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Food safety —

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.

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.

The site selection shall consider, among others, the following aspects:

a) results of internal audits, management reviews or previous audits;

b) records of complaints, product withdrawals/recalls, and other relevant aspects of corrective action;

c) variations in the site characteristics;

d) other relevant changes since the last audit.

9.1.5.8 If any site has a major nonconformity and satisfactory corrective action have not been implemented in the agreed time frame, certification shall not be granted or maintained for the whole multi-site organization pending satisfactory corrective action.

9.1.5.9 The certification body shall identify and include in the scope of certification the processes of the FSMS implemented at each sampled site.

9.1.6 Multiple management systems standards

ISO/IEC 17021-1:2015, 9.1.6, shall be followed.

9.2 Planning audit

ISO/IEC 17021-1:2015, 9.2, shall be followed.

9.3 Initial certification

9.3.1 ISO/IEC 17021-1:2015, 9.3, shall be followed.

9.3.2 The objectives of stage 1 are to provide a focus for the planning of stage 2 of the initial audit by gaining an understanding of the organization's FSMS and the organization's state of preparedness for stage 2 by reviewing the extent to which:

a) the organization has identified PRPs that are appropriate to the business (e.g. regulatory, statutory, customer and certification scheme requirements);

b) the FSMS includes adequate processes and methods for the identification and assessment of the organization's food safety hazards, and subsequent selection and categorization of control measures (combinations);

c) the FSMS includes adequate processes and methods for the identification and implementation of relevant food safety legislation;

d) the FSMS is designed to achieve the organization's food safety policy;

e) the FSMS implementation programme justifies proceeding to stage 2;

f) the validation of control measures, verification of activities and improvement programmes conform to the requirements of the FSMS standard;

g) the FSMS documents and arrangements are in place to communicate internally and with relevant suppliers, customers and interested parties;

h) there is any additional documentation which needs to be reviewed and/or information which needs to be obtained in advance.

9.3.3 Where an organization has implemented externally developed elements of a FSMS, stage 1 shall review the documentation included in the FSMS to determine if the combination of control measures:

— is suitable for the organization;

— was developed in conformity to the requirements of ISO 22000 or other sets of specified FSMS requirements;

— is kept up to date.

9.3.4 The availability of relevant authorizations shall be checked when collecting the information regarding the compliance to regulatory aspects.

9.3.5 For FSMS, stage 1 shall be carried out at the client's premises in order to achieve the objectives stated above. In exceptional circumstances or events, all or part of stage 1 can take place off-site or remotely through the use of ICT and shall be fully justified. The evidence demonstrating that stage 1 objectives are fully achieved shall be provided.

NOTE 1 Exceptional circumstances or events can include a very remote location, a natural disaster, a pandemic, a short seasonal production and other special situations.

NOTE 2 Any part of the FSMS that is audited during the stage 1 audit, and determined to be fully implemented, effective and in conformity with requirements, does not necessarily need to be re-audited during stage 2. In this case, the audit report includes these findings and clearly states that conformity has been established during the stage 1 of the audit.

9.3.6 The interval between stage 1 and stage 2 shall not be longer than six months. Stage 1 shall be repeated if a longer interval is needed.

9.3.7 ISO/IEC 17021-1:2015, 9.3.1.3 and 9.3.1.4, shall be followed.

9.4 Conducting audits

ISO/IEC 17021-1:2015, 9.4, shall be followed.

9.5 Certification decision

ISO/IEC 17021-1:2015, 9.5, shall be followed.

9.6 Maintaining certification

9.6.1 ISO/IEC 17021-1:2015, 9.6, shall be followed.

9.6.2 Where the certification body conducts unannounced audits as part of surveillance activities, the certification body shall describe and make known in advance to the certified clients the conditions under which such audits will be organized and conducted.

9.7 Appeals

ISO/IEC 17021-1:2015, 9.7, shall be followed.

9.8 Complaints

ISO/IEC 17021-1:2015, 9.8, shall be followed.

