

Second edition
2018-06

**Food safety management systems —
Requirements for any organization in
the food chain**

*Systèmes de management de la sécurité des denrées alimentaires —
Exigences pour tout organisme appartenant à la chaîne alimentaire*

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[ISO 22000:2018](#)

<https://standards.iteh.ai/catalog/standards/sist/c869a6a0-53ad-4736-81d8-3b1e9b2d81be/iso-22000-2018>



Reference number
ISO 22000:2018(E)

© ISO 2018

iTeh STANDARD PREVIEW (standards.iteh.ai)

[ISO 22000:2018](#)

<https://standards.iteh.ai/catalog/standards/sist/c869a6a0-53ad-4736-81d8-3b1e9b2d81be/iso-22000-2018>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2018

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

	Page
Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Context of the organization	9
4.1 Understanding the organization and its context	9
4.2 Understanding the needs and expectations of interested parties	9
4.3 Determining the scope of the food safety management system	9
4.4 Food safety management system	10
5 Leadership	10
5.1 Leadership and commitment	10
5.2 Policy	10
5.2.1 Establishing the food safety policy	10
5.2.2 Communicating the food safety policy	10
5.3 Organizational roles, responsibilities and authorities	11
6 Planning	11
6.1 Actions to address risks and opportunities	11
6.2 Objectives of the food safety management system and planning to achieve them	12
6.3 Planning of changes	12
7 Support	13
7.1 Resources	13
7.1.1 General	13
7.1.2 People	13
7.1.3 Infrastructure	13
7.1.4 Work environment	13
7.1.5 Externally developed elements of the food safety management system	14
7.1.6 Control of externally provided processes, products or services	14
7.2 Competence	14
7.3 Awareness	14
7.4 Communication	15
7.4.1 General	15
7.4.2 External communication	15
7.4.3 Internal communication	15
7.5 Documented information	16
7.5.1 General	16
7.5.2 Creating and updating	16
7.5.3 Control of documented information	17
8 Operation	17
8.1 Operational planning and control	17
8.2 Prerequisite programmes (PRPs)	17
8.3 Traceability system	18
8.4 Emergency preparedness and response	19
8.4.1 General	19
8.4.2 Handling of emergencies and incidents	19
8.5 Hazard control	19
8.5.1 Preliminary steps to enable hazard analysis	19
8.5.2 Hazard analysis	21
8.5.3 Validation of control measure(s) and combinations of control measures	23
8.5.4 Hazard control plan (HACCP/OPRP plan)	24
8.6 Updating the information specifying the PRPs and the hazard control plan	25

8.7	Control of monitoring and measuring	25
8.8	Verification related to PRPs and the hazard control plan	26
8.8.1	Verification	26
8.8.2	Analysis of results of verification activities	26
8.9	Control of product and process nonconformities	27
8.9.1	General	27
8.9.2	Corrections	27
8.9.3	Corrective actions	27
8.9.4	Handling of potentially unsafe products	28
8.9.5	Withdrawal/recall	29
9	Performance evaluation	29
9.1	Monitoring, measurement, analysis and evaluation	29
9.1.1	General	29
9.1.2	Analysis and evaluation	29
9.2	Internal audit	30
9.3	Management review	31
9.3.1	General	31
9.3.2	Management review input	31
9.3.3	Management review output	31
10	Improvement	32
10.1	Nonconformity and corrective action	32
10.2	Continual improvement	32
10.3	Update of the food safety management system	32
Annex A (informative) Cross references between the CODEX HACCP and this document		33
Annex B (informative) Cross references (standards.iteh.ai) ISO 22000:2005		34
Bibliography		37

ISO 22000:2018

<https://standards.iteh.ai/catalog/standards/sist/c869a6a0-53ad-4736-81d8-3b1e9b2d81be/iso-22000-2018>

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 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.
ITEH STANDARD REVIEW
(standards.iteh.ai)

This document was prepared by Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 17, *Management systems for food safety*.

<https://standards.iteh.ai/catalog/standards/sist/c869a6a0-53ad-4736-81d8-0121101111002018>

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

This second edition cancels and replaces the first edition (ISO 22000:2005), which has been technically revised through the adoption of a revised clause sequence. It also incorporates the Technical Corrigendum ISO 22000:2005/Cor.1:2006.

