BS ISO 22004:2014

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Food safety management systems — Guidance on the application of ISO 22000

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National foreword

This British Standard is the UK implementation of ISO 22004:2014.

The UK participation in its preparation was entrusted to Technical Committee AW/90, Quality systems for the food industry.

A list of organizations represented on this committee can be obtained on request to its secretary.

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INTERNATIONAL STANDARD

ISO 22004

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Food safety management systems — Guidance on the application of ISO 22000

Systèmes de management de la sécurité des denrées alimentaires — Recommandations pour l'application de l'ISO 22000

Reference number
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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 34, *Foods products*, Subcommittee SC 17, *Management systems for food safety*.

This first edition of ISO 22004 cancels and replaces ISO/TS 22004:2005, which has been technically revised.

0 Introduction

0.1 General

This International Standard provides guidance on the use of ISO 22000 in four parts: planning, implementation, verification and improvement (Plan, Do, Check, Act). The clauses of ISO 22000 link together to form a food safety management system (FSMS).

Correspondence with the relevant clauses of ISO 22000 is given in the headings as well as in Annex A (see Tables A.1 and A.2).

0.2 Food chain approach

Establishing an FSMS is a tool used to mitigate the risk to public health associated with the organization's products; it is also useful for ensuring compliance with statutory/regulatory requirements and/or those specified by customers.

ISO 22000 promotes the adoption of a systematic approach for developing, documenting, implementing and maintaining an FSMS. Integral to this approach are supply chain management (supplier evaluation and approval) and ensuring the safety of products during distribution.

0.3 Process approach

ISO 22000 also follows the "process approach" (i.e. management of a system of interrelated processes with identified interactions).

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

When used within an FSMS, the process approach emphasizes the importance of:

a) understanding and fulfilling the ISO 22000 requirements;

b) considering food safety as a process;

c) considering traceability as a process;

d) monitoring of process performance and effectiveness;

e) continual improvement of processes based on objective measurement(s).

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

0.4 The ISO 22000-related documents

The ISO 22000 family of documents comprises of a number of individual International Standards and Technical Specifications, which are interrelated and supplementary to each other (see Figure 1). ISO 22000 is the primary International Standard, which defines the requirements and to which the other International Standards and Technical Specifications within the family are linked.

ISO/TS 22002 (all parts)[6] provides guidance to meet the requirements for prerequisite programmes (PRPs). It is intended to be used in support of the requirements for PRPs specified by ISO 22000. PRP documents of the ISO/TS 22002 series address food chain categories according to ISO/TS 22003:2013, Clause A.1, and potentially related categories.[7]

ISO/TS 22003 provides guidance for the accreditation of certification bodies, that is, those groups which can audit organizations in the food chain under ISO 22000. It also defines the basic requirements for companies applying for ISO 22000 certification, the rules applicable to audit and certification, and provides for customers the necessary information and confidence in the certification process regarding suppliers.

ISO 22005 provides guidance on the establishment and operation of traceability systems including traceability for food safety purposes. Some of this guidance is also included in this International Standard (see 5.12 and Reference [8]).

Reference [10] on ISO 22000, also referred to as the "fitness checker", is a handbook first published in 2006, which specifically targets small businesses that are not familiar with ISO and its standards.[10] It provides these organizations with guidance for future certification.

Reference [11] on how to use ISO 22000 is a handbook providing generic guidance to assist organizations, in particular small- and medium-sized organizations, on how to develop, document, implement and maintain an FSMS in accordance with ISO 22000.[11]

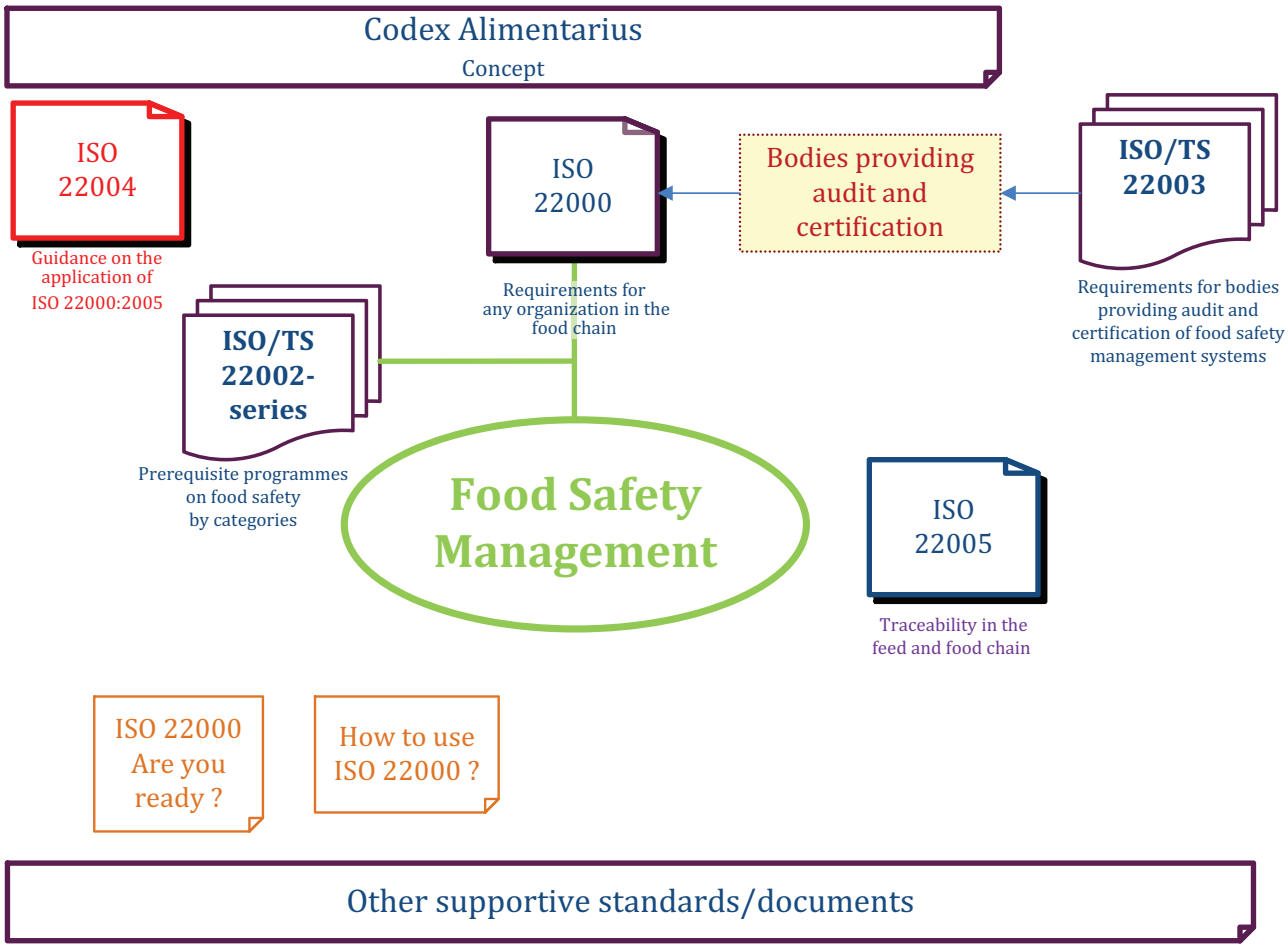


Figure 1 — Overview of ISO 22000-related documents

0.5 Relationship with ISO 9001

ISO 22000 has been designed to work in harmony with ISO 9001[1] and its supporting standards.

ISO 9001 provides requirements for a quality management system, which can be used internally by organizations, for certification or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customers' requirements.

ISO 22000 provides the essential elements of an FSMS for similar purposes.

0.6 Compatibility with other management systems

An FSMS is most effective when developed, documented, implemented and maintained within the framework of a structured management system, which is incorporated into the overall management activities of the organization.

ISO 22000 enables an organization to align or integrate its own FSMS with other related ISO management systems (e.g. ISO 9001,[1] ISO 14001,[4] ISO 28000[9]).

It is possible for an organization to adapt the management part of its existing ISO 22000 system(s) so as to facilitate the implementation of other ISO management system Standards. For example, the following system elements might be common to any other ISO management system, however, managed differently and/or independently, when needed:

— policy;

— management responsibilities (commitment, resources and objectives);

— competencies (training);

— management review;

— monitoring and measurement;

— document control;

— audit of the system;

— corrective actions;

— continual improvement;

— traceability;

— communication.

INTERNATIONAL STANDARD **ISO 22004:2014(E)**

Food safety management systems — Guidance on the application of ISO 22000

1 Scope

This International Standard provides generic advice on the application of ISO 22000.

This International Standard does not create, alter or replace any of the requirements in ISO 22000. As individual organizations are free to choose the necessary methods and approaches to fulfil the requirements of ISO 22000, the guidance provided by this International Standard, are under no circumstances, to be considered a requirement.

This International Standard has been drafted to enhance acceptance and use of ISO 22000-based food safety management systems (FSMS), as well as to improve understanding, communication and coordination between organizations in the food chain.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable to its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 22000:2005, *Food safety management systems — Requirements for any organization in the food chain*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 22000 and the following apply.

NOTE In the context of food safety, the terms “hazard” and “risk” are still translated into and/or used for the single word: “risk”, thus leading to the use of the incorrect expression “risk analysis” instead of the correct expression “hazard analysis” (see 3.3 of ISO 22000:2005).

3.1
significant hazard
biological, chemical or physical hazard, identified through the hazard analysis process, which needs to be controlled at critical control point(s) [CCP(s)], or by operational PRP(s) and/or by combinations thereof

Note 1 to entry: Lack of control will lead to a potentially unsafe product. Identified hazards, not assessed as significant, need not be controlled at CCP(s) and/or by operational PRP(s).

Note 2 to entry: Operational prerequisite programme is abbreviated as OPRP.

