TECHNICAL SPECIFICATION

ISO/TS 22003

Redline version
compares second edition
to first edition

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

Systèmes de management de la sécurité des denrées alimentaires — Exigences pour les organismes procédant à l'audit et à la certification de systèmes de management de la sécurité des denrées alimentaires

IMPORTANT — PLEASE NOTE

This is a provisional mark-up copy and uses the following colour coding:

Text example 1 — indicates added text (in green)

~~Text example 2~~ — indicates removed text (in red)

— indicates added graphic figure

— indicates removed graphic figure

1.x ... — Heading numbers containing modifications are highlighted in yellow in the Table of Contents

DISCLAIMER

This Redline version provides you with a quick and easy way to compare the main changes between this edition of the standard and its previous edition. It doesn't capture all single changes such as punctuation but highlights the modifications providing customers with the most valuable information. Therefore it is important to note that this Redline version is not the official ISO standard and that the users must consult with the clean version of the standard, which is the official standard, for implementation purposes.

COPYRIGHT PROTECTED DOCUMENT

Contents

Page

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.

~~International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.~~

~~The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.~~

~~In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative document:~~

~~— an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote,~~

~~— an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.~~

~~This document is being issued in the Technical Specification series of publications (according to~~ The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part ~~1, 3.1) as a "prospective standard for provisional application" in the field of food safety because there is an urgent need for guidance on how standards in this field should be used to meet an identified need~~ 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).

~~This document is not to be regarded as an "International Standard". It is proposed for provisional application so that information and experience of its use in practice may be gathered. Comments on the content of this document should be sent to the ISO Central Secretariat.~~

~~A review of this Technical Specification will be carried out not later than 3 years after its publication with the options of: extension for another 3 years, conversion into an International Standard, or withdrawal.~~

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 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

~~ISO/TS 22003 was prepared by Technical Committee~~ 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* (~~ISO/~~CASCO).

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

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 ~~FSMSs~~an FSMS can originate from a number of sources~~, and this~~. This Technical Specification has been developed to assist in the certification of ~~FSMSs~~FSMS that fulfil the requirements of ISO 22000~~, Food safety management systems — Requirements for any organization in the food chain~~. The contents of this Technical Specification ~~may~~can also be used to support certification of ~~FSMSs~~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 ~~FSMSs. It gives~~FSMS by providing generic requirements for such ~~certification bodies performing audit and certification in the field of food safety management systems~~bodies. Such bodies are referred to as certification bodies. This wording ~~should not~~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 ~~document. Indeed, this Technical Specification should be usable by any body~~Technical Specification. This Technical Specification is intended to be used by anybody involved in the assessment of ~~FSMSs.~~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 (~~for example~~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 (~~including~~e.g. ~~ISO 22000 FSMS~~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 ~~FSMSs~~FSMS within the wider organization.

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.

— 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), and

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

Certification of FSMSs (named "certification" in this Technical Specification)FSMS is a third-party conformity assessment activity (seeas described in ISO/IEC 17000:2004, 5.5). Bodies, 5.5), and bodies performing this activity are therefore third-party conformity assessment bodies (named "certification body/bodies" in this Technical Specification).

NOTE 1   Certification of an FSMS is sometimes also called "registration", and certification bodies are sometimes called "registrars"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   A certification body can be non-governmental or governmental (with or without regulatory authority).

NOTE 32   This Technical Specification is primarily intended tocan 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 found useful by anyuseful to other parties involved in the conformity assessment of such certification bodies, and in the conformity assessment of anybodies that undertake to certify the compliance of FSMSsFSMS 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.

It is important to note that certification of an FSMS according to ISO 22000 is a management system certification and not a product certification.

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 are indispensable for the application of this document, 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 19011:2002, *Guidelines for quality and/or environmental management systems auditing*~~

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:~~2006~~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.

~~NOTE In this Technical Specification, the terms "product" and "service" are used separately, which is not in accordance with the definition of product given in ISO/IEC 17000.~~

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]

~~Note 1 to entry: Adapted from Reference [8].~~

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 ~~3.2.1, 3.2.2 and 3.2.3 of ISO 9000:2005~~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 ~~given in~~of ISO/IEC 17021:2011, ~~Clause 4 of ISO/IEC 17021:2006~~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.

~~The term "management system" used in ISO/IEC 17021 shall be replaced by "food safety management system" in the context of this Technical Specification.~~

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

All the requirements given in The requirements of ISO/IEC 17021:2011, Clause 5 of ISO/IEC 17021:2006 Clause 5, apply.

5.2   Management of impartiality

The certification body and FSMS consultancy shall not be provided by either the certification body or any part of the same legal entity shall not offer or provide hazard analysis consultancy, FSMS consultancy or management system consultancy.

The fact that the organization employing the auditor is known to have provided hazard analysis consultancy, FSMS consultancy or management system consultancy on the management system, within two years following the end of the consultancy, is likely to be considered as a high threat to impartiality.

The term "management system consultancy" mentioned in 5.2 of ISO/IEC 17021:2006 shall be replaced in the context of this Technical Specification by "hazard analysis consultancy, FSMS consultancy or management system consultancy".

6   Structural requirements

All the requirements given in The requirements of ISO/IEC 17021:2011, Clause 6 of ISO/IEC 17021:2006 Clause 6, apply.

7   Resource requirements

7.1   Competence of management and personnel

All the requirements given in 7.1 of ISO/IEC 17021:2006 apply.

Additionally, the certification body shall have processes to ensure that personnel have appropriate knowledge relevant to the categories (see Annex A) in which it operates.