The following annexes are included to provide the users of this document with further information:

- [Annex A](#): cross references between the CODEX HACCP principles and this document;
- [Annex B](#): cross reference between this document and ISO 22000:2005.

Introduction

0.1 General

The adoption of a food safety management system (FSMS) is a strategic decision for an organization that can help to improve its overall performance in food safety. The potential benefits to an organization of implementing a FSMS based on this document are:

- a) the ability to consistently provide safe foods and products and services that meet customer and applicable statutory and regulatory requirements;
- b) addressing risks associated with its objectives;
- c) the ability to demonstrate conformity to specified FSMS requirements.

This document employs the process approach (see 0.3), which incorporates the Plan-Do-Check-Act (PDCA) cycle (see 0.3.2) and risk-based thinking (see 0.3.3).

This process approach enables an organization to plan its processes and their interactions.

The PDCA cycle enables an organization to ensure that its processes are adequately resourced and managed, and that opportunities for improvement are determined and acted on.

Risk-based thinking enables an organization to determine the factors that could cause its processes and its FSMS to deviate from the planned results, and to put in place controls to prevent or minimize adverse effects.

iTeh STANDARD PREVIEW

In this document, the following verbal forms are used:
(standards.iteh.ai)

- “shall” indicates a requirement; ISO 22000:2018
- “should” indicates a recommendation; <https://www.iteh.ai/catalog/standards/sist/c869a6a0-53ad-4736-81d8-3b1e9b2d81be/iso-22000-2018>
- “may” indicates a permission;
- “can” indicates a possibility or a capability.

“NOTES” provide guidance in understanding or clarifying the requirements in this document.

0.2 FSMS principles

Food safety is related to the presence of food safety hazards at the time of consumption (intake by the consumer). Food safety hazards can occur at any stage of the food chain. Therefore, adequate control throughout the food chain is essential. Food safety is ensured through the combined efforts of all the parties in the food chain. This document specifies the requirements for a FSMS that combines the following generally recognized key elements:

- interactive communication;
- system management;
- prerequisite programmes;
- hazard analysis and critical control point (HACCP) principles.

In addition, this document is based on the principles that are common to ISO management system standards. The management principles are:

- customer focus;
- leadership;
- engagement of people;

- process approach;
- improvement;
- evidence-based decision making;
- relationship management.

0.3 Process approach

0.3.1 General

This document adopts a process approach when developing and implementing a FSMS and improving its effectiveness to enhance production of safe products and services while meeting applicable requirements. Understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its intended results. The process approach involves the systematic definition and management of processes, and their interactions, so as to achieve the intended results in accordance with the food safety policy and strategic direction of the organization. Management of the processes and the system as a whole can be achieved using the PDCA cycle, with an overall focus on risk-based thinking aimed at taking advantage of opportunities and preventing undesirable results.

The recognition of the organization's role and position within the food chain is essential to ensure effective interactive communication throughout the food chain.

0.3.2 Plan-Do-Check-Act cycle

iTeh STANDARD PREVIEW

The PDCA cycle can be described briefly as follows:

(standards.iteh.ai)

- | | |
|--------|---|
| Plan: | establish the objectives of the system and its processes, provide the resources needed to deliver the results, and identify and address risks and opportunities; |
| Do: | implement what was planned; https://standards.iteh.ai/catalog/standards/sist/c869a6a0-53ad-4736-81d8-5b1e9b2d81be/iso-22000-2018 |
| Check: | monitor and (where relevant) measure processes and the resulting products and services, analyse and evaluate information and data from monitoring, measuring and verification activities, and report the results; |
| Act: | take actions to improve performance, as necessary. |

In this document, and as illustrated in [Figure 1](#), the process approach uses the concept of the PDCA cycle at two levels. The first covers the overall frame of the FSMS ([Clause 4](#) to [Clause 7](#) and [Clause 9](#) to [Clause 10](#)). The other level (operational planning and control) covers the operational processes within the food safety system as described in [Clause 8](#). Communication between the two levels is therefore essential.