3.2
deviation
failure to meet an expected outcome

3.3
action limit
action criterion
measurable or observable criterion established for the monitoring of a control measure applied as an OPRP

Note 1 to entry: An action limit or criterion expresses whether or not the control measure is under control, and distinguishes between what is acceptable (limit met or achieved means the control measure is operating as intended) and unacceptable (limit not met nor achieved means the control measure is not operating as intended).

4 General (Clause 7 of ISO 22000:2005)

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

The FSMS is developed and implemented through a Plan-Do-Check-Act (PDCA) approach as follows:

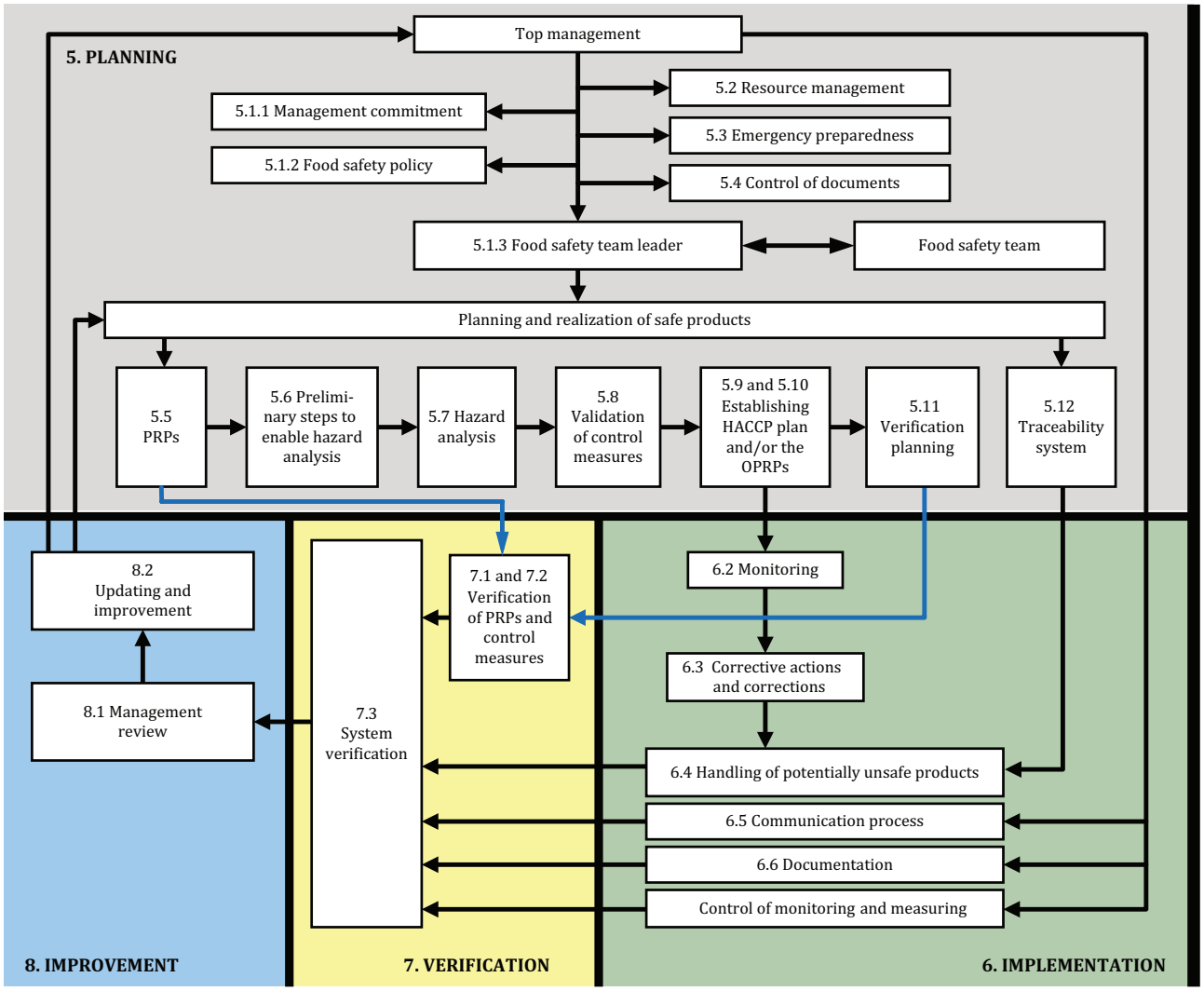
a) planning (Plan) of the steps; from the establishment of the PRPs, hazard analysis and critical control point (HACCP) plan and/or by similar means for OPRP such as an OPRP plan (see Note below), through conducting hazard analysis and validating the selected control measures, to establishing verification procedures and developing a system for traceability;

   NOTE An OPRP plan is a controlled document that describes how the food safety hazards are managed and controlled by OPRPs.

b) implementation (Do) of monitoring, corrections, corrective actions and handling of unsafe products (day-to-day operations);

c) verification (Check) of PRPs, control measures and system performance;

d) improvement (Act) by reviewing the overall system performance (management review), updating of the system and/or enhancing its effectiveness.



NOTE The numbering refers to the (sub)clauses of this International Standard.

Figure 2 — Illustration of the PDCA approach to FSMS

Development, maintenance and improvement of the system are addressed by planning, monitoring, verification and updating as shown in Figure 2. Maintenance and improvement of the system is addressed through a number of cycles of planning, validation, monitoring, verification and updating. Within an operating system, changes can be initiated at any of these phases.

PRPs are established to ensure that basic requirements and activities are in place, thus ensuring the establishment of a hygienic environment. Additionally, some PRPs are practices globally recognized as contributing to the provision of safe and suitable[13] food.

Significant hazards identified during hazard analysis are controlled by identified control measures that are subsequently categorized into two categories of control measures (given in 7.4.4 of ISO 22000:2005):

— control measures applied at CCPs: these control measures are managed by a HACCP plan. Such control measures have defined critical limits that can separate acceptable product from potentially unacceptable (unsafe) product. In addition, their implementation can be monitored in a manner that enables detection of any loss of control within a timeframe sufficient to effectively control affected product. Failure to meet critical limits will result in a potentially unsafe product.

— control measures applied as OPRPs: these control measures cannot be managed by an HACCP plan but can be managed by similar means such as an OPRP plan. In the case of OPRPs, such control measures do not have a critical limit, but should have an action limit or an action criterion, which

demonstrates that the OPRP is in control. Failure to meet these established criteria will lead to corrective actions.

The affected products "shall be evaluated with respect to the cause(s) of the nonconformity and to the consequences thereof in terms of food safety and shall, where necessary, be handled in accordance with 7.10.3" (of ISO 22000:2005).

NOTE The traditional Codex decision tree does not include the concept of OPRP.

Control measures applied at CCPs and as OPRPs are intended to control all the hazards assessed as significant during hazard analysis. Control measures or combinations of control measures applied at CCPs and as OPRPs should be validated to ensure that they are effective. Validation is not required for PRPs.

Table 1 — Actions linked to PRPs, OPRPs and CCPs, as well as the relationship between them

<table>
<tr><th>PRP[a]</th><th colspan="2">OPRP</th><th>CCP</th></tr>
<tr><td>Preliminary development based on experience and assessment of reference documents.</td><td colspan="3">Identified once PRPs are developed, and based on the hazard analysis taking the PRPs into account. OPRPs and CCPs are product and/or process specific.</td></tr>
<tr><td>Measures impacting food suitability[13] and safety.</td><td colspan="3">Measures (or combination of measures) controlling hazards that are remaining after the implementation of PRPs.</td></tr>
<tr><td>General measures that are not specific to any hazard.</td><td colspan="3">Measures (or combination of measures) that are specific to each hazard or group of hazards.</td></tr>
<tr><td>Measures related to creating the environment for the production of safe food.</td><td colspan="3">Environment- and/or product-related measures (or combination of measures) to prevent contamination or to prevent, eliminate or reduce hazards to an acceptable level in the end product.</td></tr>
<tr><td rowspan="5">Monitoring where relevant and feasible[b].</td><td colspan="3">Validation</td></tr>
<tr><td colspan="2">Measurable or observable action criterion(a) or action limit(s) demonstrating that the OPRP is in control.</td><td>Measurable critical limit(s) is (are) demonstrating that the control measures (or combination of measures) associated with each CCP is in control.</td></tr>
<tr><td colspan="3">Monitoring of the implementation of control measures (or combination of measures).</td></tr>
<tr><td colspan="2">Corrective actions, and/or corrections as needed.</td><td>Corrective actions, and/or corrections.</td></tr>
<tr><td colspan="3">Monitoring records kept.</td></tr>
<tr><td>Scheduled verification of implementation</td><td colspan="3">Scheduled verification of implementation.
Verification of achievement of planned hazard controls.</td></tr>
<tr><td colspan="4">[a] PRPs are often referred to as good practices, such as good hygienic practices, good agricultural practices and good manufacturing practices.
[b] Many PRPs do not lend themselves to monitoring. Thus monitoring activities should be in place where feasible.</td></tr>
</table>

External competences may be used by the organization to develop the combination of PRPs and control measures; provided they meet the requirements of 7.2 to 7.8 of ISO 22000:2005 (see Clause 9).

5 Planning

5.1 Management responsibility (Clause 5 of ISO 22000:2005)

5.1.1 Management commitment (5.1 of ISO 22000:2005)

The organization's FSMS should be based on the key elements of food safety described in the Introduction and Scope of ISO 22000:2005.

It is intended that top management allows enough time to review the management system. It is the responsibility of top management to ensure that the review includes an assessment of performance against the food safety policy and the related objectives that have been set.

The organization can achieve sustained success by consistently meeting the needs and expectations of its interested parties.