9.9 Client records

ISO/IEC 17021-1:2015, 9.9, shall be followed.

10 Management system requirements for certification bodies

ISO/IEC 17021-1:2015, Clause 10, shall be followed.

Annex A
(normative)

Classification of food chain categories

The certification body shall use Table A.1 for the following purposes:

a) to define the subcategory (or category if no subcategory) within which it wishes to operate;

b) to identify the subcategories (or category if no subcategory) to which the client's scope will be audited or certified;

c) to assess the auditor and audit team competence given in Annex C within a particular subcategory of Table A1;

d) to define the audit duration in accordance with Annex B;

e) to identify the appropriate PRPs, if applicable.

The scope of one specific client organization may cover more than one subcategory or category.

NOTE Relevant activities within the category H "services": for operators in the food chain, there are many different types of services that can be provided or called upon. Some of these services can fall outside the scope of a certification that includes FSMS. If the organization/service is susceptible to introduce a food safety hazard within the food chain, the service provider and its operator(s) can be considered within the scope.

Where a scheme owner has established their own rules for determination for categories/subcategories, the outcome of the scheme rules shall apply provided that the scheme rules are not less than those required in this annex as a common basis.

Table A.1 — Food chain categories

Cluster[a]	Category		Subcategory		Examples of included activities
Primary production	A	Farming or handling of animals	AI	Farming of animals for meat/milk/ eggs/honey	Raising animals (other than fish and aquaculture) used for meat production, egg production, milk production or honey production. Growing, keeping, trapping and hunting (slaughtering at point of hunting). Associated temporary packing without modification or processing of the product.
			AII	Farming of fish and seafood	Raising fish and seafood used for meat production. Growing, trapping and fishing (slaughtering at point of capture). Associated temporary packing without modification or processing of the product.

[a] Clusters can be used for accreditation scope of accredited certification bodies, and for accreditation bodies witnessing certification bodies.

NOTE "Perishable" can be considered as food of a type or condition such that it can spoil and must be preserved in a temperature controlled environment.

Table A.1 *(continued)*

Cluster[a]	Category		Subcategory		Examples of included activities
	B	Farming or handling of plants	BI	Farming – Handling of plants (other than grains and pulses)	Growing or harvesting of plants (other than grains and pulses): horticultural products (fruits, vegetables, spices, mushrooms, etc.) and hydrophytes for food. On farm storage of plants (other than grains and pulses), including horticultural products and hydrophytes for food.
			BII	Farming – Handling of grains and pulses	Growing and harvesting of grains and pulses for food. Handling grains and pulses. On farm storage of grains and pulses for food.
			BIII	Pre-process handling of plant products	Activities on harvested plants that do not transform the product from original whole form, including horticultural products and hydrophytes for food. These include cleaning, washing, rinsing, fluming, sorting, grading, trimming, bundling, cooling, hydro-cooling, waxing, drenching, aeration preparing for storage or processing, packing, repacking, staging, storing and loading.
Processing food for humans and animals	C	Food, ingredient and pet food processing	CO	Animal – Primary conversion	Conversion of animal carcasses intended for further processing including lairage, slaughter, evisceration, bulk chilling, bulk freezing, bulk storage of animals and game gutting, bulk freezing of fish and storage of game.
			CI	Processing of perishable animal products	Processing and packaging including fish, fish products, seafood, meat, eggs and dairy requiring chilled or frozen temperature control. Processing of pet food from animal products only.
			CII	Processing of perishable plant-based products	Processing and packaging including fruits and fresh juices, vegetables, grains, nuts, pulses, frozen water-based products, plant-based meat and dairy substitutes. Processing pet food from plant products only.
			CIII	Processing of perishable animal and plant – Products (mixed products)	Processing and packaging including pizza, lasagne, sandwiches, dumplings and ready-to-eat meals. Includes off-site catering kitchens. Includes products of industrial kitchens not offered for immediate consumption. Processing perishable pet food from mixed products

[a] Clusters can be used for accreditation scope of accredited certification bodies, and for accreditation bodies witnessing certification bodies.