7.2 7.1 Personnel involved in the certification activities Competence of management and personnel

7.2.1 7.1.1   General considerations

All the requirements given in 7.2 of ISO/IEC 17021:2006 apply.

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

The certification body shall ensure that all personnel involved in the audit and certification activities possess the following personal attributes. The personnel shall be

a)   ethical (i.e. fair, truthful, sincere, honest and discreet);

b)   open-minded (i.e. willing to consider alternative ideas or points of view);

c)   diplomatic (i.e. tactful in dealing with people);

d)   observant (i.e. actively aware of physical surroundings and activities);

e)   perceptive (i.e. instinctively aware of and able to understand situations);

f)   versatile (i.e. adjust readily to different situations);

g)   tenacious (i.e. persistent, focused on achieving objectives);

h)   decisive (i.e. reach timely conclusions based on logical reasoning and analysis), and

i)   self-reliant (i.e. act and function independently while interacting effectively with others).

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.

7.2.2   Personnel carrying out contract review

7.2.2.1   Education

The certification body shall ensure that personnel carrying out contract review have the knowledge corresponding to a secondary education.

7.2.2.2   Food safety training

The certification body shall ensure that personnel carrying out contract review have successfully completed training in

a)   hazard analysis and critical control point (HACCP) principles, hazard assessment and hazard analysis,

b)   food safety management principles including prerequisite programmes (PRPs), and

c)   relevant FSMS standards (e.g. ISO 22000).

7.2.2.3   Audit training

The certification body shall ensure that personnel carrying out contract review have successfully completed training in audit processes based on the guidance given in ISO 19011.

NOTE   It is not mandatory for personnel carrying out contract review to have or to maintain audit experience.

7.2.2.4   Competences

The certification body shall ensure that personnel carrying out contract review demonstrate the ability to apply knowledge and skills in the following areas:

a)   classification of applicants in food chain categories and sectors;

b)   assessment of applicant products, processes and practices;

c)   deployment of FSMS auditor competences and requirements;

d)   determination of audit time (see Annex B) and duration requirements;

e)   certification body's policies and procedures related to contract review.

7.2.3   Personnel granting certification

7.2.3.1   General

The certification body shall ensure that the personnel who take the decision on granting certification have the same education, food safety training, audit training and work experience as required for an auditor in one category (see Annex A).

NOTE   It is not mandatory for personnel granting certification to have or to maintain audit experience.

7.2.3.2   Competences

The certification body shall ensure that personnel granting certification demonstrate the ability to apply knowledge and skills in the following areas:

a)   current principles of HACCP,

b)   understanding of PRPs,

c)   identification of food safety hazards;

d)   implementation and management of food safety hazards, critical control points (CCPs) and the ability to assess the effectiveness of selected control measures;

e)   corrections and corrective actions to be taken with regards to food safety matters;

f)   assessment of potential food safety hazards linked to the food supply chain;

g)   laws and regulations relevant to food safety, in order to be able to conduct an effective audit of the FSMS;

h)   products, processes and practices;

i)   relevant food safety management system requirements;

j)   relevant standards;

k)   assessment and review of an audit report for accuracy and completeness;

l)   assessment and review of the effectiveness of corrective actions;

m)   the certification process.

7.2.4 7.1.2   Auditors Determination of competence criteria

7.2.4.1   Education

The certification body shall ensure that auditors have the knowledge corresponding to a post-secondary education that includes general microbiology and general chemistry.

The certification body shall also ensure that auditors have the knowledge corresponding to a post-secondary education that includes courses in the food chain industry category in which they conduct FSMS audits.

a)   For the food industry (Categories C, D, E, F, G and H in Table A.1): food microbiology, food processing fundamentals and food chemistry including food analysis.

b)   For farming (plants) (Category B in Table A.1): crop production.

c)   For farming (animals) (Categories A and F in Table A.1): animal production.

d)   For packaging/food machine/engineering industry (Categories I to M in Table A.1): science/engineering courses related to the discipline.

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

7.2.4.2   Food safety training

The certification body shall ensure that auditors have successfully completed training in

a)   HACCP principles, hazard assessment and hazard analysis, and

b)   food safety management principles including PRPs.

The training course(s) should be recognized by the industry (and its stakeholders) as being appropriate and relevant. The approval or certification of the training courses by an independent body with the relevant expertise can provide some assurance that the course meets specified criteria.

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.

7.2.4.3   Audit training

The certification body shall ensure that auditors have successfully completed training in

a)   audit techniques based on ISO 19011, and

b)   relevant FSMS standards (e.g. ISO 22000).

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.

7.2.4.4   Work experience

For a first qualification of an auditor in one or more categories, the certification body shall ensure that the auditor has a minimum of five years of full-time work experience in the food chain-related industry, including at least two years of work in quality assurance or food safety functions within food production or manufacturing, retailing, inspection or enforcement, or the equivalent.

The number of years of total work experience may be reduced by one year if the auditor has completed appropriate post-secondary education.

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.

7.2.4.5   Audit experience

For a first qualification, the certification body shall ensure that within the last three years the auditor has performed at least twelve FSMS audit days in at least four organizations under the leadership of a qualified auditor.

NOTE   FSMS audit days include audit days dealing with ISO 9001 in the food industry or other FSMS audits.

For extension to a new category, the certification body shall demonstrate that the auditor has the required competences through relevant education as required in 7.2.4.1, food-safety-related training in the new category, and either

    six months of work experience in the new category, or

    four FSMS audits under the supervision of a qualified auditor in the new category.

For maintaining the qualification of the auditor, the certification body shall ensure that auditors have performed either

    a minimum of five external audits per year, including at least two FSMS audits, or

    a minimum of four FSMS on-site external audits or ten FSMS audit days per year.

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.