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Food safety

Part 1: Requirements for bodies providing audit and certification of food safety management systems

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This British Standard is the UK implementation of ISO 22003-1:2022. It supersedes PD ISO/TS 22003:2013, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee AW/90, Quality systems for the food industry.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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Part 1: Requirements for bodies providing audit and certification of food safety management systems

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

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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.

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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 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.

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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*

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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.

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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.

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