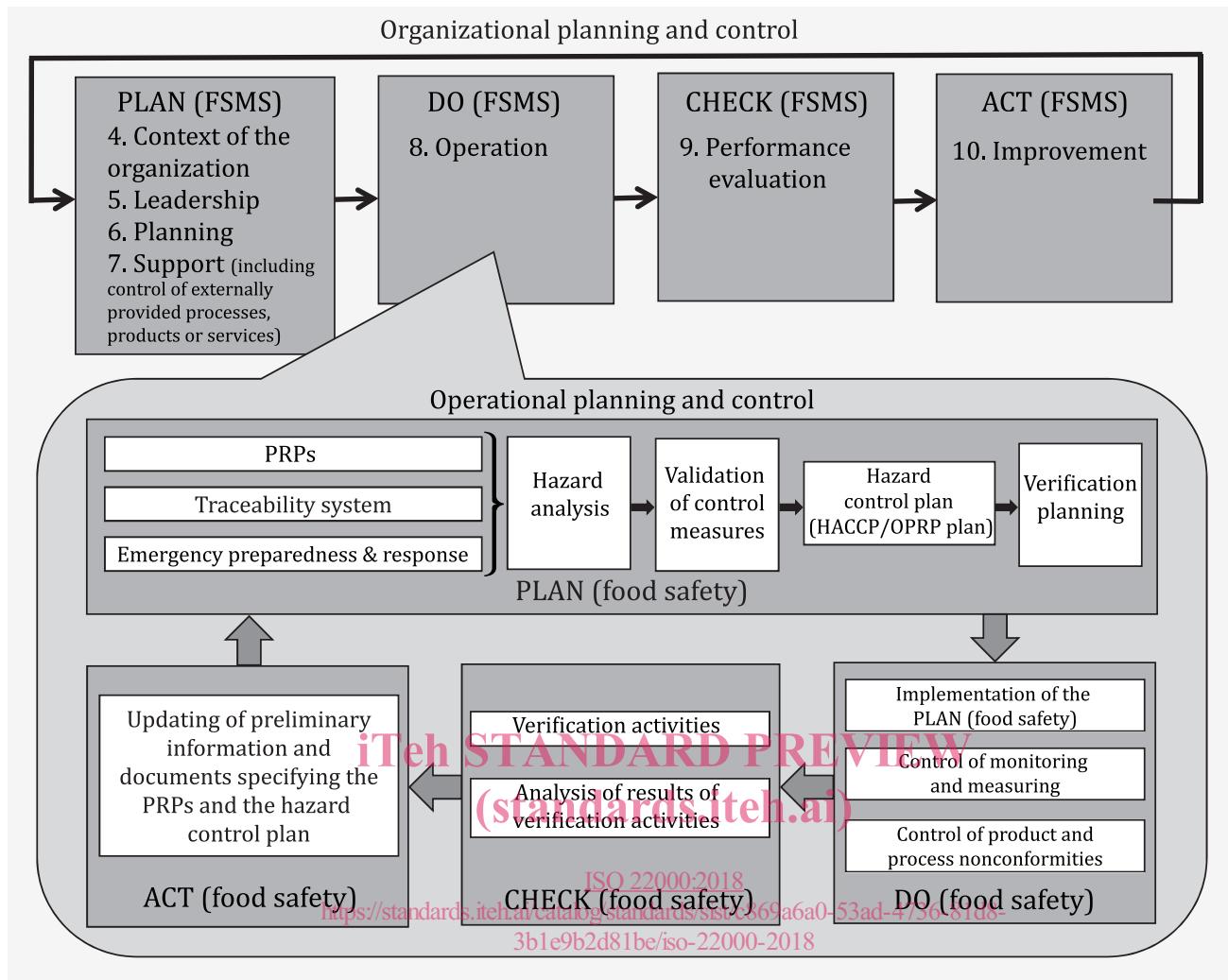


Figure 1 — Illustration of the Plan-Do-Check-Act cycle at the two levels

0.3.3 Risk-based thinking

0.3.3.1 General

Risk-based thinking is essential for achieving an effective FSMS. In this document, risk-based thinking is addressed on two levels, organizational (see 0.3.3.2) and operational (see 0.3.3.3), which is consistent with the process approach described in 0.3.2.

