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**Food safety —**

Part 2:

**Requirements for bodies providing  
evaluation and certification of  
products, processes and services,  
including an audit of the food safety  
system**

*Sécurité des denrées alimentaires —*

*Partie 2: Exigences pour les organismes procédant à l'évaluation et  
à la certification de produits, de procédés et de services, incluant un  
audit du système de sécurité des denrées alimentaires*

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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](http://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](http://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](http://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).

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](http://www.iso.org/members.html).

## Introduction

Certification of the food safety system (FSS) 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 FSS can originate from a number of sources. This document has been developed to assist in the certification of the organization's products, processes or services and its FSS, including its management system elements.

This document is intended for use, in combination with ISO/IEC 17065, by bodies that carry out evaluation and certification of products, processes or services including an audit of the FSS. 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.

Certification of an organization's products, processes or services including an audit of the FSS in accordance with this document can involve a number of activities. Because this document is intended for product certification schemes that include a management system element, these activities involve an audit of the organization's FSS. The form of attestation of conformity of an organization's FSS to a specific standard, certification scheme requirements or other specified requirements is normally a certification document or a certificate.

It is for the organization seeking certification to develop its own FSS and related systems according to the scheme requirements. Other than where relevant legislative, customer or certification scheme 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 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 FSS within the wider organization.

This document was developed in conjunction with ISO 22003-1, which is used in combination with ISO/IEC 17021-1.

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 2:

# Requirements for bodies providing evaluation and certification of products, processes and services, including an audit of the food safety system

## 1 Scope

This document is supplemental to ISO/IEC 17065. It specifies the rules applicable for the audit of a food safety system (FSS) and certification of products, processes and services complying with requirements of a certification scheme that is based on the internationally accepted principles of food safety (e.g. CODEX *General Principles of Food Hygiene*<sup>[8]</sup>) and includes management system elements.

This document does not apply to certifications that are solely based on product testing (e.g. performed by an organization applying ISO/IEC 17025) or inspection (e.g. performed by an organization applying ISO/IEC 17020) and does not apply to ISO/IEC 17065-based food safety schemes that do not include both internationally accepted principles of food safety and management system elements.

It also provides the necessary information and confidence to customers about the way certification of their suppliers has been granted.

Certification of FSS 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** 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 organization's products, processes and services and its FSS comply with the requirements of a certification scheme. 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 organization's FSS complies with a certification scheme's requirements. 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 an FSS with additional criteria.

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

## 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 17065:2012, *Conformity assessment — Requirements for bodies certifying products, processes and services*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000, ISO/IEC 17065 and the following apply.

## ISO 22003-2:2022(E)

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 system

#### FFS

*prerequisite programmes* (3.2), supplemented with *control measures* (3.16), as appropriate, based on internationally accepted principles of food safety, combined with *management system elements* (3.17), that, when implemented by the organization, provide products and services that are safe, according to their intended use

Note 1 to entry: The prerequisite programmes and control measures of an FSS may be based on either a hazard analysis specific to the organization, its products and processes, or a generic hazard analysis conducted by a competent external body (e.g. competent authority, academia, trade or industry association, certification scheme owner) appropriate to the products and processes of the organization and adapted and tailored by the organization to its operations.

### 3.2 prerequisite programme

#### PRP

basic conditions and activities that are necessary within the organization and throughout the food chain to maintain food safety

Note 1 to entry: The PRPs needed depend on the segment of the food chain in which the organization operates and the type of organization. Examples of equivalent terms are good agricultural practice (GAP), good veterinary practice (GVP), good manufacturing practice (GMP), good hygiene practice (GHP), good production practice (GPP), good distribution practice (GDP) and good trading practice (GTP).

[SOURCE: ISO 22000:2018, 3.35]

### 3.3 competence

ability to apply knowledge and skills to achieve intended results

[SOURCE: ISO/IEC 17021-1:2015, 3.7]

### 3.4 audit

process for obtaining relevant information about an object of conformity assessment and evaluating it objectively to determine the extent to which specified requirements are fulfilled

Note 1 to entry: The specified requirements are defined prior to performing an audit so that the relevant information can be obtained.

