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

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National foreword

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

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

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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).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 17, *Management systems for food safety*, in collaboration with the *ISO Committee on conformity assessment* (CASCO).

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

Introduction

Certification of the food safety management system (FSMS) of an organization is one means of providing assurance that the organization has implemented a system for the management of food safety in line with its policy.

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

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

Certification activities involve the audit of an organization's FSMS. The form of attestation of conformity of an organization's FSMS to a specific FSMS standard (e.g. ISO 22000) or other specified requirements is normally a certification document or a certificate.

It is for the organization being certified to develop its own management systems (e.g. FSMS in accordance with ISO 22000, other sets of specified FSMS requirements, quality management systems, environmental management systems or occupational health and safety management systems) and, other than where relevant legislative requirements specify to the contrary, it is for the organization to decide how the various components of these will be arranged. The degree of integration between the various management system components will vary from organization to organization. It is therefore appropriate for certification bodies that operate in accordance with this Technical Specification to take into account the culture and practices of their clients with respect to the integration of their FSMS within the wider organization.

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

1 Scope

This Technical Specification defines the rules applicable for the audit and certification of a food safety management system (FSMS) complying with the requirements given in ISO 22000 (or other sets of specified FSMS requirements). It also provides the necessary information and confidence to customers about the way certification of their suppliers has been granted.

Certification of FSMS is a third-party conformity assessment activity (as described in ISO/IEC 17000:2004, 5.5), and bodies performing this activity are third-party conformity assessment bodies.

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

NOTE 2 This Technical Specification can be used as a criteria document for the accreditation or peer assessment of certification bodies which seek to be recognized as being competent to certify that an FSMS complies with ISO 22000. It is also intended to be used as a criteria document by regulatory authorities and industry consortia which engage in direct recognition of certification bodies to certify that an FSMS complies with ISO 22000. Some of its requirements could also be useful to other parties involved in the conformity assessment of such certification bodies, and in the conformity assessment of bodies that undertake to certify the compliance of FSMS with criteria additional to, or other than, those in ISO 22000.

FSMS certification does not attest to the safety or fitness of the products of an organization within the food chain. However, ISO 22000 requires an organization to meet all applicable food-safety-related statutory and regulatory requirements through its management system.

NOTE 3 Certification of an FSMS according to ISO 22000 is a management system certification, not a product certification.

Other FSMS users can use the concepts and requirements of this Technical Specification provided that the requirements are adapted as necessary.

2 Normative references

The following referenced documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 22000:2005, *Food safety management systems — Requirements for any organization in the food chain*

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

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

3 Terms and definitions

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

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

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

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

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

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

4 Principles

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

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

5 General requirements

5.1 General

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

5.2 Management of impartiality

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

6 Structural requirements

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

7 Resource requirements

7.1 Competence of management and personnel

7.1.1 General considerations

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

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

7.1.2 Determination of competence criteria

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

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

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

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

NOTE 3 Qualification(s) and experience can be used as part of the criteria; however, competence is not based on these alone, as it is important to ensure that a person can demonstrate the ability to apply the specific knowledge and skills that one would expect a person to have after completing a qualification or having a certain amount of industry experience.

7.1.3 Evaluation processes

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

Evaluation processes shall evaluate, in particular, the individual's knowledge relating to food safety, including knowledge of specific prerequisite programmes (PRP) and food safety hazards related to the categories within which the certification body personnel operate. These shall have been identified for these categories under the requirements of 7.1.2.

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

7.1.4 Other considerations

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

7.2 Personnel involved in the certification activities

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

7.3 Use of individual external auditors and external technical advisors

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

7.4 Personnel records

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

7.5 Outsourcing

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

8 Information requirements

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

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

9 Process requirements

9.1 General requirements

9.1.1 The certification body shall use Annex A to define the relevant scope for the organization applying for certification. The certification body shall not exclude activities, processes, products or services from the scope of certification when those activities, processes, products or services can have an influence on the food safety of the end products as defined in the scope of certification.