0.3.3.2 Organizational risk management

Risk is the effect of uncertainty, and any such uncertainty can have positive or negative effects. In the context of organizational risk management, a positive deviation arising from a risk can provide an opportunity, but not all positive effects of risk result in opportunities.

To conform to the requirements of this document, an organization plans and implements actions to address organizational risks ([Clause 6](#)). Addressing risks establishes a basis for increasing the effectiveness of the FSMS, achieving improved results and preventing negative effects.

0.3.3.3 Hazard analysis — Operational processes

The concept of risk-based thinking based on the HACCP principles at the operational level is implicit in this document.

The subsequent steps in HACCP can be considered as the necessary measures to prevent hazards or reduce hazards to acceptable levels to ensure food is safe at the time of consumption ([Clause 8](#)).

Decisions taken in the application of HACCP should be based on science, free from bias and documented. The documentation should include any key assumptions in the decision-making process.

0.4 Relationship with other management system standards

This document has been developed within the ISO high level structure (HLS). The objective of the HLS is to improve alignment between ISO management system standards. This document enables an organization to use the process approach, coupled with the PDCA cycle and risk-based thinking, to align or integrate its FSMS approach with the requirements of other management systems and supporting standards.

This document is the core principle and framework for FSMSs and sets out the specific FSMS requirements for organizations throughout the food chain. Other guidance related to food safety, specifications and/or requirements specific to food sectors can be used together with this framework.

In addition, ISO has developed a family of associated documents. These include documents for:

- prerequisite programmes (ISO/TS 22002 series) for specific sectors of the food chain;
- requirements for auditing and certification bodies;
- traceability.

ISO also provides guidance documents for organizations on how to implement this document and related standards. Information is available on the ISO website.

**ITEH STANDARD REVIEW
(standards.iteh.ai)**

[ISO 22000:2018](#)

<https://standards.iteh.ai/catalog/standards/sist/c869a6a0-53ad-4736-81d8-3b1e9b2d81be/iso-22000-2018>

iTeh STANDARD PREVIEW

(standards.iteh.ai)

[ISO 22000:2018](#)

<https://standards.iteh.ai/catalog/standards/sist/c869a6a0-53ad-4736-81d8-3b1e9b2d81be/iso-22000-2018>

Food safety management systems — Requirements for any organization in the food chain

1 Scope

This document specifies requirements for a food safety management system (FSMS) to enable an organization that is directly or indirectly involved in the food chain:

- a) to plan, implement, operate, maintain and update a FSMS providing products and services that are safe, in accordance with their intended use;
- b) to demonstrate compliance with applicable statutory and regulatory food safety requirements;
- c) to evaluate and assess mutually agreed customer food safety requirements and to demonstrate conformity with them;
- d) to effectively communicate food safety issues to interested parties within the food chain;
- e) to ensure that the organization conforms to its stated food safety policy;
- f) to demonstrate conformity to relevant interested parties;
- g) to seek certification or registration of its FSMS by an external organization, or make a self-assessment or self-declaration of conformity to this document.

All requirements of this document are generic and are intended to be applicable to all organizations in the food chain, regardless of size and complexity. Organizations that are directly or indirectly involved include, but are not limited to, feed producers, animal food producers, harvesters of wild plants and animals, farmers, producers of ingredients, food manufacturers, retailers, and organizations providing food services, catering services, cleaning and sanitation services, transportation, storage and distribution services, suppliers of equipment, cleaning and disinfectants, packaging materials and other food contact materials.

This document allows any organization, including small and/or less developed organizations (e.g. a small farm, a small packer-distributor, a small retail or food service outlet) to implement externally-developed elements in their FSMS.

Internal and/or external resources can be used to meet the requirements of this document.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

acceptable level

level of a *food safety hazard* (3.22) not to be exceeded in the *end product* (3.15) provided by the organization (3.31)

3.2

action criterion

measurable or observable specification for the *monitoring* (3.27) of an *OPRP* (3.30)

Note 1 to entry: An action criterion is established to determine whether an OPRP remains in control, and distinguishes between what is acceptable (criterion met or achieved means the OPRP is operating as intended) and unacceptable (criterion not met nor achieved means the OPRP is not operating as intended).