NOTE "Perishable" can be considered as food of a type or condition such that it can spoil and must be preserved in a temperature controlled environment.

Table A.1 *(continued)*

Cluster[a]	Category		Subcategory		Examples of included activities
			CIV	Processing of ambient stable products	Processing and packaging of products stored and sold at ambient temperature including canned foods, biscuits, snacks, oil, drinking water, beverages, pasta, flour, sugar and food-grade salt. Processing ambient stable pet food.
	D	Feed and animal food processing			Processing feed material intended for food and non-food producing animals not kept in households, e.g. meal from grain, oilseeds, by-products of food production. Processing feed mixtures, with or without additives, intended for food-producing animals, e.g. premixes, medicated feed, compound feeds.
Catering/food service	E	Catering/food service			Open exposed food activities such as cooking, mixing and blending, preparation of components and products for on-site direct consumer consumption or take away. Examples include restaurants, hotels, food trucks, institutions, work places (school or factory cafeteria), including retail with on-site preparation (e.g. rotisserie chicken). Includes reheating of food, event catering, coffee shops and pubs.
Retail, transport and storage	F	Trading, retail and e-commerce	FI	Retail/ wholesale	Storage and provision of finished products to customers and consumers (retail outlets, shops, wholesalers). Includes minor processing activities, e.g. slicing, portioning, reheating.
			FII	Brokering/ trading	Buying and selling products on its own account without physical handling or as an agent for others of any item that enters the food chain.
	G	Transport and storage services			Storage facilities and distribution vehicles for perishable food and feed where temperature integrity shall be maintained. Storage facilities and distribution vehicles for ambient stable food and feed. Relabelling/repackaging excluding open exposed product materials. Storage facilities and distribution vehicles for food packaging material.
Auxiliary services	H	Services			Services provisioned related to the safe production of food and feed including water supply, pest control, cleaning services and waste disposal.

[a] Clusters can be used for accreditation scope of accredited certification bodies, and for accreditation bodies witnessing certification bodies.

NOTE "Perishable" can be considered as food of a type or condition such that it can spoil and must be preserved in a temperature controlled environment.

Table A.1 *(continued)*

Cluster[a]	Category		Subcategory		Examples of included activities
Packaging material	I	Production of packaging material			Production of packaging material in contact with food, feed and animal food. May include packaging produced on-site for use in processing.
Auxiliary equipment	J	Equipment			Equipment for food, feed or packaging processing, vending machines, kitchen equipment, processing utensils, filters, hygienic design of equipment and facilities.
Bio/chemical	K	Chemical and bio-chemical			Production of food and feed processing aids, additives (e.g. flavourings, vitamins), gases and minerals. Production of bio-cultures and enzymes.

[a] Clusters can be used for accreditation scope of accredited certification bodies, and for accreditation bodies witnessing certification bodies.

NOTE "Perishable" can be considered as food of a type or condition such that it can spoil and must be preserved in a temperature controlled environment.

Annex B
(normative)

Minimum audit duration

B.1 Audit outcome requirements

Audit duration shall be justified to accomplish the following audit outcomes:

a) assesses effective implementation (identification and selection if allowed) of the management of food safety hazards [this includes hazard analysis and critical control points (HACCP) and PRPs] as defined by the scheme;

b) assesses effective management of the interrelated processes of the FSMS;

c) assesses system ability to meet applicable statutory and regulatory requirements;

d) assesses the organization's use of an effective risk-based approach to products and processes and management of change;

e) assesses whether the requirements of the scheme and of the organization, if any, are met;

f) verifies that the certification scope is appropriate to the activities of the organization and audit sampling is representative.