To achieve sustained success its top management should:

— have a long-term planning perspective (applying the continual improvement principle);

— list stakeholders involved with external and internal communication, assess their individual potential impacts on the organization's performance, as well as determining how to meet their needs and expectations in a balanced way;

— engage stakeholders and keep them informed of the organization's activities and plans;

— identify associated short- and long-term risks and implement an overall strategy for the organization to mitigate them;

— regularly assess compliance with current plans and procedures, and take appropriate corrective actions and update the programmes as required.

5.1.2 Food safety policy (5.2 and 5.8.1 of ISO 22000:2005)

Top management should establish the organization's food safety policy, so that the mission, vision and values are accepted by relevant interested parties. The organization's policies should be reviewed on a regular schedule and revised as needed.

The organization's food safety policy should incorporate activities needed to achieve food safety statutory/regulatory requirements, and the food safety requirements of customers.

Programmes should be developed, documented, implemented, maintained and updated, in such a way as to enable the continuous review of the performance regarding the FSMS, and allowing for any necessary improvements.

5.1.3 Food safety team leader (5.5 of ISO 22000:2005)

ISO 22000 requires that organizations establish a food safety team and designate a leader (nominated by top management), who is responsible for developing, documenting, implementing, maintaining and updating the FSMS.

The food safety team leader has a permanent function, which is central to the FSMS of any organization. The individual should be a member of the organization and should understand its food safety issues. Where the food safety team leader has other responsibilities within the organization, these should not conflict with food safety responsibilities.

The responsibility of the food safety team leader may include liaison with external parties on matters relating to the FSMS (e.g. chamber of commerce, consultant, inspection agencies, suppliers, customers).

It is recommended that the food safety team leader has extensive knowledge of hygiene, food safety management and application of the HACCP principles.

5.2 Resource management (Clause 6 of ISO 22000:2005)

5.2.1 Provision of resources (6.1, 6.3 and 6.4 of ISO 22000:2005)

The organization should ensure resources (such as equipment, facilities, materials, energy, knowledge, budget and personnel) are used effectively. A process, which provides, allocates, monitors, evaluates, optimizes and maintains those resources, should be in place.

The organization should periodically review the availability and suitability of the identified resources, including outsourced resources, and take action as necessary. The results of these reviews should also be used as inputs into the organization's reviews of its strategy, objectives and plans.

5.2.2 Training (6.2.2.1 and 6.2.2.2 of ISO 22000:2005)

Personnel are a most valuable and critical resource. It is necessary to ensure that their work environment encourages personal growth, learning, knowledge transfer and teamwork (see 5.2.1). The organization should ensure that the personnel understand the key elements of an FSMS (e.g. HACCP, PRP, management) and the importance of their contribution and roles in the FSMS.

Personnel involved in food safety (see 6.2.1 and 6.2.2 of ISO 22000:2005) need to be trained, training should be documented. In addition, organizations in the food chain should establish protocols that the training is effective and that the workers being trained demonstrate that they are competent (see Annex C).

5.3 Emergency preparedness (5.7 of ISO 22000:2005)

The organization should be aware of potential emergency situations, including but not limited to, natural disasters, environmental accidents, bioterrorism, or other incidents that can affect food safety and/or production.

Response is dependent on local or national regulatory expectations and may include communication about the crisis both within and outside the organization. This would include communication with relevant stakeholders such as media, customers, employees, law enforcement and governmental agencies (see 6.5).

An example of verification method is a mock/test exercise for emergencies that could be conducted to assess response and business continuity plans (see 5.11). Effective traceability and product withdrawal/recall procedure(s) is (are) essential (see 5.12).

NOTE ISO/TS 22002-1:2009, Clause 18 specifies details relating to food defence, biovigilance and bioterrorism.

5.4 Control of documents including records (4.2.2 and 4.2.3 of ISO 22000:2005)

Document control is a basic management programme to ensure that only approved, up-to-date documentation (see 6.6) is available and used throughout the organization. Inadvertent use of out-of-date documents can have significant negative consequences on food safety, costs and customer satisfaction.

The organization should implement a written procedure to establish a document control programme. The document control programme should include the following elements:

a) how documents are approved prior to issue;

b) how documents are amended, updated and re-approved, including disposal of outdated and obsolete documents;

c) how to identify the current revision status of, and changes to, documents (e.g. by date or issue number) and by highlighting changes made to the previous version;

d) how it is ensured that documents are available where needed (storage and accessibility policy);

e) how the distribution of documents is controlled. The site may maintain a master list of documents;

f) how documents of external origin, needed for the FSMS' planning, operation and assessing, are identified, controlled and distributed in accordance with list item e);

g) a records control procedure specifying which records are kept, how they are stored, retrieved, identified and destroyed.

Document/record control and document/record management programmes are intended to conform to applicable government regulations.

5.5 PRPs (7.2 of ISO 22000:2005)

Prerequisite programmes (PRPs) are basic programmes essential for maintaining a hygienic environment for production, processing and/or handling of product and are not implemented for the purpose of controlling specific identified hazards. ISO/TS 22002 (all parts)[6] provides guidance on the selection of PRPs applicable to different sectors/categories of the food chain. Other sources for selecting appropriate PRPs are listed in Annex C of ISO 22000. The organization should design the PRPs so that they are appropriate to the type of food, premise, facilities, process, location in the food chain, etc.

While PRPs and control measures are implemented and applied simultaneously in the organization, they should be developed sequentially. PRPs provide the environment for the safe production of products. This explains why the PRPs should be established and designed before proceeding to the hazard analysis. However, planning, implementation and updating of the PRPs and other parts of the FSMS may trigger the need for changes or improvements to the PRPs.

The implementation of PRPs should be verified.

5.6 Preliminary steps to enable hazard analysis (7.3 and 7.7 of ISO 22000:2005)

All relevant data and information needed to conduct a complete hazard analysis should be gathered and documented. This includes identifying and assessing hazard occurrence in the raw materials, ingredients, processing, storage/handling environments and in the end products. Operations should be assessed to identify areas for potential cross contamination. Products may be grouped into similar categories depending on ingredients, processes and/or hazards.

The food safety team should also describe the intended use of the end product and consumer categories. Where appropriate, part of this process is to determine the consumption mode and to determine whether or not instructions for the proper preparation or use of the product are included in the label or otherwise communicated.

When establishing shelf-life, the food safety team should investigate:

— the transportation and storage conditions;

— information of actual use of the product (e.g. how the end product is cooked before consumption or how the food is intended to be used by another organization in the food chain);

— reasonably expected handling and mishandling of the end product by the end-user (e.g. subsequent processing or handling by the consumer including at the consumer's home).

All relevant data and information that are part of the hazard analysis should be maintained and updated as needed.

5.7 Hazard analysis (7.4 of ISO 22000:2005)

5.7.1 General

The process of hazard analysis is illustrated in Figure 3.

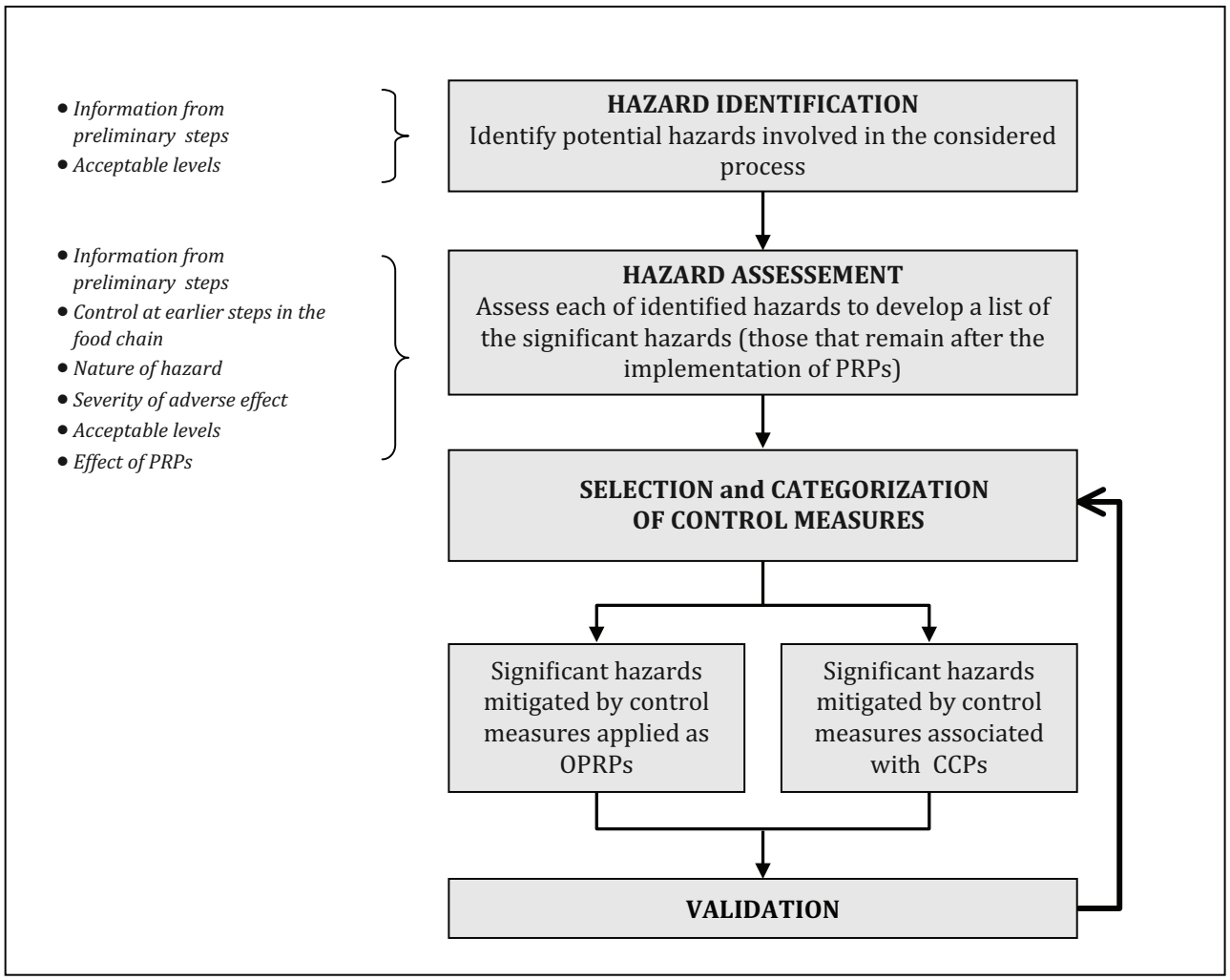


Figure 3 — Illustration of the hazard analysis process

5.7.2 Hazard identification and determination of acceptable levels (7.4.2 of ISO 22000:2005)

According to ISO 22000, for each significant hazard, the organization shall establish acceptance levels[1)] for the end product(s). Acceptance levels relate to the hazards in question. Determination of acceptance levels may be based on multiple sources such as:

a) criteria established by relevant statutory/regulatory authorities;

b) food safety specifications[2)] or other information provided by buyers, in particular for end products intended for further processing or use other than direct consumption;

c) in-house or external data collected by the food safety team related to specific hazards.