Note 2 to entry: In the context of this document, “audit” includes any applicable evaluation activity (in accordance with ISO/IEC 17065), such as inspection, testing and management system audit (in accordance with ISO/IEC 17021-1).

[SOURCE: ISO/IEC 17000:2020, 6.4, modified — Notes 2 and 3 to entry have been deleted and a new Note 2 to entry has been added.]

### 3.5 audit duration

part of *audit time* (3.6) spent conducting *audit* (3.4) activities from the opening meeting to the closing meeting, inclusive

[SOURCE: ISO/IEC 17021-1:2015, 3.17, modified — The term has been changed from “duration of management system certification audits”.]



**3.6****audit time**

time needed to plan and accomplish a complete and effective *audit* (3.4) of the client organization's FSS

[SOURCE: ISO/IEC 17021-1:2015, 3.16, modified — “FSS” has replaced “management system” in the definition.]

**3.7****nonconformity**

non-fulfilment of a requirement

[SOURCE: ISO/IEC 17021-1:2015, 3.11]

**3.8****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)

**3.9****auditor**

person who conducts an *audit* (3.4)

[SOURCE: ISO/IEC 17021-1:2015, 3.6]

**3.10****guide**

person appointed by the client to assist the audit team

[SOURCE: ISO/IEC 17021-1:2015, 3.8]

**3.11****observer**

person who accompanies the audit team but does not *audit* (3.4)

[SOURCE: ISO/IEC 17021-1:2015, 3.9]

**3.12****technical expert**

person who provides specific knowledge or expertise to the audit team

[SOURCE: ISO/IEC 17021-1:2015, 3.14, modified — Note 1 to entry has been deleted.]

**3.13****permanent site**

location (physical or virtual) where a client organization performs work or provides a service on a continuing basis

[SOURCE: ISO/IEC TS 17023:2013, 3.4]

**3.14****temporary site**

location (physical or virtual) where a client organization performs specific work or provides a service for a finite period of time and which is not intended to become a *permanent site* (3.13)

[SOURCE: ISO/IEC TS 17023:2013, 3.5]

**3.15****audit plan**

description of the activities and arrangements for an *audit* (3.4)

[SOURCE: ISO 19011:2018, 3.6]

**3.16**

**control measure**

action or activity that can be used to prevent or eliminate a hazard or reduce it to an acceptable level

**3.17**

**management system element**

element of a management system (e.g. management commitment, responsibility and review, documented information, internal audit) that supports the production of safe food

**4 General requirements**

**4.1 Legal and contractual matters**

**4.1.1** ISO/IEC 17065:2012, 4.1, shall be followed.

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

**4.2 Management of impartiality**

ISO/IEC 17065:2012, 4.2, shall be followed.

**4.3 Liability and financing**

ISO/IEC 17065:2012, 4.3, shall be followed.

**4.4 Non-discriminatory conditions**

ISO/IEC 17065:2012, 4.4, shall be followed.

**4.5 Confidentiality**

ISO/IEC 17065:2012, 4.5, shall be followed.

**4.6 Publicly available information**

ISO/IEC 17065:2012, 4.6, shall be followed.

**5 Structural requirements**

**5.1 Organizational structure and top management**

ISO/IEC 17065:2012, 5.1, shall be followed.

**5.2 Mechanism for safeguarding impartiality**

ISO/IEC 17065:2012, 5.2, shall be followed.

## 6 Resource requirements

### 6.1 Certification body personnel

#### 6.1.1 General

ISO/IEC 17065:2012, 6.1.1, shall be followed.

#### 6.1.2 Management of competence for personnel involved in the certification process

6.1.2.1 ISO/IEC 17065:2012, 6.1.2, shall be followed.

In addition to ISO/IEC 17065:2012, 6.1.2.1, the procedure shall require a certification body to apply [Annexes A](#) and [C](#) in the determination of competencies.

NOTE 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.

6.1.2.2 Determination of personnel competence shall include the individual's ability to apply knowledge, 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 [6.1.2.1](#).

The certification body shall periodically evaluate the performance of each auditor during an on-site audit.

Those responsible for determining personnel competence shall have knowledge of determination methods and shall have demonstrated the ability to apply them and also have equivalent competence to those functions they are evaluating.

#### 6.1.3 Contract with the personnel

ISO/IEC 17065:2012, 6.1.3, shall be followed.

