysis) testify that the affected product complies with the identified acceptable levels (ISO 2005a).

### **Disposal of nonconforming products**

When the assessment for release presents unsatisfactory results and the product is not acceptable for release, it shall be subjected to one of the following activities (ISO 2014):

- reprocessing or new processing of the product inside or outside the organization, in order to ensure that the food safety hazard is eliminated or reduced to acceptable levels;
- reformulation or usage for other purposes for which the product is acceptable (e.g., use in products which have an intended use that ensures their safety such



as mandatory thermal processing or changes in the composition of the product to ensure that it meets the requirements for food safety); or

- destruction.

## Withdrawals

The withdrawal concept refers to any measure aimed at preventing the distribution and exhibition of a hazardous product and its supply to consumers (EC & EP 2002). The withdrawal process is performed when a product is assessed as unsafe and the organization identifies that it is already in the next step of the food chain. As mentioned in Section 4.5.2, Prerequisite 12, the need to remove products produced under the same conditions should equally be evaluated.

The product withdrawal process may be generated when the product is not safe for human consumption (e.g., microbiological contamination) or does not fulfill the legal requirements (e.g., labeling).

When a nonconformity is detected and withdrawal conducted, as much information as possible should be gathered about the product including (at least): full product description including the identification of the lots of raw materials and packaging materials; product lot and quantity produced; date of manufacture and expiration date; and other information related to the product or process (e.g., identification of the production line and manufacturing time and manufacturing operators responsible for it).

For the recall of products to be complete and on time, the top management should nominate personnel to start and manage the withdrawal process. Traceability is a fundamental process for the withdrawal to be completed. This system is able to identify incoming material, as well as the initial distribution route of the finished product. The organization shall establish and maintain a documented procedure for the management of withdrawals which should include the following:

- the interested parties to be notified of the occurrence (e.g., statutory authorities, customers, consumers);
- actions to be taken at each stage;
- the treatment method of products/lots both withdrawn and still in stock and the process to keep them safe and under proper supervision until assessment;
- the method by which the withdrawals are documented (e.g., causes, size, results) and which ensures that they are included in the management review (Section 4.3.8); and
- procedures for verifying the effectiveness of the withdrawal program.<sup>19</sup>

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<sup>19</sup> The organization must be able to demonstrate that all planned steps are met and allow for the withdrawal of any unsafe product. At the end of the withdrawal process, the quantity of product must match that identified initially; in case of deviations, these must be justified. The organization must define a frequency for market withdrawals simulation in order to verify that the procedure is maintained operational and effective. Although ISO 22000:2005 and its implementation guide does not provide a minimum period to carry out simulations, it is advisable that these are held annually (except in years in which effective withdrawals have been carried out). In fact, this is also the indication present in references BRC Issue 7, IFS Food version 6 and SQF Code edition 7.2.

## 4.6 Validation, verification, and improvement of food safety management system (Clause 8)

For relevant keywords, please refer to Figure 4.18.



**Figure 4.18** Keywords from Section 4.6.

### 4.6.1 General (Clause 8.1)

Clause 8 of the standard establishes the requirements that the organization should meet to validate, monitor, verify, and improve the food safety management system in order to demonstrate that it provides the expected level of control.

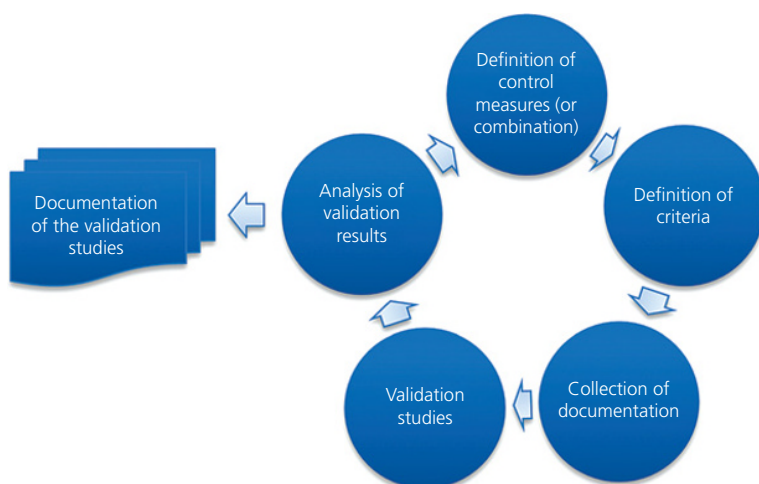
The update and enhancement of the food safety management system should guarantee that the information that was the basis of its development remains current and is characterized by a solid scientific basis originated from credible sources (e.g., academic, official bodies, relevant international organizations). It is the responsibility of the Food Safety Team to plan and implement the necessary processes to comply with this clause.