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1) The "acceptable level" means level of a hazard in the end product that shall not be exceeded in order to ensure food safety.

2) According to Codex Alimentarius, such specifications or levels can be expressed as Performance objectives.

5.7.3 Hazard assessment (7.4.3 of ISO 22000:2005)

The role of hazard assessment is to determine each of the hazards identified above in 5.7.2 in order to specify significant hazards. In conducting the hazard assessment, the following should be taken into consideration:

a) the source(s) of the hazard (e.g. where and how it can be introduced into the product and/or its environment);

b) the probability or likelihood of occurrence of the hazard (such as frequency of occurrence at the highest possible levels and/or statistical distribution of levels). Consideration should be given to steps preceding and following the specified operation within the same system, the process equipment, service activities and surroundings, as well as to the preceding and following links in the food chain. In addition, consideration should be given to areas of possible cross contamination;

c) the nature of the hazard (e.g. ability to multiply, deteriorate the food and/or produce toxins);

d) the severity of the adverse health effects which can be caused by the hazard, with consideration to vulnerable population;

e) the acceptable level in the end product taking into account measures taken at subsequent steps in the food chain (e.g. further processing, transportation, distribution and consumption).

The hazard analysis is performed to establish which hazards are significant and, therefore, subject to validated control measures. It may occur that identified hazards are not determined to be significant: for example, when an identified hazard is within acceptable levels without further intervention by the organization.

If the information required for conducting the hazard assessment is unavailable to the food safety team or organization, additional information can be obtained from scientific literature, databases, regulatory agencies, or industry experts.

A list of those hazards that have been identified as significant and need to be controlled by OPRPs or at CCPs should be established. Where no such hazards can be identified, the PRPs in place are effective and sufficient to achieve safe products.

5.7.4 Selection and assessment of control measures (7.4.4 of ISO 22000:2005)

An appropriate combination of control measures should be selected which are capable of preventing, eliminating or reducing to acceptable levels those food safety hazards identified as significant.

Guidance on categorizing control measures is provided in Table 1. See also the Note to 5.9.2.

5.8 Validation of control measures or combination of control measures (8.2 of ISO 22000:2005)

Validation is the obtaining of evidence, demonstrating that the control measures selected above in 5.7.4, managed by the HACCP plan and by the OPRPs are capable of controlling the identified hazards (see 6.1 and References [12] and [16]).

The validation process measures and/or assesses the control measures, or combination of control measures, to determine that they are capable of achieving the intended level of hazard control.

Validation is carried out after any hazard analysis, and prior to implementation of new control measures, or changes to existing control measures.

Typically, the validation consists of the following:

— definition of the decision making parameters and criteria that will demonstrate that the control measures, if properly implemented, are capable of consistently controlling the hazard to the specified outcome;

— collection of pertinent documentation needed to the validation;

— conduct of the validation studies;

— analysis of validation results;

— documentation of the validation study.

Different methods may be used to validate control measures. It is imperative that the most appropriate validation method be selected. If the expertise is not available within the organization, the use of external expertise will be needed (see also Clause 9). Validation studies should be conducted before the actual food process is operated for the first time. Validation methods include, but need not be limited to:

a) reference to scientific or technical literature;

b) previous validation studies, or historical knowledge of the performance of the control measure(s);

c) scientifically valid experimental data for example to demonstrate the adequacy of control measure(s);

d) collection of data during operation of the entire food production process;

e) mathematical modelling: predictive microbiology where appropriate, for example, to validate shelf-life (including reasonably foreseeable time/temperature variation) or to determine alternative time/temperature combinations for heat treatment or conditions for no heat treatment. Mathematical models should only be used if they have been validated using actual processing conditions and product characteristics (e.g. a_w, pH);

f) surveys, which should be developed by experts. Sample size and individual selection for the survey should be established in accordance with proven survey techniques.

If relying upon validations carried out by others, care should be taken to ensure that the conditions of the intended application are consistent with those identified in the referenced validations.

For some well-established processes (e.g. time and temperature combinations for milk pasteurization), it may be sufficient to gather only the data on the conditions or attributes specific to the operation in question.

Validation data should be reviewed following new scientific or statutory/regulatory information, a system failure, or any significant change to the processes or products. Changes to products or processes include changes in raw material or ingredients, in a process step, in organizational management, or changes implemented in response to a critical limit, or in the conditions of use by end-consumers, etc.

5.9 Establishing the HACCP plan (7.6 of ISO 22000:2005)

5.9.1 HACCP plan (7.6.1 of ISO 22000:2005)

The HACCP plan is a controlled document (see 6.6.2). Among its many parts are descriptions of how the control measures associated with CCPs are managed. ISO 22000 specifies the requirements for the content of the HACCP plan.

5.9.2 Identification of critical control points (7.6.2 of ISO 22000:2005)

A CCP is a step in the process at which control can be applied, essential to prevent or eliminate a food safety hazard, or reduce it to an acceptable level. Control measures associated with CCP will meet the following criteria:

— critical limits need to be established that differentiate an acceptable product from a potentially unacceptable product. Failure to meet critical limits will result in potentially unsafe product;

— critical limits can be monitored in a timely manner so that action(s) can be taken to ensure foods will meet acceptable levels of hazards in the end product.

NOTE In practice, control measures associated with CCPs are identified during the categorization of control measures (see Clause 4).

5.9.3 Determination of critical limits for critical control points (7.6.3 of ISO 22000:2005)

The critical limits have to be achievable as part of normal process operations and be validated as part of the validation described in 5.8.

For CCPs intended to control more than one hazard, the critical limit(s) should be determined relative to each hazard, and the most stringent limit applied.

5.9.4 System for the monitoring of critical control points (7.6.4 of ISO 22000:2005)

The control measures applied at CCPs are typically monitored through chemical or physical measurements such as pH, time, temperature etc. The results of monitoring should be recorded.

The frequency of monitoring is determined by the organization, to enable it to detect any loss of control within a specified time frame sufficient to control the affected product. Critical limits may be monitored continuously or intermittently.

5.9.5 Actions when monitoring results exceed critical limits (7.6.5 of ISO 22000:2005)

Exceeding critical limits means that the products are potentially unsafe. Both corrections and corrective actions should be planned, documented where possible, and applied when necessary (see 6.2 and 6.3).

5.10 Establishing the OPRPs (7.5 of ISO 22000:2005)

5.10.1 OPRP plan

ISO 22000 specifies the requirements establishing and managing OPRPs. This can be organized through an OPRP plan [see Note to item a) Clause 4].

5.10.2 Monitoring of OPRPs

To meet the requirements for monitoring of OPRPs, the organization should establish appropriate action limits or action criteria.

These limits should correspond to any operational parameters used in validation as described in 5.8. Where limits cannot be determined due to the nature of the measure, it is the actual application of the specific procedure that is to be monitored. Monitoring frequency should be established by the organization.

5.10.3 Actions when monitoring results exceed action limits or action criteria

When monitoring results exceed action limits or action criteria, corrective actions and, where appropriate, corrections should be planned and applied (see 6.2 and 6.3).

5.11 Verification planning (7.8 of ISO 22000:2005)

Verification is an assessment carried out during or after the operation. The role of verification is to demonstrate that the intended level of control has actually been achieved and that the food safety system is operating as designed (see 6.1).

Verification plans should identify the following:

— purpose (e.g. verifying the functionality of control measures, performance of the food safety control system, effectiveness of the traceability system or communication);

— scope of the verification (e.g. control of documents);

— verification method (e.g. internal audit, external audit, on-site inspection, sampling and testing, review of the results, trend analysis);

— frequency: the frequency of verification should be established based on evaluations of the FSMS by the food safety team;[3)]

— action to be taken if verification shows unsatisfactory results (e.g. hold, withdrawal/recall, training, review of monitoring procedures). If verification activities indicate that there is a potential food safety issue (hold, withdrawal/recall, training, etc.), corrections and/or corrective actions should be implemented;

— reporting requirements (e.g. where records are kept and who needs to be informed in case of unacceptable verification results).

When results of planned verification demonstrate nonconformity, it triggers review of those elements of the FSMS that were subjected to verification such as the hazard analysis, the HACCP plan, the OPRP plan and the PRPs, communication, traceability system, resources, as appropriate.

5.12 Traceability (7.9 of ISO 22000:2005)

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

NOTE 1 Guidelines on traceability are also provided by ISO 22005:2007.[8]

The following terms are associated with a traceability system:

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

NOTE 2 External traceability requirements do not include the final consumer.

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

NOTE 3 Transport or transfer steps are covered by internal traceability of the organization that has the ownership of the goods/units (e.g. products, materials, reagents).