B.2 Determining audit duration

In determining the audit duration, the certification body shall consider, among other things, the following aspects:

a) the requirements of the relevant standards or schemes that may be included in, or in addition to, audit duration;

b) the categories and subcategories given in Table A.1 (if the scope of the organization covers more than one category, the audit duration calculation shall be taken from the highest recommended basic audit duration);

c) the complexity of the client activities (e.g. number of product and process types, number of product lines, number of people or type and variety of tasks affecting food safety, product development, in-house laboratory testing, sanitation) and its FSMS;

d) the hazards associated with the products, processes and services of the organization;

e) the statutory and regulatory context;

f) any outsourcing of any activities included in the scope of certification;

g) the maturity and effectiveness of the FSMS, type of audit (e.g. initial, surveillance, unannounced, follow-up) and the results of any prior audits;

h) the site size, infrastructure and number of sites, their geographical locations and seasonality;

i) the multi-site considerations;

j) whether audits are combined, joint or integrated;

k) the audit delivery method (e.g. ICT and the extent used);

l) the level of centralized control of the FSMS;

m) the level of automation, closed production systems, use of technology, mechanization and labour intensiveness;

n) any language or interpretation needs.

B.3 Calculation of minimum audit duration

B.3.1 General

FSMS audits shall meet the minimum audit duration calculation given in B.3.2 using the requirements of Annexes A and B. FSMS schemes may design their own categories and audit duration calculations in excess of Annex B. Certification bodies shall follow scheme categories and audit duration calculations referenced in the requirements of Annexes A and B. The minimum audit duration includes stage 1 and stage 2 of the initial certification.

When determining the number of employees involved in any aspect of food safety, it shall be expressed as the number of full-time equivalent (FTE) employees. When an organization deploys workers in shifts and the products and/or processes are similar, the FTE number will be calculated based on employees on the main shift (including seasonal workers) plus non-production staff having an impact on food safety.

In cases of unusually high repetitive shifts or process, a coherent and consistent reduction can be applied on a company-to-company basis within the scope of certification. The determination and its justification by the certification body shall be recorded.

Audit duration does not include time for audit planning, audit preparation, travel to and from site, audit follow-up activities if there are nonconformities, or team member(s) not assigned as an auditor (i.e. technical experts, translators, interpreters, observers and auditors-in-training, and report writers).

Where a scheme owner has established their own rules for determination for audit duration, the outcome of the scheme rules shall apply provided that the scheme rules are not less than those required in this annex as a common minimum.

B.3.2 Initial audit duration calculation

The minimum initial certification audit duration for FSMS certification audits shall be given as D_S, expressed in days, which is calculated, considering Table B.1:

$$D_S = (T_D + T_H + T_{FTE})$$

where

D_S is the total audit duration;

T_D is the basic site audit duration for (sub) category and scope of certification (includes one HACCP study), in days;

T_H is the number of audit days for additional HACCP studies;

T_{FTE} is the number of audit days per number of FTE employees.

Table B.1 — Variables for calculation of minimum audit duration

Category or subcategory	Basic site audit duration, in audit days T_D	Number of audit days for each additional HACCP study T_H	Effective number FTE T_{FTE}
AI	1,0	0,25	1 to 5 = 0 6 to 49 = 0,5 50 to 99 = 1,0 100 to 199 = 1,5 200 to 499 = 2,0 500 to 999 = 2,5 > 1 000 = 3
AII	1,0	0,25	
BI	1,0	0,25	
BII	1,0	0,25	
BIII	1,0	0,25	
CO	2,0	0.50	
CI	2,0	0,50	
CII	2,0	0,50	
CIII	2,0	0,50	
CIV	2,0	0,50	
D	1,0	0,50	
E	1,5	0,50	
FI	1,0	0,50	
FII	1,0	0,5	
G	1,5	0,25	
H	1,5	0,25	
I	1,5	0,50	
J	1,5	0,50	
K	2,0	0,5	

If there are multiple categories or subcategories, use the category or subcategory with the highest T_D value to determine D_S. The combined parameters (HACCP study, FTE) for all the categories/subcategories shall be used when calculating the audit duration.

When the scheme requirements encompass other interrelated elements [e.g. good agricultural practice (GAP), agronomic] audited in conjunction with the FSMS, these shall be included in the minimum audit duration.