### 4.6.2 Validation of control measure combinations (Clause 8.2)

Despite this clause not having a direct correspondence to any of the stages of the HACCP methodology, in step 11 (*establishment of procedures of verification*) it is stated that, whenever possible, validation activities should be developed to confirm the effectiveness of all HACCP system elements.

ISO 22000:2005 defines the term ‘validation’ as the achievement of evidence that the control measures managed by the HACCP plan and by the OPRPs are effective (ISO 2005a). The validation focuses on gathering and assessing scientific, technical, and observational information, and should be performed prior to the implementation of the control measures or whenever changes are made to the control measures implemented. Validation of control measures should also be reassessed when new scientific or statutory information is produced or the products or process change. Figure 4.19 depicts the process of validation of the control measures (ISO 2014).

The definition of methods to demonstrate that the control measures, or combinations thereof, are able to control the risk in order to achieve the desired results should be (and commonly are) based on validated scientific/technical information



**Figure 4.19** Validation of the control measures.

and previous<sup>20</sup> or historical knowledge of the performance of control measures. Other methods suggested by ISO 22004:2014 are mathematical modeling and surveys. Validation studies should be preceded by the gathering of information necessary for such an assessment and should result in a report record that supports the decision.

During the validation of the control measures, if the results are not satisfactory the control measures should be revised and improved. When this is necessary, the Food Safety Team may take different approaches that can include changing (ISO 2005a): control measures (e.g., in the process parameters, the level of accuracy and/or their combination); raw materials; manufacturing technologies; or the characteristics or intended use of the finished product.

### 4.6.3 Control of monitoring and measuring (Clause 8.3)

Equipment and measurement methods must be controlled by people with competence to ensure that these provide valid results. It is up to the organization to establish which monitoring and measurements should be carried out and which equipment is necessary to ensure that those procedures are implemented, and provide evidence of conformity with the established requirements (ISO 9001:2008b).

<sup>20</sup> When validation is based on past experience of the Food Safety Team or when it was carried out by other people, it must be demonstrated that the same conditions of the intended application remain valid (ISO 2014).

The standard identifies procedures and tasks that must be established whenever it is necessary to ensure the validity of results obtained by equipment and methods of measuring and monitoring (ISO 2005a):

- ensure the calibration or verification at specific intervals and whenever necessary proceed to their adjustment;
- identify all equipment<sup>21</sup> and protect it from damage and deterioration; and
- safeguard equipment from adjustments that might invalidate the measurement result (e.g., adjustments by noncompetent people).

The organization must guarantee that the accuracy of the equipment is appropriate for the measures performed. The uncertainty defined by the calibration must be taken into consideration when the equipment assesses critical limits (e.g., when defining temperature set point).

Noncalibrated equipment must be immediately identified and, when possible, physically segregated from the rest of the equipment in order to ensure that it will not be used until recalibration. The validity of the previous measuring results must be evaluated, as well as the consequences to the safety of food products. The use of software for measurement/monitoring requires prior validation of its ability to control the specific requirements.

#### **4.6.4 Food safety management system verification (Clause 8.4)**

Verification activities and methods are not the clearest subjects when implementing a FSMS. In fact, it was not one of the three original principles of HACCP but, as described in Box 4.12, it was soon found to be decisive for the success of HACCP. Verification is defined in ISO 9000:2005 as confirmation, through the provision of objective evidence, that specified requirements have been fulfilled. The entire FSMS should be subject to verification activities that may include (ISO 2014):

- review of records and documents (e.g., verify if the CCP or OPRP records have been completed correctly);
- evaluate whether a PRP or a process has operated within requirements (e.g., verify if hand cleaning is being correctly executed and efficient);
- verify if the training, calibration, maintenance, or cleaning plans are being correctly carried out;
- confirm that external documentation (e.g., regulatory/statutory and customer requirements, customer complaints, external audits) are being evaluated and used to improve the FSMS effectiveness; or
- end-product testing.

