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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

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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

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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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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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]

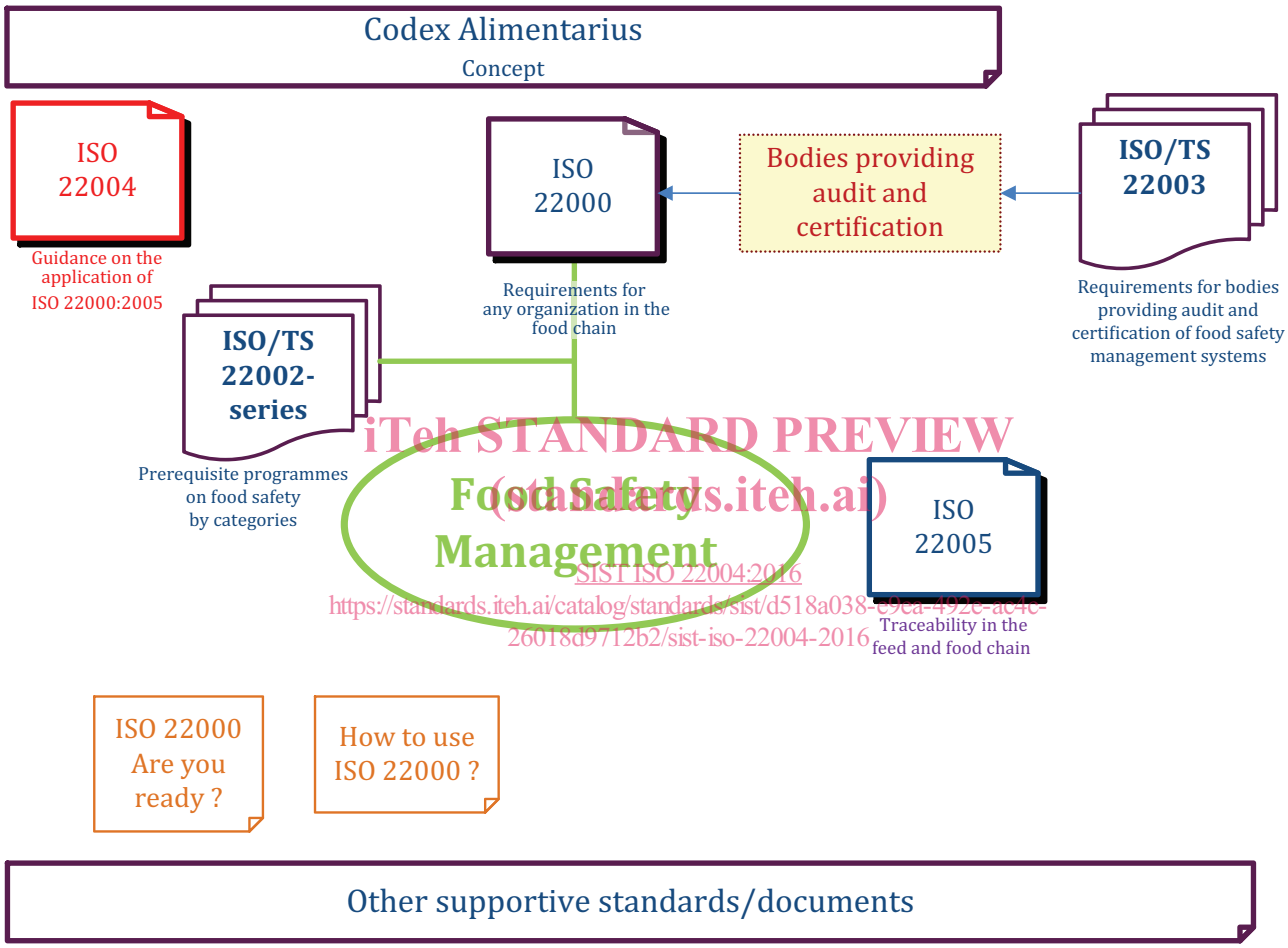


Figure 1 — Overview of ISO 22000-related documents

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.