The resulting audit duration using the factors in Clause B.2 and Table B.1 shall be justified and documented.

A minimum 50 % of total audit duration shall be spent on auditing the operational food safety planning and the implementation of PRPs and control measures.

NOTE 1 Operational food safety planning does not include activities related to FSMS development, training, internal audit, management review and improvement.

In cases of a FSMS which is integrated with another relevant management system or food safety system (FSS), a reduction in audit duration is possible. The combined audit duration shall be determined and recorded as follows:

— calculate the audit duration for each scheme separately (including scheme restrictions and allowed reductions);

— add the audit durations together;

— determine the degree of reduction considering a maximum of 20 % reduction can be made on the combined duration. The reduction range based on integration is 0 % to 20 % determined by the level of integration of overall business strategy, management reviews, approach to policy, objectives, systems, processes, internal audits and effective corrective action to prevent reoccurrence.

NOTE 2 “Relevant management system” means a quality or food safety system which covers the same processes, products and services.

Deviations from Table B.1 can be justified and shall be recorded, determined by factors such as maturity of the management system, prior knowledge of client processes and systems (e.g. already certified by same certification body to different scheme), client preparedness (e.g. already certified by a relevant third-party scheme) and a high level of automation.

B.3.3 Multi-site certification

The site audit duration of the central function shall be equal to or greater than D_s.

The site audit duration for each site audited shall be equal to or greater than half of D_s for that site.

B.3.4 Calculation of minimum surveillance and recertification audit duration

The minimum surveillance audit duration shall not be less than one third of the initial certification audit duration, with a minimum of 1 audit day (0,5 audit day for categories A and B).

The minimum recertification audit duration shall not be less than two thirds of the initial certification audit duration, with a minimum of 1 audit day (0,5 audit day for categories A and B).

Annex C
(normative)

Required food safety management system knowledge and skills to determine competence

C.1 General

Table C.1 specifies the knowledge and skills that a certification body shall define for specific certification functions. "X" indicates that the certification body shall define the criteria and depth of knowledge and skills.

Table C.1 — Table of knowledge and skills

Knowledge and skills	Certification functions		
	Conducting the application review to determine the audit team competence required, to select the audit team members, and to determine the audit time	**Auditing and leading the audit team**	**Reviewing audit reports and making certification decisions**
1. Ability to apply the application review requirements in this document, specific scheme rules and certification body procedures including: — categorizing the organization into food categories and subcategories, in accordance with Annex A; — determining the complexity of the organization's activities; — multi-site sampling; — calculating audit duration[a].	X		
2. Ability to identify and to determine factors relevant to food chain categories (with reference to Table A.1) and to the organization, including: — PRPs; — food safety hazards; — statutory and regulatory requirements; — any specific seasonality factors related to the organization and its food category or products; — specific cultural and social customs related to the categories and geographic areas to be assessed; — specific factors required to audit the FSMS, food product, process or service.	X	X	X

[a] For the team leader, the ability to understand the principles of audit duration calculation in order to alert the certification body in case of significant change.

[b] It is not expected that the certification decision function requires competence specific to the food chain category.

Table C.1 *(continued)*

Knowledge and skills	Certification functions		
	Conducting the application review to determine the audit team competence required, to select the audit team members, and to determine the audit time	**Auditing and leading the audit team**	**Reviewing audit reports and making certification decisions**
3. Ability to identify the auditor competencies required for categories and subcategories in accordance with Table A.1 and certification body procedures.	X	X	X
4. Ability to apply generic audit principles, practices and techniques, as specified in this document, sufficient to conduct certification audits and to evaluate internal audit processes.		X	X
5. Ability to conduct and manage an audit to achieve the audit objectives within the agreed time frame. For the team leader, the ability to facilitate meetings for the effective exchange of information and the ability to make assignments or re-assignments where necessary.		X	
6. Knowledge of the terminology, practices and processes common to an/the organization's business sector sufficient to understand the sector's expectations in the context of the standard/scheme or other normative documents.		X	X
7. Knowledge of general organization types, size, governance, structure and workplace practices, information and data systems, documentation systems and information technology.		X	X
8. Knowledge of the role and impact of the leadership of the organization and the ability to evaluate whether the top management of the organization under audit is demonstrating commitment to the FSMS, providing adequate resources and achieving its intended outcomes.		X	
9. Ability to apply normative documents being specified for certification sufficient to determine if its scope and audit duration is appropriate and that the scheme/standard has been effectively implemented and conforms to requirements.		X	X
10. Knowledge related to the types of products or processes of a client sufficient to understand how such an organization can operate, and how the organization can apply the requirements of the standard/scheme or other relevant normative documents.	X	X	