3.3

audit

systematic, independent and documented *process* (3.36) for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled

Note 1 to entry: An audit can be an internal audit (first party) or an external audit (second party or third party), and it can be a combined audit (combining two or more disciplines).

Note 2 to entry: An internal audit is conducted by the organization itself, or by an external party on its behalf.

Note 3 to entry: "Audit evidence" and "audit criteria" are defined in ISO 19011.

Note 4 to entry: Relevant disciplines are, for example, food safety management, quality management or environmental management. **iTeh STANDARD PREVIEW**

3.4 **competence**

ability to apply knowledge and skills to achieve intended results

[ISO 22000:2018](#)

3.5

conformity

fulfilment of a *requirement* (3.38)

<https://standards.iteh.ai/catalog/standards/sist/c869a6a0-53ad-4736-81d8-3b1e9b2d81be/iso-22000-2018>

3.6

contamination

introduction or occurrence of a contaminant including a *food safety hazard* (3.22) in a *product* (3.37) or processing environment

3.7

continual improvement

recurring activity to enhance *performance* (3.33)

3.8

control measure

action or activity that is essential to prevent a significant *food safety hazard* (3.22) or reduce it to an *acceptable level* (3.1)

Note 1 to entry: See also *significant food safety hazard* (3.40).

Note 2 to entry: Control measure(s) is (are) identified by hazard analysis.

3.9

correction

action to eliminate a detected *nonconformity* (3.28)

Note 1 to entry: A correction includes the handling of potentially unsafe products and can therefore be made in conjunction with a *corrective action* (3.10).

Note 2 to entry: A correction may be, for example, reprocessing, further processing and/or elimination of the adverse consequences of the nonconformity (such as disposal for other use or specific labelling).

3.10**corrective action**

action to eliminate the cause of a *nonconformity* (3.28) and to prevent recurrence

Note 1 to entry: There can be more than one cause for a nonconformity.

Note 2 to entry: Corrective action includes cause analysis.

3.11**critical control point****CCP**

step in the *process* (3.36) at which *control measure(s)* (3.8) is (are) applied to prevent or reduce a *significant food safety hazard* (3.40) to an acceptable level, and defined *critical limit(s)* (3.12) and *measurement* (3.26) enable the application of *corrections* (3.9)

3.12**critical limit**

measurable value which separates acceptability from unacceptability

Note 1 to entry: Critical limits are established to determine whether a CCP (3.11) remains in control. If a critical limit is exceeded or not met, the products affected are to be handled as potentially unsafe products.

[SOURCE: CAC/RCP 1-1969, modified — The definition has been modified and Note 1 to entry has been added.]

3.13**documented information****Teh STANDARD PREVIEW**

information required to be controlled and maintained by an *organization* (3.31) and the medium on which it is contained

(standards.iteh.ai)

Note 1 to entry: Documented information can be in any format and media, and from any source.

Note 2 to entry: Documented information can refer to:
<https://standards.iteh.ai/catalog/standards/sist/c869a6a0-53ad-4736-81d8-3b1e9b2d81be/iso-22000-2018>

- the management system (3.25), including related processes (3.36);
- information created in order for the organization to operate (documentation);
- evidence of results achieved (records).

3.14**effectiveness**

extent to which planned activities are realized and planned results achieved

3.15**end product**

product (3.37) that will undergo no further processing or transformation by the *organization* (3.31)

Note 1 to entry: A product that undergoes further processing or transformation by another organization is an end product in the context of the first organization and a raw material or an ingredient in the context of the second organization.

3.16**feed**

single or multiple product(s), whether processed, semi-processed or raw, which is (are) intended to be fed to food-producing animals

Note 1 to entry: Distinctions are made in this document between the terms *food* (3.18), *feed* (3.16) and *animal food* (3.19):

- food is intended for consumption by humans and animals, and includes feed and animal food;
- feed is intended to be fed to food-producing animals;