
Food safety —

Part 1:

**Requirements for bodies providing
audit and certification of food safety
management systems**

iTeh STANDARD PREVIEW

Sécurité des denrées alimentaires —

*Partie 1: Exigences pour les organismes procédant à l'audit et à la
certification de systèmes de management de la sécurité des denrées
alimentaires*

ISO 22003-1:2022

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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 (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.

This document was prepared by Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 17, *Management systems for food safety*, in collaboration with the ISO Committee on conformity assessment (CASCO).

This first edition cancels and replaces ISO/TS 22003:2013, which has been technically revised throughout.

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.

Introduction

Certification of the food safety management system (FSMS) of an organization is one means of providing assurance that the organization has implemented a system for the management of food safety in line with its policy and the internationally accepted principles of food safety.

Requirements for an FSMS can originate from a number of sources. This document has been developed to assist in the certification of FSMS that fulfil the requirements of ISO 22000. The contents of this document can also be used to support certification of FSMS that are based on other sets of specified FSMS requirements.

This document is intended for use, in combination with ISO/IEC 17021-1:2015, by bodies that carry out audit and certification of FSMS. It provides generic requirements for such bodies, who are referred to as “certification bodies”. This wording is not intended to be an obstacle to the use of this document by bodies with other designations that undertake activities covered by the scope of this document. This document is intended to be used by anybody involved in the assessment of FSMS.

Certification activities involve the audit of an organization’s FSMS. The form of attestation of conformity of an organization’s FSMS to a specific FSMS standard (e.g. ISO 22000) or other specified requirements is normally a certification document or a certificate.

It is for the organization seeking certification to develop its own management systems and, other than where relevant legislative requirements specify to the contrary, it is for the organization to decide how the various components of these will be arranged. The degree of integration between the various management system components will vary from organization to organization. It is therefore appropriate for certification bodies that operate in accordance with this document to take into account the culture and practices of their clients with respect to the integration of their FSMS within the wider organization.

This document was developed in conjunction with ISO 22003-2, which is used in combination with ISO/IEC 17065.

In this document, the following verbal forms are used:

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” indicates a permission;
- “can” indicates a possibility or a capability.

Food safety —

Part 1:

Requirements for bodies providing audit and certification of food safety management systems

1 Scope

This document specifies the requirements for the audit and certification of a food safety management system (FSMS) complying with the requirements given in ISO 22000 (or other specified FSMS requirements). It also provides the necessary information and confidence to customers about the way certification of their suppliers has been granted.

Certification of FSMS is a third-party conformity assessment activity (as described in ISO/IEC 17000:2020, 4.3), and bodies performing this activity are third-party conformity assessment bodies.

NOTE 1 In this document, the terms “product” and “service” are used separately (in contrast with the definition of “product” given in ISO/IEC 17000).

NOTE 2 This document can be used as a criteria document for the accreditation or peer assessment of certification bodies which seek to be recognized as being competent to certify that an FSMS complies with ISO 22000 or other sets of specified FSMS requirements. It is also intended to be used as a criteria document by regulatory authorities and industry consortia which engage in direct recognition of certification bodies to certify that an FSMS complies with ISO 22000. Some of its requirements can also be useful to other parties involved in the conformity assessment of such certification bodies, and in the conformity assessment of bodies that undertake to certify the compliance of FSMS with criteria additional to, or other than, those in ISO 22000.

FSMS certification does not attest to the safety or fitness of the products of an organization within the food chain. However, an FSMS requires an organization to meet all applicable food-safety-related statutory and regulatory requirements through its management system.

NOTE 3 Certification of an FSMS according to ISO 22000 is a management system certification, not a product certification.

Other FSMS users can use the concepts and requirements of this document provided that the requirements are adapted as necessary.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 17000, *Conformity assessment — Vocabulary and general principles*

ISO/IEC 17021-1:2015, *Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements*

ISO 22000, *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/IEC 17000, ISO/IEC 17021-1, ISO 22000 and the following apply.

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

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

3.1 food safety management system FSMS

set of interrelated or interacting elements of an organization to establish policies and objectives and processes to achieve food safety management system objectives

Note 1 to entry: In this document, “food safety management system” replaces the term “management system” used in ISO/IEC 17021-1.

3.2 hazard analysis and critical control points study HACCP study

hazard analysis for a family of products/processes/services with similar hazards and similar processes and technology (e.g. production, packaging, storage or implementation of services)

4 Principles

The principles of ISO/IEC 17021-1:2015, Clause 4, are the basis for the subsequent specific performance and descriptive requirements in this document. This document does not set specific requirements to address all issues related to audit and certification process. These principles should be applied as guidance for the decisions that sometimes need to be made for unanticipated situations. Principles are not requirements.

5 General requirements

ISO/IEC 17021-1:2015, Clause 5, shall be followed.

6 Structural requirements

ISO/IEC 17021-1:2015, Clause 6, shall be followed.