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<sup>21</sup> Identification should state when the equipment was calibrated or be used to identify the equipment in the list of equipment (see Section 4.5.1, Prerequisite 5) where this information should be included.

**Box 4.12** The verification principle

In Box 4.3 Dr William Sperber describes how in 1972 in Pillsbury they found that, despite the 'hole being monitored,' nothing was done to correct it. The story finishes below describing how the HACCP principles become 7 (from the original 3) in the subsequent years.

Sure enough, the sifter had indeed been inspected regularly and the inspector had first noted 'hole in sifter screen' (see Box 4.3). Immediately we created another HACCP principle: take corrective actions when deviations occur at a CCP. In the same time period our engineers had established another CCP: establish critical limits at each CCP.

By 1975 Pillsbury's HACCP system consisted of 5 principles. Principles 6 and 7, for verification and record-keeping, were added in 1992 by the US National Advisory Committee on Microbiological Criteria for Food and by the UN Codex Alimentary Commission. More than 20 years later this program with 7 principles is still in use worldwide. It has greatly assisted global food producers as it is a standard for food safety management that can be used in all countries that are signatories to the World Trade Organization.

**Internal audit**

ISO 19011:2011 (ISO 2011) defines audit as a systematic, independent, and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are met.

The audit is a key factor in assessing the effectiveness of the food safety management system and verification of compliance of the planned provisions with the requirements of ISO 22000:2005. The organization shall establish a procedure to define the responsibilities, the qualification, and appointment criteria of auditors. The evidence of competence of auditors should be documented and archived (e.g., *Curriculum vitae*, certificates of qualification). Internal audits should be conducted by auditors that ensure the independence and impartiality of the process and should be conducted by people external to the process/audited area or even to the the organization when necessary.<sup>22</sup>

Since the frequency of assessment of the FSMS is not defined by the standard, the organization should set time intervals to perform internal audits. These intervals are defined according to the importance of the processes and audited areas, as well as the results of previous audits. The processes/areas of greatest relevance to food safety or that have obtained poor results in previous audits shall be subject to more constant checks. The criteria, scope, frequency, and methods of audits should be defined (ISO 2005a).

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<sup>22</sup> The guide for application of the standard (ISO 22004:2014) identifies the possibility, particularly in small businesses (one or two managers), of failure to meet these requirements fully. In these cases it is required that the manager that performs the functions of auditor is objective and ensures fairness in the process. Another alternative proposal is to establish a partnership with another small company so that their managers perform the internal audit of the other company.

Records from internal audits should be maintained and results communicated not only to the process/area managers but also to the Food Safety Team and, if necessary, to the top management. The noncompliances detected during the audits shall be treated in accordance with the requirements specified in Section 4.5.10.

### **Evaluation of individual verification results**

The results of verification activities should be registered and include information on (ISO 2014):

- the effectiveness of the food safety management system;
- the personnel responsible for its management and updating;
- the records associated with the monitoring activities and equipment calibration; and
- the results of the review of records and analyzed samples.

The Food Safety Team should regularly evaluate the results from the planned verification activities (Section 4.5.8). When this assessment does not demonstrate compliance with the requirements, the organization should act in order to obtain the required compliance. For this purpose, any requirements for revision of existing procedures and communication channels, the hazard analysis, the PRPs, OPRPs, the HACCP plan, and the effectiveness of human resource management and training activities (ISO 2005a) should be identified. All the activities that the organization considers necessary to perform in order to restore compliance should be recorded as evidence.