— mock withdrawal/recall (a programme used to verify the functionality of the withdrawal/recall procedure using the traceability system). The verification may be extended to a mock trace test of other parts of the traceability system.

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

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

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3) The frequency of the measurement required is a function of the stability of the performance of the control measures (e.g. process variability). Where validation shows that the control measure is delivering a significantly more stringent control of the hazard than needed, the frequency of verification regarding the effectiveness of that control measure may be reduced.

Traceability records should be retained for a defined period, and readily available for system assessment to enable the identification and location of potentially unsafe products in the event of a product withdrawal/recall (see 6.4). Records should be in accordance with the organization's document control programme (see 5.4).

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

NOTE 4 Traceability is essential for conducting an effective withdrawal/recall (see 6.4).

The organization should establish a format for traceability information and its flow (electronic or paper) (see 6.6.3). This information may include:

a) identification of organizations involved;

b) identification of products;

c) identification of logistics units (e.g. batches/lots, pallets, containers, bulk).

6 Implementation

6.1 General (7.6.4, 7.8 and 8.2 of ISO 22000:2005)

The concepts of validation, monitoring and verification can be confused. In relation to control measures, these three concepts apply as follows:

— **Validation** (see 5.8 and References [12] and [16]) is defined as: obtaining evidence that the control measures managed by the HACCP plan and by the OPRPs plan are capable of being effective.

  Validation focuses on the collection and evaluation of scientific, technical and observational information, to determine whether a control measure is able to achieve its specified purpose in terms of hazard control. Validation is performed at the time a control measure combination is designed, or whenever changes are made to the implemented control measures. Validation is performed, whenever possible, before the full implementation of (a) control measure(s).

— **Monitoring** (see 6.2) is defined as: conducting a planned sequence of observations or measurements to assess whether control measures are operating as intended.

  Monitoring of control measures is the ongoing collection of information about how they are functioning. The information establishes that the measure is functioning as intended, i.e. within established limits or standards. Monitoring activities are typically focused on "real-time" measurements and on the performance of a specific control measure.

— **Verification** (see Clause 7) is defined as: confirmation, by the provision of objective evidence, that specified requirements have been fulfilled.

  Verification is an ongoing activity typically conducted during or after the operations, and is used to determine whether control measures have been implemented as intended. Verification occurs during or after operation of a control measure, through a variety of activities.

6.2 Monitoring (7.6.4 of ISO 22000:2005)

Monitoring is the process used to detect and record deviations and to ensure that critical/action limits are being achieved.

Monitoring should be conducted in real time, thus allowing the detection of any loss of control and the triggering of corrective actions and corrections, as necessary (see 6.3).

6.3 Corrections and corrective actions (7.10.1 and 7.10.2 of ISO 22000:2005)

The organization should have documented procedures for corrections and corrective actions.

Corrections aim at ensuring that potentially unsafe product remains under control of the organization and is not released to consumers. Corrections are carried out immediately as soon as a nonconformity is detected and include:

— identification and location of potentially unsafe products (e.g. batch/lot numbers);

— appropriate handling of potentially unsafe products (see 6.4).

Corrective actions aim at identifying and eliminating/reducing the cause(s) of nonconformities, preventing reoccurrence, and bringing the system back under control. Corrective actions are carried out on a short-term, as well as long-term basis.

A correction can be carried out in conjunction with a corrective action.

Appropriate corrections and corrective actions should be developed and planned whenever possible, ready to be used in the event of deviations from OPRPs or at CCPs. They should be documented.

Corrective actions may include language that instructs operators to take the appropriate actions to bring the process back under control. Examples of corrective actions are immediate repair of equipment, redesign of equipment, increase the stringency of the control measure, reinforcement of instructions, retraining.

If there are frequent reoccurrences of deviations at a CCP or from an OPRP, the organization should re-evaluate their processes and the HACCP plan.

Corrections and corrective actions should be approved by a responsible person(s) with adequate competencies and authority and designated by the organization.

6.4 Handling of potentially unsafe products (7.10.3 and 7.10.4 of ISO 22000:2005)

According to ISO 22000:2005, nonconforming products shall be identified and controlled to prevent potentially unsafe product from entering the marketplace.

Nonconforming products may be released should any of the following apply:

a) evidence other than the monitoring system demonstrating the control measures have been effective. This may include data from other control devices, systems or evaluations;

b) evidence showing that the combined effect of control measures for a particular product, comply with the intended result;

c) results of sampling and analysis, and/or other verification activities demonstrating that the affected product lot/batch complies with the identified acceptable levels for the food safety hazard in question.

Following evaluation, product deemed to be unsafe may be handled as follows:

— reworked to ensure the food safety hazard is eliminated or reduced to an acceptable level;

— used for other purposes if acceptable (e.g. animal feed, further processed food);

— destroyed.

If products are determined to be potentially unsafe after leaving the organization's control, the organization needs to identify the suspect product and initiate a withdrawal/recall (see 5.12).

In the event of a situation requiring the withdrawal/recall of potentially unsafe product, a traceability system (see 5.12) and adequate procedures should be in place.

These procedures may include:

a) notification to relevant parties, such as statutory/regulatory authorities, customers, and consumers; contact details should be updated and maintained;

b) the sequence of actions to be taken, need to be documented and available;

c) methods used in handling recovered product, and identifying lots/batches still in stock;

d) methods used in ensuring that external events such as withdrawals/recalls are documented;

e) methods used in ensuring that withdrawals/recalls are included in management reviews;

f) methods used in determining and documenting the effectiveness of the withdrawal/recall procedure.

6.5 Communication process (5.6 of ISO 22000:2005)

6.5.1 General

Communication ensures that there is proper transfer of information between stakeholders. Policies for effective communication should be developed, documented, implemented and maintained. Training of designated personnel in communication skills is an important aspect of any communication process.

ISO 22000 requires that systems for both external and internal communication be developed, documented, implemented and maintained as part of the FSMS.

Communication should include a feedback mechanism, a review cycle and provisions to proactively address changes in the organization's environment.

The organization's communication process should operate both vertically and horizontally, and should be tailored to the differing needs of its recipients. The communication process should address the issues of:

— ensuring effective two-way communication;

— enhancing trust and credibility;

— involving, where appropriate, relevant stakeholders in the process;

— adjusting or modifying the communication programme as needed based on system reviews.

6.5.2 External communication (5.6.1 of ISO 22000:2005)

External communication aims to exchange information, in order to ensure that any relevant hazard is controlled at a particular point in the food chain for example:

a) a food safety hazard(s) that may not, or cannot, be controlled by the organization and consequently need(s) to be controlled at other points, up or down within the food chain;

b) with suppliers, contractors and customers, as the basis for mutual acceptance of the level of food safety required (by the customer) and;

c) with statutory/regulatory authorities and other organizations.

External communication is used between the organization and an external organization to agree, by contract or other means, on the level of food safety required, and on the capability of meeting the agreed specifications.

Channels of communication with statutory/regulatory authorities and other organizations should be established. This provides a basis for determining levels of food safety acceptable to the public and for ensuring the reliability of the organization (see 5.7.2).

Care should be taken to take full advantage of any statutory/regulatory reporting, or early warning systems of noted or perceived hazards.

Labelling is, in its broadest sense, a tool for communication with customers/consumers.

6.5.3 Internal communication (5.6.2 of ISO 22000:2005)

The internal communication system of the organization should ensure that sufficient relevant information and data are available to all personnel involved in the various operations and procedures. The food safety team leader has a major role in the internal communication of food safety issues within the organization.

Any member of the organization observing an activity which may have an impact on food safety should know how to report the issue and to whom.

6.6 Documentation (4.2 of ISO 22000:2005)

6.6.1 General

ISO 22000 requires that the FSMS be documented (given in 4.1 of ISO 22000:2005) and that the organization establishes a document control programme (see 5.4).

A document is a paper or any other media providing information.

ISO 22000 refers to a documented procedure or statement.

Documentation should be a value-adding activity to the benefit of the organization.

Documentation consists of:

— documents used to document the FSMS, such as policy statements, PRP, HACCP plan, verification plan, communication plan, and traceability system;

— documents describing how to carry out an activity and/or intended input or outcome, such as procedures, work instructions and specifications;

— records providing evidence that an activity has been performed or results have been achieved.

6.6.2 Documents used to document the FSMS

The type and extent of system documentation vary from one organization to another. This is due to the size and complexity of the activity, the skills of personnel, OPRPs and HACCP plans.

All documents relevant for food safety, whether developed externally or in-house, should be a part of the FSMS.

NOTE Additional guidance on use of consultancy and externally developed generic guidelines is provided in Clause 9.

Documents include, but are not limited to, product specifications, HACCP plan, OPRPs and PRPs, and contracts for any outsourced processes (e.g. pest control, product testing). The documents used by the organization should be available when and where required and may be in any approved format (e.g. paper, electronic or picture).

All documents relevant for food safety should be accessible to the involved personnel.

Documentation required by the standard to document the FSMS includes:

a) food safety policy (given in 4.2.1 of ISO 22000:2005);

b) list of measurable food safety related objectives (given in 4.2.1 of ISO 22000:2005);

c) food safety requirements from statutory/regulatory authorities (given in 5.6.1 of ISO 22000:2005);

d) procedures and instructions related to the PRP(s) includes monitoring procedures, where applicable and verification plans (given in 7.2.3 of ISO 22000:2005);

e) competencies of the food safety team (given in 7.3.2 of ISO 22000:2005), e.g. curriculum vitae, training records or résumé;

f) description of raw materials, ingredients and product-contact materials (given in 7.3.3.1 of ISO 22000:2005);

g) description of the characteristics of end products (given in 7.3.3.2 of ISO 22000:2005) and intended use (given in 7.3.4 of ISO 22000:2005);

h) flow diagrams (given in 7.3.5.1 ISO 22000:2005);

i) description of control measures, process parameters and/or the rigorousness with which they are applied, or procedures that may influence food safety (given in 7.3.5.2 of ISO 22000:2005);

j) description of external requirements that may impact the choice and the rigorousness of the control measures (given in 7.3.5.2 of ISO 22000:2005);

k) OPRPs plan (given in 7.5 of ISO 22000:2005) and HACCP plan (given in 7.6.1 of ISO 22000:2005), including monitoring system (given in 7.6.4 of ISO 22000:2005) and corrective action (given in 7.6.5 of ISO 22000:2005);

l) verification plan (given in 7.8 of ISO 22000:2005);

m) rationale and supporting documentation for chosen critical limits (given in 7.6.3 of ISO 22000:2005).