7 Resource requirements

7.1 Competence of personnel

7.1.1 General considerations

ISO/IEC 17021-1:2015, 7.1.1, shall be followed.

The certification functions for which competence shall be identified are those given in [Annex C](#).

7.1.2 Determination of competence criteria

ISO/IEC 17021-1:2015, 7.1.2, shall be followed.

Technical areas shall be defined using [Annex A](#).

The competence criteria, specifying required knowledge and skills, in [Annex C](#) shall apply.

NOTE 1 [Annex D](#) provides guidance to the certification body on many of the generic certification functions identified in ISO/IEC 17021-1:2015, Annex A, for which competence criteria need to be determined for personnel involved in the audit and certification of an FSMS.

NOTE 2 Qualification(s) and experience can be used as part of the criteria; however, competence is not based on these alone, as it is important to ensure that a person can demonstrate the ability to apply the specific knowledge and skills that one would expect a person to have after completing a qualification or having a certain amount of industry experience.

7.1.3 Evaluation processes

ISO/IEC 17021-1:2015, 7.1.3, shall be followed.

The certification body shall evaluate, in particular, the individual's knowledge relating to food safety, including knowledge of specific prerequisite programmes (PRPs), food safety hazards and control measures related to the categories within which the certification body personnel operate. These shall have been identified for these categories under the requirements of [7.1.2](#).

Evaluators shall have knowledge of (one or more) evaluation methods (see ISO/IEC 17021-1:2015, Annex B) and shall demonstrate the ability to apply them.

NOTE ISO/IEC 17021-1:2015, 7.1.3, requires the certification body to demonstrate the effectiveness of the evaluation methods used to evaluate personnel against identified competence criteria.

7.1.4 Other considerations

ISO/IEC 17021-1:2015, 7.1.4, shall be followed.

7.2 Personnel involved in the certification activities

ISO/IEC 17021-1:2015, 7.2, shall be followed.

7.3 Use of individual external auditors and external technical experts

ISO/IEC 17021-1:2015, 7.3, shall be followed.

7.4 Personnel records

ISO/IEC 17021-1:2015, 7.4, shall be followed.

7.5 Outsourcing

ISO/IEC 17021-1:2015, 7.5, shall be followed.

8 Information requirements

8.1 ISO/IEC 17021-1:2015, Clause 8, shall be followed except where as amended in [8.2](#), [8.3](#) and [8.4](#).

8.2 The certification documents shall identify in detail the categories and subcategories in [Table A.1](#) to which the FSMS applies.

8.3 A certification body shall not authorize the use of the FSMS certification mark on the product nor the product packaging. In the context of this document, product packaging referred to in ISO/IEC 17021-1:2015, 8.3, shall cover all product packaging, both primary packaging (which contains the product) and any outer or secondary packaging.

8.4 A certification body shall not permit the use of any statement on product packaging that the client has a certified FSMS. This includes all product packaging, both primary packaging (which contains the product) and any outer or secondary packaging.

9 Process requirements

9.1 Pre-certification activities

9.1.1 Application

ISO/IEC 17021-1:2015, 9.1.1, shall be followed.

The certification body shall require the applicant organization to provide the information concerning products and processes relevant to determination of the audit duration, as per [Annexes A](#) and [B](#).

9.1.2 Application review

9.1.2.1 ISO/IEC 17021-1:2015, 9.1.2, shall be followed.

9.1.2.2 The certification body shall use [Annex A](#) to define the relevant scope for the organization applying for certification. The scope statement shall:

- identify the category(s) or subcategory(s) in scope of certification for each site or sites;
- briefly describe the main types of activities/processes for the products and/or services that are audited by the certifying body.

9.1.2.3 The defined scope of certification shall not:

- be misleading;
- exclude activities, processes, products or services from the scope of certification when those activities, processes, products or services can have an influence on the food safety of the end products as defined by the legal responsibility of the organisations' activities;
- include any promotional statements, brands or claims.

9.1.3 Audit programme

9.1.3.1 ISO/IEC 17021-1:2015, 9.1.3, shall be followed.

9.1.3.2 In addition, the certification body shall have a process for choosing the audit timing and season, so that the audit team has the opportunity of auditing the organization operating on a representative number of product lines and/or services covered by the scope of certification.

9.1.4 Determining audit time

9.1.4.1 ISO/IEC 17021-1:2015, 9.1.4, shall be followed.

9.1.4.2 The certification body shall have documented procedures for determining audit time, and for each client, the certification body shall determine the time needed to plan and accomplish a complete and effective audit of the client's FSMS. In determining the audit duration, the certification body shall use the methodology described in [Annex B](#). The audit time determined by the certification body, and the justification for the determination, shall be recorded including justification for any reductions or additions.

