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

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National foreword

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

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
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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).

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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 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 second edition cancels and replaces the first edition (ISO/TS 22003:2007), which has been technically revised.

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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.

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

This Technical Specification is intended for use by bodies that carry out audit and certification of FSMS by providing generic requirements for such bodies. Such bodies are referred to as certification bodies. This wording is not intended to be an obstacle to the use of this Technical Specification by bodies with other designations that undertake activities covered by the scope of this Technical Specification. This Technical Specification is intended to be used by anybody involved in the assessment of FSMS. It can also be used to support other types of food safety certifications based on a combination of ISO/IEC 17021 and ISO/IEC 17065.

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 being certified to develop its own management systems (e.g. FSMS in accordance with ISO 22000, other sets of specified FSMS requirements, quality management systems, environmental management systems or occupational health and safety 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 Technical Specification to take into account the culture and practices of their clients with respect to the integration of their FSMS within the wider organization.

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

1 Scope

This Technical Specification defines the rules applicable for the audit and certification of a food safety management system (FSMS) complying with the requirements given in ISO 22000 (or other sets of 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 17000:2004, 5.5), and bodies performing this activity are third-party conformity assessment bodies.

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

NOTE 2 This Technical Specification 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. 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 could 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, ISO 22000 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 Technical Specification provided that the requirements are adapted as necessary.

2 Normative references

The following referenced documents, in whole or in part, are normatively referenced in this document and are indispensable for 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*

ISO/IEC 17000:2004, *Conformity assessment — Vocabulary and general principles*

ISO/IEC 17021:2011, *Conformity assessment — Requirements for bodies providing audit and certification of management systems*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000, ISO/IEC 17021, ISO 22000 and the following apply.

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3.1
hazard analysis and critical control point
HACCP
system which identifies, evaluates and controls hazards which are significant for food safety [SOURCE: *Codex Alimentarius Food Hygiene Basic Texts*,[12] modified]

3.2
food safety management system
FSMS
set of interrelated or interacting elements to establish policy and objectives and to achieve those objectives, used to direct and control an organization with regard to food safety

Note 1 to entry: See ISO 9000:2005, 3.2.1, 3.2.2 and 3.2.3.

Note 2 to entry: In this Technical Specification, "food safety management system" replaces the term "management system" used in ISO/IEC 17021.

3.3
competence
ability to apply knowledge and skills to achieve intended results

4 Principles

The principles of ISO/IEC 17021:2011, Clause 4, are the basis for the subsequent specific performance and descriptive requirements in this Technical Specification. This Technical Specification does not give specific requirements for all situations that can occur. These principles should be applied as guidance for the decisions that may need to be made for unanticipated situations. Principles are not requirements.

NOTE Annex E has been included to address the needs of parties interested both in FSMS and food product certification.

5 General requirements

5.1 General

The requirements of ISO/IEC 17021:2011, Clause 5, apply.

5.2 Management of impartiality

FSMS consultancy shall not be provided by either the certification body or any part of the same legal entity.

6 Structural requirements

The requirements of ISO/IEC 17021:2011, Clause 6, apply.

7 Resource requirements

7.1 Competence of management and personnel

7.1.1 General considerations

The requirements of ISO/IEC 17021:2011, 7.1.1, apply.

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The technical areas referred to in ISO/IEC 17021:2011, 7.1.1, shall be those categories identified in Annex A. The functions of certification for which competence shall be identified are those given in Annex C.

7.1.2 Determination of competence criteria

The requirements of ISO/IEC 17021:2011, 7.1.2, apply.

The competence criteria included in Annex C shall form the basis for the criteria developed for each category. Competence criteria can be generic or specific. The competence criteria in ISO/IEC 17021:2011, Annex A, shall be considered to be generic.

NOTE 1 The competence criteria identified in Annex C are food safety related criteria for certification body personnel. The certification body can identify specific competences required for the identified categories and for each certification function.

NOTE 2 Annex D provides guidance to the certification body on many of the generic certification functions identified in ISO/IEC 17021:2011, Annex A, for which competence criteria need to be determined for personnel involved in the audit and certification of an FSMS.

NOTE 3 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

The requirements of ISO/IEC 17021:2011, 7.1.3, apply.

Evaluation processes shall evaluate, in particular, the individual's knowledge relating to food safety, including knowledge of specific prerequisite programmes (PRP) and food safety hazards 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.

NOTE ISO/IEC 17021:2011, 7.1.3, requires the certification body to demonstrate the effectiveness of the evaluation methods used to evaluate personnel against identified competence criteria. ISO/IEC 17021:2011, Annex B, contains five examples of methods of evaluation.

7.1.4 Other considerations

The requirements of ISO/IEC 17021:2011, 7.1.4, apply.

7.2 Personnel involved in the certification activities

The requirements of ISO/IEC 17021:2011, 7.2, apply.

7.3 Use of individual external auditors and external technical advisors

The requirements of ISO/IEC 17021:2011, 7.3, apply.

7.4 Personnel records

The requirements of ISO/IEC 17021:2011, 7.4, apply.

7.5 Outsourcing

The requirements of ISO/IEC 17021:2011, 7.5, apply.

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8 Information requirements

The requirements of ISO/IEC 17021:2011, Clause 8, apply.

The certification documents shall identify in detail what activity is certified, referring to categories and subcategories (see Table A.1).

9 Process requirements

9.1 General requirements

9.1.1 The certification body shall use Annex A to define the relevant scope for the organization applying for certification. The certification body shall not 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 in the scope of certification.

9.1.2 The certification body shall have a process for choosing the audit day, time and season, so that the audit team has the opportunity of auditing the organization operating on a representative number of product lines, categories and subcategories covered by the scope of certification.

9.1.3 The requirements of ISO/IEC 17021:2011, 9.1.1 to 9.1.3, apply.

9.1.4 The requirements of ISO/IEC 17021:2011, 9.1.4, apply.

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. The audit time determined by the certification body, and the justification for the determination, shall be recorded.

9.1.5 For the certification of multi-site organizations, 9.1.5.1 to 9.1.5.4 apply.

NOTE This subclause (9.1.5) is intended to apply only to operations directly affecting food safety, and not to exclusively administrative sites.

9.1.5.1 A multi-site organization is an organization having an identified central function (hereafter referred to as a central office – but not necessarily the headquarters of the organization) 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;

— 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.

9.1.5.2 The certification body can certify a multi-site organization under one management system, providing that the following conditions apply:

a) all sites are operating under one centrally controlled and administered FSMS as defined in ISO 22000:2005, Clause 4, or equivalent for other FSMS;

b) an internal audit has been conducted on each site within one year prior to certification;

c) audit findings of the individual sites shall be considered indicative of the entire system and correction shall be implemented accordingly.

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