Other documents that may be included (not specifically required by the standard):

— list of documents applicable for the FSMS (given in 4.1 of ISO 22000:2005);

— organizational charts;

— list of members of the food safety team (internal and external experts);

— layout of premises and buildings;

— job descriptions;

— contractual agreements and/or warranty statement from subcontractors;

— list of external reference documents consulted when establishing PRPs;

— composition, organization and contact details of the food safety team responsible for addressing possible emergency situations and potential accidents, should be documented and kept up to date.

6.6.3 Documents describing how to carry out a specified activity and/or intended input or outcome

6.6.3.1 Documented procedures

Well-written procedures describe the step-by-step sequence of activities that should be followed to correctly perform a task.

A procedure defines which process, task, work or activity to be carried out, how it should be done, by whom (the responsibility), and the resources required.

Documented procedures that are required by the International Standard:

a) procedure for the control of documents (given in 4.2.2 of ISO 22000:2005);

b) procedure for the control of records (given in 4.2.3 of ISO 22000:2005);

c) procedure for corrections (given in 7.10.1 of ISO 22000:2005);

d) procedure for corrective actions (given in 7.10.2 of ISO 22000:2005);

e) procedure for handling of potential unsafe products (given in 7.10.3 of ISO 22000:2005);

f) withdrawal/recall procedure (given in 7.10.4 of ISO 22000:2005);

g) an internal audit procedure (given in 8.4.1 of ISO 22000:2005).

Other procedures that may assist in documenting the system may include for example (given in 4.2.1 of ISO 22000:2005):

— procedures for identifying product/batch codes and traceability;

— procedures for internal and external communication, for example: a procedure ensuring the food safety team is informed of changes (e.g. raw materials, ingredients, services, products, procedures, equipment, cleaning and disinfection products, regulations), and a procedure for communication with customers/consumers in following up on customer and/or consumer complaints.

6.6.3.2 Instructions describe the step-by-step sequence of activities that should be followed to correctly perform a task

Instructions that are required by the standard are those needed to the carrying out and follow up on results of the monitoring of critical limits based on subjective data (such as visual inspection of product, process, handling, etc.).

Competencies can be ensured through education, training or by other appropriate means (given in 7.6.3 of ISO 22000:2005).

Examples of other instructions that may assist in documenting the system:

— protocol for saving computer data, where documentation is kept electronically;

— instructions required to implement and maintain PRPs;

— manufacturer's instructions for use of detergents and sanitizers;

— instructions for transport;

— instructions for staff hygiene.

6.6.3.3 Specifications

A specification is a documented technical requirement or characteristics that describe a material, product, supplier, process or a service. Specifications may include permissible variations and tolerances, which are required to achieve a defined level of acceptability.

Specifications that assist in documenting the system may include:

— specifications describing acceptable levels of relevant hazards for ingredients, including additives, processing aids;

— specifications describing the acceptable levels of hazards for end products (given in 7.4.2.3 of ISO 22000:2005);

— specifications for contracted/outsourced services;

— specifications for methods/conditions of production;

— specifications for physical parameters (e.g. a_w, pH);

— specifications for food contact material (e.g. packaging materials, equipment, tools);

— water quality requirements;

— compressed gas specifications.

6.6.4 Records

A critical activity for any organization is the retention of appropriate records for specified periods and under controlled conditions.

Records provide objective evidence that the FSMS is operating as designed. Records can, for example, be used to show that the operation has been carried out as intended, that verification is being performed, and that corrective actions are being carried out.

Among the factors which an organization should base its decision for how long to retain records, is the intended use of its products, expected shelf-life, statutory/regulatory requirements and when applicable, customer requirements.

Records may be in the form of: measured data, reports, minutes, notes, electronically recorded information, certificates, statements, etc.

Type of record(s) needed to demonstrate compliance with the requirements of the standard:

— information concerning food safety obtained through external communication (given in 5.6.1 of ISO 22000:2005);

— information of changes that may impact on food safety (given in 5.6.2 of ISO 22000:2005);

— input to, and output of, management reviews (given in 5.8 of ISO 22000:2005);

— agreements or contracts defining the responsibility and authority of external experts or contractors assisting the food safety team or working to support the FSMS (given in 6.2.1 of ISO 22000:2005);

— training or other actions to ensure personnel competencies (given in 6.2.2 of ISO 22000:2005), (e.g. training plan/request forms for training);

— changes to PRPs (given in 7.2.3 of ISO 22000:2005);

— flow diagrams (given in 7.3.5.1 of ISO 22000:2005);

— food safety hazards that have been identified as reasonably expected to occur (given in 7.4.2.1 of ISO 22000:2005);

— justification for, and the result of the determination, regarding the acceptable level of a food safety hazard in the end product (given in 7.4.2.3 of ISO 22000:2005);

— the methodology used to assess which of the hazards need to be controlled, and the results of the food safety hazard assessment (given in 7.4.3 of ISO 22000:2005);

— the methodology parameters used and results for the categorization of control measures (given in 7.4.4 of ISO 22000:2005);

— monitoring records for OPRPs and CCPs (given in 7.5 and 7.6.1 of ISO 22000:2005);

— results of verification (given in 7.8 of ISO 22000:2005);

— traceability records (given in 7.9 of ISO 22000:2005) (e.g. production sheet, delivery code, packing record, batch code, invoice);

— results of evaluation of potentially unsafe products and of corrections (given in 7.10.1 of ISO 22000:2005);

— corrective actions taken (given in 7.10.2 of ISO 22000:2005);

— the cause, extent and result of a withdrawal/recall (given in 7.10.4 of ISO 22000:2005);

— results of verification regarding the effectiveness of the withdrawal/recall programme (given in 7.10.4 of ISO 22000:2005);

— results of calibration and verification of measuring equipment (given in 8.3 of ISO 22000:2005);

— results of assessment regarding nonconforming measuring equipment, including actions on affected product (given in 8.3 of ISO 22000:2005);

— system updating activities (given in 8.5.2 of ISO 22000:2005).

Other records that may assist in documenting the system:

a) implementation schedule of planned activities;

b) communication plan;

c) results of validation, and the method used (see Clause 5);

d) results of verification for outsourced or subcontracted activities (e.g. validation studies, audits and certification activities and/or subcontracted activities);

e) records of each withdrawal/recall event (including cause, extent and success of withdrawal/recall).

7 Verification

7.1 General (7.8 and 8.4 of ISO 22000:2005)

Verification activities should be planned prior to implementation of the process (see 5.11).

The objective of verification is to confirm that planned activities are implemented and operating as intended. The entire food safety management system should be subjected to verification. This is carried out by using various methods and techniques depending on the activity subjected to verification.

Verification is carried out at different levels and through different activities. It may include, for example:

— a simple review and evaluation of the records and documents, such as reviewing CCP and/or OPRP records (trend analysis, number of deviations, corrective actions, etc.);

— conducting measurements and evaluation activities to ensure that a PRP or a process has operated within defined parameters, such as collecting environmental microbial swabs to ensure that the cleaning and disinfection programme is compliant with internal specifications;

— evaluating whether other components of the FSMS has operated as planned, such as determining if training programmes produce the expected improvements in employee behaviours, calibration of measurement equipment essential for food safety.

— carrying out internal and external audits;

— conducting on-site inspections;

— ensuring that all indicators, such as analytical results, conclusions of internal and external audits, and customer complaints are evaluated to assess whether the system is operating as designed or whether there is a need to implement change;

— demonstrating the accomplishment of a particular step by evaluating verification results and audit reports, etc.;

— carrying out end product testing to verify the performance of the system or part thereof (see Reference [15]).

The main sources that provide the information to confirm the fulfilment of requirements are:

a) the internal audit: this will provide information to confirm that requirements in procedures or instructions are being met;

b) the results of sampling and analysis: these can provide confirmation that the PRPs and the combination of control measures applied up to the point of sampling were performing as intended.

Verification activities should be performed by personnel with the required competences. Initial verification should be performed after the first production run. Whenever resources permit, verification activities should be conducted by individuals not directly involved in the activities.

7.2 Verification of specifications for incoming materials and contracted services (7.8 of ISO 22000:2005)

The organization should establish specifications for incoming materials and contracted services. Compliance with these specifications should also be subject to verification, especially where compliance with specific hazard levels in ingredients or raw materials are essential towards ensuring food safety.

The methodology applied and the frequency of verification depends on the hazard analysis conducted on the materials including consideration of hazard occurrence and the level of confidence in the individual supplier.

Examples of methods include: a supplier may be required to send results of analysis of materials delivered; a food business operator can also do its own testing; another way to verify the performance of a supplier/contractor is to do a supplier/contractor audit by either second-party or third-party.

NOTE ISO/TS 22002-1:2009, Clause 9, specifies details relating to the management of purchased materials.

7.3 System verification (8.4 of ISO 22000:2005)

Verification of the FSMS should demonstrate that it is functioning as designed, and is being updated based upon currently available information. Verification occurs in two stages that may be loosely classified as, ongoing, and periodic.