9.1.4.3 In determining and documenting audit time needed, the certification body shall determine:

- a) the time for audit preparation;
- b) the minimum duration for auditing for each site for on-site or remote auditing, as specified in [Clauses B.1, B.2 and B.3](#) and [Table B.1](#);
- c) the time for reporting and, if applicable, conducting post-audit activities;
- d) where additional meetings are necessary (e.g. review meetings, coordination, audit team briefing), an increase in audit time can be required;
- e) where applicable and agreed, the time needed to ensure effective remote auditing or use of information and communication technology (ICT).

9.1.5 Multi-site sampling

9.1.5.1 ISO/IEC 17021-1:2015, 9.1.5, shall be followed.

NOTE The whole of subclause 9.1.5 is intended to apply only to operations where activities present in the scope statement are performed.

9.1.5.2 A multi-site organization is an organization having an identified central function at which certain FSMS activities are planned, controlled or managed, and a network of sites at which such activities are fully or partially carried out. Examples of possible multi-site organizations are:

- organizations operating with franchises;
- producer groups (for categories A and B);
- a manufacturing company with one or more production sites and a network of sales offices;
- service organizations with multiple sites offering a similar service;
- organizations with multiple branches.

Sampling of multi-site organizations shall cover all activities (see the criteria given in [9.1.5.3](#)).

9.1.5.3 The certification body shall demonstrate that the sampling of sites does not undermine effective auditing. When multi-site sampling is undertaken, the certification body shall justify and document the rationale based on the following conditions:

- a) sites are operating under one centrally controlled and administered FSMS;
- b) sites subject to sampling are similar (food chain subcategory, geographical location, processes and technologies, size and complexity, regulatory and statutory requirements, customer requirements, food safety hazards and control measures);
- c) the central function is part of the organization, clearly identified and not subcontracted to an external organization;
- d) all sites have a legal or contractual link with the central function;
- e) the central function has organizational authority to define, establish and maintain the FSMS;
- f) all sites are subject to the organization's internal audit programme and have been audited;
- g) audit findings at a site are considered indicative of the entire FSMS and corrective actions are implemented accordingly;
- h) the central function is responsible for ensuring that outcomes of performance evaluation and customer complaints from all sites are collected and analysed;

- i) the organization's FSMS is subject to central management review;
- j) the central function has authority to initiate continual improvement of the FSMS.

NOTE The central function is where operational control and authority from the top management of the organization is exerted over every site. There is no requirement for the central function to be located in a single site.

9.1.5.4 The use of multi-site sampling is permitted for categories A and B. Sampling may be applied to multi-site organizations, with the minimum sample size being the square root of the total number of sites: \sqrt{x} , rounded up to the next whole number. The square root sample shall be taken per risk category based on production complexity of the sites (e.g. open field plant production, perennial plant production, indoor production, open field livestock production, indoor livestock production).

The use of multi-site sampling is permitted for categories F and G, and only for re-heating-type facilities (e.g. event catering, coffee shops, pubs) for category E and only for facilities with limited preparation or cooking (e.g. re-heating, frying) (see [Table A.1](#)). For organizations with 20 sites or fewer, all sites shall be audited. For organizations with more than 20 sites, the minimum number of sites to be sampled shall be 20 plus the square root of the total number of other sites: $y = 20 + \sqrt{x - 20}$, rounded up to the next whole number. This applies to the initial certification, to surveillance and to recertification audits.

The use of multi-site sampling is not permitted for any other categories identified in [Annex A](#).

9.1.5.5 Where multi-site sampling is permitted, the certification body shall ensure (e.g. via contractual arrangements) that the organization has conducted an internal audit for each site within one year prior to certification and when applicable the effectiveness of corrective actions shall be available. Following certification, the annual internal audit shall cover all sites of the organization included in the certification scope of the multi-site organization and ongoing effectiveness of corrective actions shall be demonstrated.

9.1.5.6 Where multi-site sampling is permitted, the certification body shall define and utilize a sampling programme to ensure an effective audit of the FSMS where the following conditions apply.

- a) At least annually, an audit of the central function for the FSMS shall be performed by the certification body prior to the sampled site audits.
- b) At least annually, audits shall be performed by the certification body on the required number of sampled sites.
- c) Audit findings of the sampled sites shall be assessed to ascertain if these indicate an overall FSMS deficiency and therefore can be applicable to some or all other sites.
- d) Where audit findings of the sampled sites are considered indicative of the entire FSMS, corrective actions shall be implemented accordingly.
- e) For organizations with 20 sites or fewer, all sites shall be audited.

The certification body shall increase the size of sample or terminate the site sampling where the FSMS subject to certification does not indicate the ability to achieve the intended results.

9.1.5.7 The sample shall be partly selective and partly random and shall result in a representative range of different sites being selected, ensuring all processes covered by the scope of certification will be audited.

At least 25 % of the sample shall be selected at random. The remainder shall be selected so that the differences among the sites selected over the period of validity of the certification are as large as possible.