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:

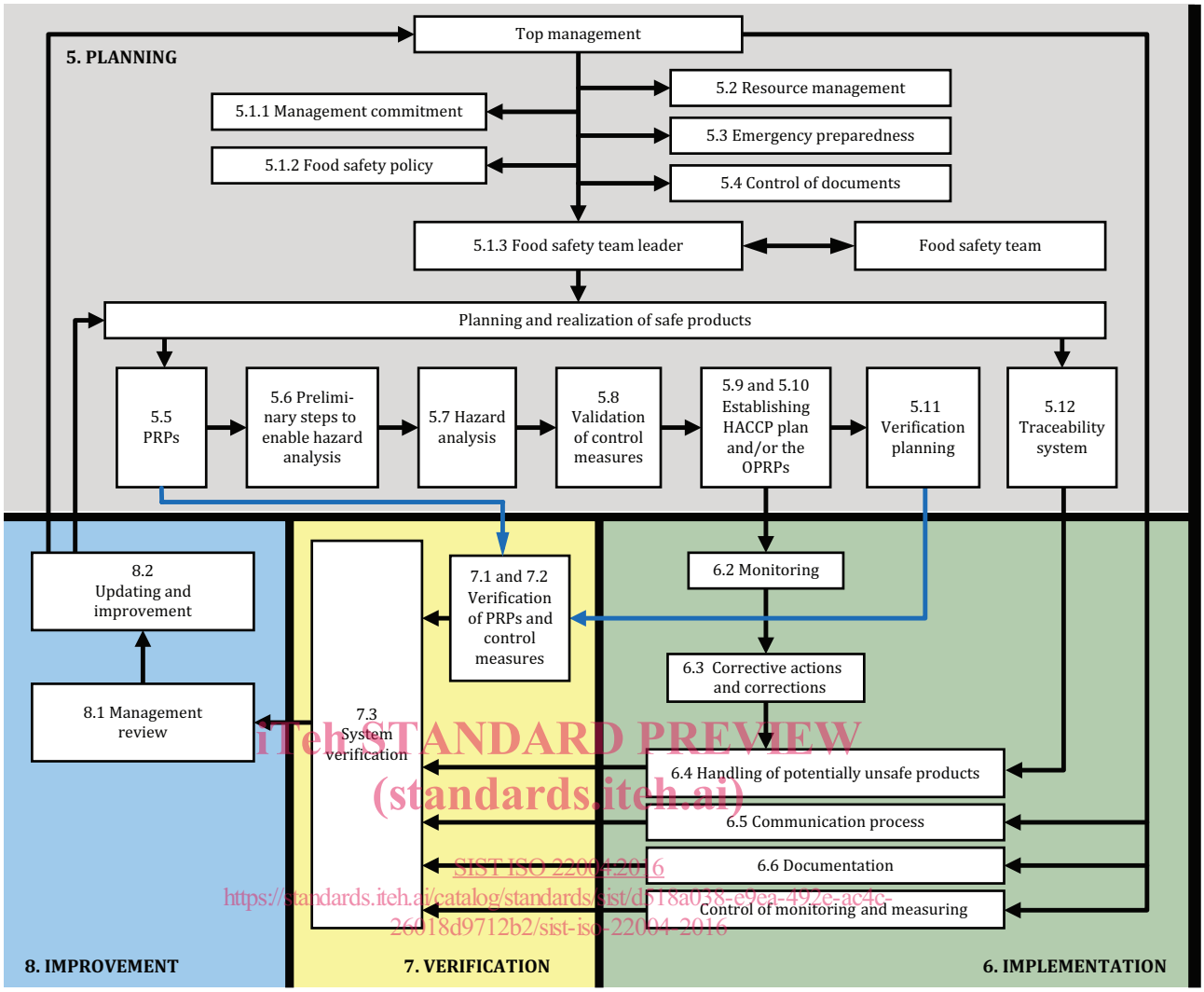
a) planning (Plan) of the steps; from the establishment of the PRPs, hazard analysis and critical control point (HACCP) plan and/or by similar means for OPRP such as an OPRP plan (see Note below), through conducting hazard analysis and validating the selected control measures, to establishing verification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