Ongoing activities use methods, procedures or tests separate from, and in addition to, those used in monitoring of the system. Verification reports should include information about:

— the effectiveness of the FSMS;

— the persons administering and updating it;

— the records associated with monitoring activities;

— the calibration of monitoring equipment;

— the results of records reviewed and any samples analysed.

Training records of the personnel should be reviewed and the results should be documented.

When conducting internal audits (given in 8.4.1 of ISO 22000:2005), sound audit principles should be observed. Auditors performing the audit should be competent and those competencies should be documented. They should be independent of the work or processes being audited, although they may be from the same work area or department.

In a small business with only one or two people in the management structure, this requirement might not be achievable. In such cases, when carrying out the duties of an auditor, the manager needs to step back from direct involvement in the business operations and to be very objective about the audit. An

alternative approach would be to seek the cooperation of another small business and each one provides the internal audit for the other.

This could prove attractive if there are good relations between the two businesses. Alternatively, external parties might be able to provide independent auditors.

The periodic verification activities (e.g. at least, every 12 months) involve the overall assessment of the system. This is usually performed during a management review meeting, and all the above evidence over a period of time is reviewed to ascertain if the system is functioning as planned and if updating or improvement is necessary. Notes of the meeting should be kept and should include any decisions made regarding the system.

8 Improvement

8.1 Management review (5.8 of ISO 22000:2005)

The objective of management review is to assess whether the FSMS has been operating in an effective manner, and if the objectives of the food safety policy have been met.

The results of FSMS verification (see Clause 7) have to be reported to the top management (see 8.4.3 of ISO 22000:2005). Using this information, top management provides direction on how to improve the FSMS, and determines if the food safety policy and food safety objectives need revision.

8.2 Improvement and updating (8.5 of ISO 22000:2005)

8.2.1 General

ISO 22000 mandates that organizations seek to continually improve the FSMS.

Improvement and updating can be applied to:

— the organization's ability to deliver safe products on a continuous basis;

— processes and their interfaces;

— management commitment to implement a food safety culture within the organization;

— personnel commitment to apply the food safety culture;

— infrastructure, work environment and technology;

— relations with relevant interested parties.

For an organization to make informed judgments on the basis of data analyses and the implementation of lessons learned, personnel need to be trained to not only review and analyse data/information, but also to develop adequate plans for improvement.

8.2.2 Continual improvement (8.5.1 of ISO 22000:2005)

Improvement activities for the FSMS can range from small-step continual improvements at a work place to significant improvements of the entire organization. Continual improvement is one of the main outcomes of the organization's management review.

The organization should define objectives for the improvement of processes, organizational structures, and its management system, through the analysis of data in order to become better at delivering the intended outcome.

The organization should ensure that continual improvement becomes established as part of the organization's food safety culture. This can be achieved for example by:

— providing opportunities for personnel in the organization to participate in improvement activities,

— providing the necessary resources;

— establishing recognition and reward systems for improvement;

— ensuring continual improvement regarding the effectiveness and efficiency of the improvement process itself.

The organization may encourage updating and improvement through learning (see Annex B).

8.2.3 Updating the FSMS (7.7. and 8.5.2 of ISO 22000:2005)

The food safety team plays a key role in the updating of the FSMS; the food safety team leader and top management have the primarily responsibility for it. However, involvement by personnel from all levels of the organization is essential for improving and updating the FSMS.

Updates may be initiated based on several sources of information, such as:

— internal and external communication (given in 5.6 of ISO 22000:2005);

— results of measurement of efficiency and effectiveness of the FSMS;
For example: trend analysis, number of nonconformities, customers complains, observations from daily operations.

— analysis of results of verification activities;

For example: audit (internal/external), specified needs for updating such as HACCP plan, OPRP plan, PRPs.

— management review;

For example: needs for resources, changes to food safety policy and related objectives.

9 Use of consultancy and externally developed generic guidelines (Clause 1 and 4.1 of ISO 22000:2005)

The planning, implementation, maintenance and improvement of the FSMS are site specific and the responsibility of the organization.

However, the organizations may seek assistance externally. This assistance can be referred from generic guidelines or models established externally. The assistance can also be provided by external individuals or organizations acting as consultants.

Generic guidelines on PRPs can be implemented to the extent that they are suitable and appropriate to the organization in accordance with 7.2 of ISO 22000:2005.

Generic guidelines on other parts of the FSMS can be implemented on specific conditions provided they are:

— suitable and appropriate to the organization, its processes and products;

— adjusted to be site specific;

— in accordance with the requirements of ISO 22000:2005.

NOTE The term "generic" means applicable to more than one site.

Annex A
(informative)

Correspondence between this International Standard (ISO 22004) and related documents

Table A.1 — Correspondence between ISO 22000:2005 and (sub)clauses of this International Standard (ISO 22004) (1 of 4)

ISO 22000:2005			ISO 22004 **(this International Standard)**
Introduction		**0**	**Introduction**
Scope	**1**	**1**	**Scope**
Normative references	**2**	**2**	**Normative references**
Terms and definitions	**3**	**3**	**Terms and definitions**
		4	**General**
Food safety management system	**4**		
General requirements	4.1	9	Use of consultancy and externally developed generic guidelines
Documentation requirements	4.2	6.6	Documentation
General	4.2.1	6.6.1 6.6.2 6.6.3 6.6.4	General Documents used to document the FSMS Documents describing how to carry out a specified activity and/or intended input or outcome Records
Control of documents	4.2.2	5.4	Control of documents including records
Control of records	4.2.3	5.4	Control of documents including records
		5	**Planning**
Management responsibility	**5**	5	Management responsibility
Management commitment	5.1	5.1.1	Management commitment
Food safety policy	5.2	5.1.2	Food safety policy
Food safety management system planning	5.3	5	Planning
Responsibility and authority	5.4	5.1.1 6.5.2	Management commitment Internal communication
Food safety team leader	5.5	5.1.3	Food safety team leader

(*to be continued*)

Table A.1 — Correspondence between ISO 22000:2005 and (sub)clauses of this International Standard (ISO 22004) (2 of 4)

ISO 22000:2005			ISO 22004 **(this International Standard)**
Management responsibility (*end*)	**5**	5	Management responsibility
Communication	5.6	6.5	Communication process
External communication	5.6.1	6.5.2	External communication
Internal communication	5.6.2	6.5.1	Internal communication
Emergency preparedness and response	5.7	5.3	Emergency preparedness
Management review	5.8	8.1	Management review
General	5.8.1	5.1.2	Food safety policy
Review input	5.8.2	8.1	Management review
Review output	5.8.3	8.1	Management review
		6	**Implementation**
Resource management	**6**	5.2	Resource management
Provision of resources	6.1	5.2.1	Provision of resource
Human resources	6.2	5.2.1 5.2.2	Provision of resource Training
General	6.2.1		*(no specific guidance is provided)*
Competence, awareness and training	6.2.2	5.2.2	Training
Infrastructure	6.3	5.2.1	Provision of resource
Work environment	6.4	5.2.1	Provision of resource
Planning and realization of safe products	**7**	5 6 7	Planning Implementation Verification
General	7.1	4	General
Prerequisite programmes (PRPs)	7.2	4 5.5	General PRPs
Preliminary steps to enable hazard analysis	7.3	5.6	Preliminary steps to enable hazard analysis
General	7.3.1	5.6	Preliminary steps to enable hazard analysis
Food safety team	7.3.2	5.6	Preliminary steps to enable hazard analysis
Product characteristics	7.3.3	5.6	Preliminary steps to enable hazard analysis
Intended use	7.3.4	5.6	Preliminary steps to enable hazard analysis
Flow diagrams, process steps and control measures	7.3.5	5.6	Preliminary steps to enable hazard analysis
Hazard analysis	7.4	5.7	Hazard analysis

(*to be continued*)

Table A.1 — Correspondence between ISO 22000:2005 and (sub)clauses of this International Standard (ISO 22004) (3 of 4)

ISO 22000:2005			ISO 22004 **(this International Standard)**
Planning and realization of safe products (*end*)	**7**	5	Planning
		6	Implementation
		7	Verification
General	7.4.1	5.7	Hazard analysis
Hazard identification and determination of acceptable levels	7.4.2	5.7.2	Hazard identification and determination of acceptable levels
Hazard assessment	7.4.3	5.7.3	Hazard assessment
Selection and assessment of control measures	7.4.4	5.7.4	Selection and assessment of control measures
Establishing the operational prerequisite programmes (PRPs)	7.5	5.10	Establishing the OPRPs
		5.10.1	OPRP plan
		5.10.2	Monitoring of OPRP
		5.10.3	Actions when monitoring results exceed action limit or action criteria
Establishing the HACCP plan	7.6	5.9	Establishing the HACCP plan
HACCP plan	7.6.1	5.9.1	HACCP plan
Identification of critical control points (CCPs)	7.6.2	5.9.2	Identification of critical control points
Determination of critical limits for critical control points	7.6.3	5.9.3	Determination of critical limits for critical control points
System for the monitoring of critical control points	7.6.4	5.9.4	System for the monitoring of critical control points
		6.1	General
		6.2	Monitoring
Actions when monitoring results exceed critical limits	7.6.5	5.9.5	Actions when monitoring results exceed critical limits
Updating of preliminary information and documents specifying the PRPs and the HACCP plan	7.7	5.6	Preliminary steps to enable hazard analysis
		8.2.3	Updating of the FSMS
Verification planning	7.8	5.11	Verification planning
		6.1	General
		6.2	General
		7.2	Verification of specifications for incoming materials and contracted services
Traceability system	7.9	5.12	Traceability
Control of nonconformity	7.10	6.3	Corrections and correctives actions
		6.4	Handling of potentially unsafe products
Corrections	7.10.1	6.3	Corrections and correctives actions
Corrective actions	7.10.2	6.3	Corrections and correctives actions
Handling of potentially unsafe products	7.10.3	6.4	Handling of potentially unsafe products
Withdrawals	7.10.4	6.4	Handling of potentially unsafe products