[a] For the team leader, the ability to understand the principles of audit duration calculation in order to alert the certification body in case of significant change.

[b] It is not expected that the certification decision function requires competence specific to the food chain category.

Table C.1 *(continued)*

Knowledge and skills	Certification functions		
	Conducting the application review to determine the audit team competence required, to select the audit team members, and to determine the audit time	**Auditing and leading the audit team**	**Reviewing audit reports and making certification decisions**
11. Ability to identify[b]: — biological hazards; — chemical hazards; — physical hazards; — allergens; — food safety labelling requirements; — food safety regulations that are relevant to the food chain category (see Annex A) and their recognized control mechanisms. Ability to evaluate the organization's capacity to identify and meet applicable (country of production/country of destination) food safety regulation and labelling requirements.		X	X
12. Ability to apply the principles of food safety, HACCP, hazard assessment and hazard analysis in the food chain (sub)category[b]. Ability to apply scheme requirements including, but not limited to: — outsourced processes; — food defence; — food fraud.		X	X
13. Ability to apply food chain (sub)category practices and vocabulary in relation to: — food chain relationships; — best practice with respect to PRPs and control measures; — common food chain processes; — production technologies and processing terms; — common equipment; — facility design; — packaging types and attributes; — microbiological terms and names; — chemical terms and names; — good laboratory practices; — local terminology.		X	

[a] For the team leader, the ability to understand the principles of audit duration calculation in order to alert the certification body in case of significant change.

[b] It is not expected that the certification decision function requires competence specific to the food chain category.

Table C.1 *(continued)*

Knowledge and skills	Certification functions		
	Conducting the application review to determine the audit team competence required, to select the audit team members, and to determine the audit time	**Auditing and leading the audit team**	**Reviewing audit reports and making certification decisions**
14. Understanding the organization and its responsibilities for external communication[b]. Understanding the organizational structures, cultures and communication methodologies. Ability to assess whether the organization is meeting required communication objectives.		X	X
15. Ability to evaluate audit reports, corrective action documentation and other information needed to make a certification decision.			X
16. Ability to communicate effectively to fulfil their function within the certification process. For audit team members, ability to communicate effectively with persons at any level of an organization, including top management, using appropriate terms, expressions and speech.	X	X	X
17. Ability to read and write to fulfil their function within the certification process. For audit team members, ability to read and write with sufficient speed, accuracy and comprehension to record, take notes, and effectively communicate audit findings and conclusions.	X	X	X
18. Ability to present audit findings and conclusions to be easily understood. For presenting in a public forum (e.g. closing meeting) audit findings, conclusions, and recommendations appropriate to the audience.		X	
19. Ability to interview to obtain information relevant to their function within the certification process. Ability to interview by asking open-ended, well formulated questions and listening to understand and evaluate the answers.		X	

[a] For the team leader, the ability to understand the principles of audit duration calculation in order to alert the certification body in case of significant change.

[b] It is not expected that the certification decision function requires competence specific to the food chain category.

Annex D
(informative)

Guidance on generic certification functions

D.1 General

This annex provides useful 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 for personnel involved in audit and certification of an FSMS should be determined.

D.2 Application review

— Determine if the proposed certification (contract) fits within scope of the certification body's scope of operations (e.g. accreditation, regulatory authorization).