### 6.2 Resources for audit

#### 6.2.1 Internal resources

ISO/IEC 17065:2012, 6.2.1, shall be followed.

NOTE The applicable requirements of ISO/IEC 17021-1 referred to in ISO/IEC 17065:2012, 6.2.1, have been included in this document.

#### 6.2.2 External resources (outsourcing)

ISO/IEC 17065:2012, 6.2.2, shall be followed.

NOTE The applicable requirements of ISO/IEC 17021-1 referred to in ISO/IEC 17065:2012, 6.2.2, have been included in this document.

## 7 Process requirements

### 7.1 General

ISO/IEC 17065:2012, 7.1, shall be followed.

Where a scheme owner has established its own rules for the determination of categories, audit duration and competence, the outcome of the scheme rules shall apply provided the scheme rules are not less than those required in [Clause 7](#) and related annexes as a common basis.

### 7.2 Application

ISO/IEC 17065:2012, 7.2, 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 in accordance with [Annexes A](#) and [B](#).

### 7.3 Application review

**7.3.1** The certification body shall conduct a review of the information obtained (see [7.2](#)) to ensure that:

- a) the information about the client its products/processes/services and its FSS, including the sites of the client's operations, and any other points influencing the certification activity (language, safety conditions, etc.), is sufficient for the conduct of the certification process;
- b) any known difference in understanding between the certification body and the client is resolved, including agreement regarding standards or other normative documents;
- c) the scope of certification sought is defined;
- d) the means are available to conduct audits;
- e) the certification body has the competence and capability to perform the certification activity.

**7.3.2** ISO/IEC 17065:2012, 7.3.2, shall be followed.

**7.3.3** ISO/IEC 17065:2012, 7.3.3, shall be followed.

**7.3.4** ISO/IEC 17065:2012, 7.3.4, shall be followed.

**7.3.5** ISO/IEC 17065:2012, 7.3.5, shall be followed.

**7.3.6** The certification body shall determine the relevant scope of certification for the organization applying for certification using [Annex A](#) unless the scheme provides specific categories or subcategories. The certification body shall identify the category(s) or subcategory(s) in scope of certification for each site or sites by briefly describing the main types of products and processes for the products and/or services that are evaluated by the certification body.

**7.3.7** 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 that are not in the scope of the certification scheme.

## 7.4 Evaluation

NOTE ISO/IEC 17065 refers to “evaluation” and is applicable to the various types of product, process and services certification schemes which incorporate conformity assessment activities including inspection, testing, audit, verification and validation. In the context of this document, the evaluation activity is audit, and therefore the terminology used under this subclause is audit only.

### 7.4.1 Activities prior to the audit

#### 7.4.1.1 Audit programme

NOTE 1 The “audit programme” is identified as equivalent to the “evaluation plan” required in ISO/IEC 17065:2012, 7.4.1.

The certification body shall have a programme for the audit activities, including audit activities conducted remotely, to allow for the necessary arrangements for each audit to be managed. The programme shall be clear with respect to the individual activities (e.g. audit, testing and inspection) but shall take into account that the individual activities are not always distinguishable from each other when conducted on-site.

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 products and processes covered by the scope using the criteria of the certification scheme, if any.

NOTE 2 Depending on the characteristics of the certification scheme and the FSS requirements, the audit programme can be either a generic plan applicable to all activities, including auditing of the relevant management system elements (e.g. quality or food safety management system or an integration thereof), when applicable, or a specific one for a particular activity, or a combination of both.

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#### 7.4.1.2 Determining audit time

7.4.1.2.1 The certification body shall have documented procedures for determining the audit time. For each client, the certification body shall determine the time needed to plan and accomplish a complete and effective audit of the FSS. 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.

7.4.1.2.2 In determining and documenting the 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.2](#) and [B.3](#) and [Table B.1](#);
- c) the time for reporting and, if applicable, conducting post-audit activities;
- d) the number of auditors per audit day balanced with the organization’s resources;
- e) where additional meetings are necessary (e.g. review meetings, coordination, audit team briefing), an increase in audit time can be required;
- f) where applicable and agreed, the time needed to ensure effective remote auditing or use of information and communication technology (ICT).