(*to be continued*)

Table A.1 — Correspondence between ISO 22000:2005 and (sub)clauses of this International Standard (ISO 22004) (4 of 4)

ISO 22000:2005			ISO 22004 **(this International Standard)**
Validation, verification and improvement of the food safety management system	**8**	**7** **8**	**Verification** **Improvement**
General	8.1		*(no specific guidance is provided)*
Validation of control measure combinations	8.2	5.8 6.1	Validation of control measures or combination of control measures General
Control of monitoring and measuring	8.3		*(no specific guidance is provided)*
Food safety management system verification	8.4	7.1 7.2 7.3	General Verification of specifications of incoming materials and contracted services System verification
Internal audit	8.4.1	7.3	System verification
Evaluation of individual verification results	8.4.2	7.3	System verification
Analysis of results of verification activities	8.4.3	7.3	System verification
Improvement	8.5	8.2 8.2.1	Improvement and updating General
Continual improvement	8.5.1	8.2.2	Continual improvement
Updating the food safety management system	8.5.2	8.2.3	Updating the FSMS

Table A.2 — Correspondence between this International Standard and related documents following typical sequence for the implementation of ISO 22000:2005 (1 of 3)

	Operations	ISO 22004 **(this International Standard)**	ISO 22000:2005	**Codex Alimentarius** [12][13][14]a	**ISO Handbook (How to use** ISO 22000?)[11]
Management commitment and internal organization					
	Determine food safety policy and a set of objectives, and draw up plans for a management system	5.1.1, 5.1.2	5.1, 5.2 and 5.3	HACCP Introduction	1.1
	Define and communicate the responsibilities and authorities for personnel who have an impact of the safety of foodstuffs	5.2, 6.5.2	5.4		1.2
	Appoint the Food Safety Team leader	5.1.3	5.5	HACCP Step 1	1.2
	Manage staff skills / competencies	5.2	6.2.1 and 6.2.2	HACCP Introduction	1.3
	Provide resources to implement, maintain and improve the FSMS (beyond personnel)	5.2	6.1, 6.3 and 6.4 links to PRPs (7.2)		1.4
	Define the scope of the FSMS and control / manage the outsourced activities		4.1		1.5
	Establish and maintain internal and external communications	6.5.2 and 6.5.3	5.6.1 and 5.6.2		1.6
	Manage the documentation of the FSMS	6.6 and 5.4	4.2	Section 5.7	1.7
	Plan what to do in case of emergency situations and potential accidents	5.3	5.7	Section 5.8	1.8
Establishment of the PRPs					
	Identify the PRPs needed by the organization	5.5	7.2	HACCP Introduction	2.1
	Review of the PRPs in place in the organization (applicable for existing organization)	5.5	7.2	HACCP Introduction	2.2
	Develop action plan (implementation)	5.5	7.2		2.3
	Verify that established PRPs are effectively applied	5.11	7.8 a)	HACCP Introduction	2.4
	Develop arrangements for product traceability	5.12	7.9	Sections 5.7 and 5.8	2.5
Planning of hazard control					
	Appoint the Food Safety Team leader	5.1.3	5.5	HACCP Step 1	3.1
	Establish the Food Safety Team	5.2 and 5.6	6.2.1 and 7.3.2	HACCP Step 1	3.1

(*to be continued*)

Table A.2 — Correspondence between this International Standard and related documents following typical sequence for the implementation of ISO 22000:2005 (2 of 3)

	Operations	ISO 22004 **(this International Standard)**	ISO 22000:2005	**Codex Alimentarius** [12][13][14]a	**ISO Handbook (How to use** ISO 22000?**)**[11]
Planning of hazard control (*continued*)					
	Provide information needed to conduct the hazard analysis on the product and its intended use	5.6	7.3.3	HACCP Step 2	3.2
	Provide information needed to conduct the hazard analysis on its intended use	5.6	7.3.4	HACCP Step 3	3.2
	Draw the process flow diagram	5.6	7.3.5.1	HACCP Step 4	3.3
	Describe the process steps and control measures	5.6	7.3.5.2	HACCP Step 4	3.3
	Identify the hazards associated with the food	5.7.2	7.4.2.1	HACCP Principle 1/ Step 6	3.4
	Determine acceptable levels of identified hazards in the end product	5.7.2	7.4.2.2	HACCP Principle 1/ Step 6	3.4
	Conduct hazards assessment	5.7.3	7.4.3	HACCP Principle 1/ Step 6	3.5
	Select and assess the control measure or combinations thereof	5.7.4	7.4.4	HACCP Principle 1/ Step 6	3.6
	Validate the control measures or combinations thereof	5.8	8.2		3.7
	Categorize the control measures into CCPs and operational PRPs	5.7.4 and 5.9.2	7.4.4 and 7.6.2	HACCP Principle 2/ Step 7	
	Establish the critical limits for CCPs and monitoring procedures	5.9.3	7.6.3	HACCP Principle 3/ Step 8	
	Establish the action limits for the operational PRPs	5.10	7.5		
	Establish the monitoring procedures for CCPs	5.9.4	7.6.4	HACCP Principle 4/ Step 9	
	Establish the monitoring procedures for the operational PRPs	5.10	7.5		

(*to be continued*)

Table A.2 — Correspondence between this International Standard and related documents following typical sequence for the implementation of ISO 22000:2005 (3 of 3)

	Operations	ISO 22004 **(this International Standard)**	ISO 22000:2005	**Codex Alimentarius** [12][13][14][a]	**ISO Handbook (How to use** ISO 22000?**)**[11]
Planning of hazard control (*end*)					
	Establish corrections and corrective actions for CCPs and OPRPs	5.10, 5.9.5 and 6.3	7.5, 7.6.5, 7.10.1 and 7.10.2	HACCP Principle 5/ Step 10	3.9
	Update the preliminary information	5.6	7.7		3.10
	Establish verification procedures	5.11	7.8	HACCP Principle 6/ Step 6	
	Establish a traceability system	5.12	7.9		
	Establish procedures for handling of potentially unsafe product	6.4	7.10.3	Section 5.8	
	Establish withdrawal/recall procedures	6.4	7.10.4	Section 5.8	1.9
Implementation and operation of the FSMS					
	Manage, monitor and document the control measures	5.10 and 5.9	7.5 and 7.6	HACCP Principle 7/ Step 12	3.8
	Apply corrections and corrective actions, including handling of potentially unsafe product and withdrawal, as required	6.3 And 6.4	7.10	HACCP Principle 5 / Step 10 and Section 5.8	3.9
	Verify the FSMS	5.11 and 7.3	7.8 and 8.4	HACCP Principle 6/ Step 6	4.11
	Test procedures for the withdrawal/ recall of products	6.4	7.10.4		1.9
	Conduct internal audit of the functioning of the organization and the activities having an impact on food safety	5.11 and 7.3	7.8 and 8.4.1		4.2
	Verify and analyse of the results obtained	5.11 and 7.3	7.8, 8.3, 8.4.2 and 8.4.3	HACCP Principle 6/ Step 6	4.3
	Evaluate the overall evaluation of the results of the organization with decisions made to improve the FSMS: management review	8.1 and 8.2.2	5.8 and 8.5.2		4.4

[a] When sections are indicated, they refer to CAC/RCP 1-1969 (main text); HACCP Principles and Steps make reference to the Annex to CAC/RCP 1-1969 "Hazard Analysis and Critical Control Point (HACCP) Systems and Guidelines for its Application".

Annex B
(informative)

Improvement through learning

For the organization to attain sustained success of the FSMS, it is necessary to adopt "learning as an organization" and "learning that integrates the capabilities of individuals with those of the organization". "Learning as an organization" involves consideration of:

— collecting information from various internal and external events and sources concerning the FSMS, including success stories and failures;

— gaining insight through in-depth analyses of the information collected.

"Learning that integrates the capabilities of individuals with those of the organization" is achieved by combining the knowledge, thinking and behaviour patterns of employees with the organization's values. This involves consideration of:

— the organization's values, based on its mission, vision and strategies;

— supporting initiative in learning, and demonstrating leadership through the behaviour of top management;

— stimulation of networking, connectivity, interactivity and sharing of knowledge both inside and outside of the organization;

— maintaining systems for learning and sharing of knowledge;

— recognizing, supporting and rewarding the improvement of personnel's competence, through processes for learning and sharing of knowledge;

— appreciation of creativity, supporting diversity of the opinions of different personnel in the organization.

Rapid access to, and use of, such knowledge can enhance the organization's ability to manage and maintain its sustained success.

Annex C
(informative)

Involvement and motivation through training

To enhance the involvement and motivation of its personnel, the organization should consider activities such as developing a process to share knowledge and use the competence of personnel, e.g. a scheme for collecting ideas for improvement:

— introducing an appropriate recognition and reward system, based on individual evaluations regarding the accomplishments of the personnel;

— establishing a skills qualification system and career planning, to promote personal development;

— continually reviewing the level of satisfaction and needs and expectations of personnel, and

— providing opportunities for mentoring and coaching.

In order to ensure that it has the necessary competences, the organization should establish and maintain a "personnel development plan" and associated processes; these should assist the organization in identifying, developing and improving the competence of its personnel and provide opportunities for learning for their own benefit, as well as for maintaining the vitality of the organization, and establish and maintain processes for updating and improvement:

— identifying the professional and personal competences that the organization may need in the short and long term, in accordance with its food safety mission, vision, strategy, policy, and objectives;

— identifying the competences currently available in the organization and the gaps between what is available and what is currently needed and could be needed in the future;

— implementing actions to improve and/or acquire competences to close the gaps;

— reviewing and evaluating the effectiveness of actions taken to ensure that the necessary competences have been acquired, and maintaining competences that have been acquired.

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