### **Analysis of results of verification activities**

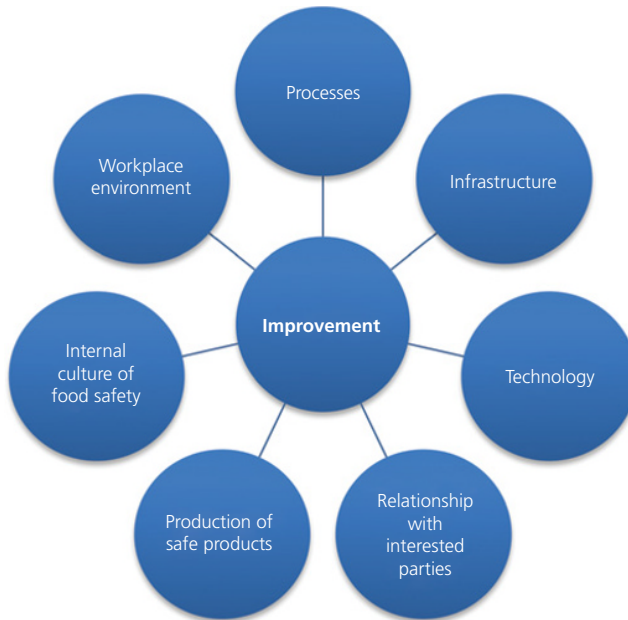
The results of verification activities, including internal and external audits (conducted according to Section 4.6.4, 'Internal audit'), should be analyzed with the purpose of (ISO 2005a):

- assessing the system's global performance;
- identifying the need for updates and improvements;
- identifying tendencies that can compromise the safety of the products;
- gathering the necessary information for the planning of audits; and
- providing evidence of the effectiveness of the corrections and corrective actions performed.

The results of the analysis and resulting activities should be registered and communicated in appropriate form to the top management, namely as an input during the management review (Section 4.3.8), and should be used for the update of the FSMS.

### **4.6.5 Improvement (Clause 8.5)**

ISO 22000:2005 determines that organizations seek to continuously improve and update the food safety management system. Figure 4.20 depicts situations where improvement and updating are usually applied (ISO 2014).



**Figure 4.20** Situations where improvement and updating are commonly applied.

### Continual improvement

The top management should ensure that the organization continually improves the efficiency of the food safety management system through activities listed in Table 4.8 (ISO 2005a).

The improvement activities should be carried out using the plan-do-check-act (PDCA) methodology as described in standard ISO 9001 for the improvement of the quality management system performance (ISO 2008b).

Top management should encourage a culture of continuous improvement to achieve better performance, implementing a cycle of goals/control/recognition/reward. As highlighted in Section 4.3, top management attitude is very important to inspire personnel to have a better attitude towards the FSMS. Despite the definition of food safety objectives being a top management responsibility (and should be strategic for the organization), the importance of recognition and reward when such objectives are achieved it is not always perceived. Without this approach, together with promoting the participation of all (even personnel that have no obvious relation to food safety), top management will find it very difficult to create an improvement culture in the organization.

**Table 4.8** Activities through which top management shall ensure the improvement of the system and examples of those activities

Activities	Examples
Communication	Ensure that there is sufficient external information available to update the FSMS. Guarantee that issues that have an impact on food safety are communicated with personnel.
Management review	The output of the FSMS performance evaluation should include decisions for its improvement. New food safety objectives and updated food safety policy.
Internal audits	Results from internal audits shall be discussed in the management review or even force the management to take immediate action (corrections or corrective actions) related to the identification of nonconformities.
Evaluation of individual verification results	Review of the training plan or PRP(s) found necessary after results of the verification activities.
Analysis of results of verification activities	Take action after identifying a trend that can generate potentially unsafe products.
Validation of the combinations of control measures	Change control measures or define new combinations when validation fails to prove its effectiveness.
Corrective actions	Take actions to eliminate the cause of a nonconformity and guarantee that the problem is not repeated in the future.

### Updating the food safety management system

The food safety management system should be regularly evaluated and updated. It is the responsibility of the Food Safety Team to set the time intervals between each assessment according to the needs identified for the review of hazard analysis, the established operational PRPs, and the HACCP plan.

Any activity of updating should be recorded (and utilized in the management review) and, according to the guide on the application of ISO 22000 (ISO 22004:2014), may result from:

- new information from internal and external communication;
- results of the evaluation of the efficiency and effectiveness of the food safety management system (e.g., trend analysis, number of nonconformities, customer complaints, observations of daily operations);
- results of verification activities (e.g., internal/external audit); and
- guidelines resulting from management review (e.g., resource requirements, changes in the food safety policy and objectives).