— Determine if there are specific issues to be considered (issues specific to locality, industry, legislation, organization, etc.)

— Determine if there are multi-site issues.

— Determine if there are seasonality issues.

— Calculate the audit duration or duration of combined or integrated audit durations.

— Create a certification agreement/contract.

— Finalize a certification agreement/contract with client.

D.3 Selection of audit teams

— Determine resource needs (e.g. competencies, number of auditors based on audit duration and number of categories, technical experts, interpreters).

— Determine if competent resources (e.g. auditors, technical experts) are available.

— Review resource (e.g. auditor) selection for impartiality.

D.4 Planning audit activities

— Verify the scope of the audit.

— Review the history of facility to be audited.

— Confirm resource needs.

— Confirm travel plans.

— Develop or confirm the audit strategy and methodology.

— Assign audit team roles, responsibilities and activities.

— Develop the audit plan, including the sampling plan.

— Review audit logistics.

— Consider the results of any previous audits and corrective actions.

— Consider any regulatory requirements.

— Plan audit team meetings.

D.5 Auditing

D.5.1 Conduct document review

— Obtain programme documentation.

— Review documentation against requirements.

— Verify the organization's management system.

— Determine if the organization's documents meet requirements or identify nonconformities.

— Establish investigative lines for the stage 2 audit.

— Confirm readiness for the stage 2 audit.

D.5.2 Conduct opening meeting

— Confirm the certification scope.

— Review the audit criteria/methodology and explain the outcome (e.g. audit as sampling, process approach).

— Establish communication channels.

— Identify guides/escorts.

— Confirm the reporting method.

— Identify food safety and security requirements.

— Confirm the audit plan.

— Reaffirm the time of the closing meeting.

— Complete the meeting records.

D.5.3 Collecting and verifying information

— Verify the process flow chart.

— Assess the effectiveness of the implementation of control measures and processes.

— Verify the effectiveness of corrective actions of previous nonconformities/deficiencies.

— Perform the process approach audit.

D.5.4 Preparation for closing meeting

— Hold an audit team preparatory meeting (if required).

— Analyse audit findings and compare them with requirements.

— Confirm the completion of the audit plan.

— Categorize, review and finalize any nonconformities and opportunities for improvement, and relate them to the process and the system.

— Prepare the preliminary audit report.

D.5.5 Conduct closing meeting

— Present and review the audit findings (nonconformities and/or opportunities for improvement).

— Confirm the objectives of the audit have been met.

— Provide positive feedback.

— Explain the next steps (e.g. appeals, post-audit processes, certification decision-making timeline).

— Obtain written acknowledgement of nonconformities.

— Complete the meeting records.

D.5.6 Audit reporting

— Describe the findings against the certification standard's requirements (e.g. nonconformities, opportunities for improvement).

— Incorporate comments of competence and conformity.

— Describe the final audit conclusions.

— Judge the effectiveness of corrective actions (when required).

— Finalize the audit report.

D.5.7 Conducting post-audit activities

— Deliver the audit report.

— Communicate any information regarding nonconformity resolution timing.

— Report any unusual circumstances that occurred during the audit.

— Review corrective actions for appropriateness.

— Determine requirements for the verification of corrective actions.

— Verify the effectiveness of implementation of corrective actions.

— Report any necessary adjustment of the audit programme, as appropriate.

D.6 Certification decision

— Review the report and other relevant information necessary to make a decision regarding certification.

— Interact with the audit team regarding audit findings (if required).

— Resolve problems with the audit team regarding the audit undertaken (if required).

— Determine if the evidence available supports the issuing of certification.

— Document the decision.

— Provide feedback to the audit team (if required).

D.7 Develop professional competence

D.7.1 Identify development needs

— Auditing.

— Technical.

— Management systems.

— Skills.

D.7.2 Expand competence

— Participate in professional development activities.

— Participate in certification body or other auditor calibration activities.

— Undertake self-study or training activities.

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