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

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

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

The certification body shall have documented procedures for determining audit time, and for each client, the certification body shall determine the time needed to plan and accomplish a complete and effective audit of the client's FSMS. The audit time determined by the certification body, and the justification for the determination, shall be recorded.

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

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

9.1.5.1 A multi-site organization is an organization having an identified central function (hereafter referred to as a central office – but not necessarily the headquarters of the organization) at which certain FSMS activities are planned, controlled or managed, and a network of sites at which such activities are fully or partially carried out. Examples of possible multi-site organizations are:

— organizations operating with franchises;

— a manufacturing company with one or more production sites and a network of sales offices;

— service organizations with multiple sites offering a similar service;

— organizations with multiple branches.

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

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

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

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

9.1.5.3 The use of multi-site sampling is only possible for categories A, B, E, F and G (see Table A.1) and for organizations with more than 20 sites operating similar processes within these categories. This applies to the initial certification, to surveillance and to recertification audits. The certification body shall justify its decision on sampling for multi-site certification.

Where multi-site sampling is permitted, following certification, the annual internal audit programme shall include all sites of the organization.

NOTE Risk is another consideration when determining sampling and can increase the level of sample indicated in Table 1.

9.1.5.4 Where the certification body offers multi-site sampling, the certification body shall utilize a sampling programme to ensure an effective audit of the FSMS where the following apply.

a) For organizations with 20 sites or less, all sites shall be audited. The sampling for more than 20 sites shall be at the ratio of 1 site per 5 sites. All sites shall be randomly selected and, after the audit, no sampled sites may be nonconforming (i.e. not meeting certification thresholds for ISO 22000).

b) At least annually, an audit of the central office for the FSMS shall be performed by the certification body.

c) At least annually, surveillance audits shall be performed by the certification body on the required number of sampled sites.

d) Audit findings of the sampled sites shall be considered indicative of the entire system and correction shall be implemented accordingly.

Table 1 gives examples of the number of sites to audit when sampling is used.

Table 1 — Examples of the number of sites to be audited when multi-site sampling is used

	Total number of sites								
	Number of sites to be audited between 1 and 20	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**
Number of sites above 20	0	1	2	3	4	5	6	7	8
Additional number of sites to audit	0	1	1	1	1	1	2	2	2
Number of sites to be audited	*x*	21	21	21	21	21	22	22	22

9.1.6 The requirements of ISO/IEC 17021:2011, 9.1.6 to 9.1.9, apply.

9.1.7 Audit report: the requirements of ISO/IEC 17021:2011, 9.1.10, apply.

9.1.8 The certification body shall provide a written report for each audit. The audit team may identify opportunities for improvement, but shall not recommend specific solutions. Ownership of the audit report shall be maintained by the certification body.

The report shall include information about PRP used by the organization, hazard analysis methodology used, comments on the food safety team, and other issues relevant to the FSMS.

NOTE The stage 1 documented conclusions do not need to meet the full requirements of a report (see ISO/IEC 17021:2011, 9.1.10).

9.1.9 The requirements of ISO/IEC 17021:2011, 9.1.11 to 9.1.15, apply.

9.2 Initial audit and certification

9.2.1 Application

The requirements of ISO/IEC 17021:2011, 9.2.1, apply.

The certification body shall require the applicant organization to provide detailed information concerning process lines, HACCP studies and the number of shifts.

9.2.2 Application review

The requirements of ISO/IEC 17021:2011, 9.2.2, apply.

9.2.3 Initial certification audit

The initial certfication audit of an FSMS shall be conducted in two stages: stage 1 and stage 2.

9.2.3.1 Stage 1

9.2.3.1.1 The requirements of ISO/IEC 17021:2011, 9.2.3.1.1, apply.

9.2.3.1.2 The objectives of the stage 1 are to provide a focus for planning the stage 2 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 PRP 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) relevant food safety legislation is implemented,

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

e) the FSMS implementation programme justifies proceeding to the audit (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, and

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

Where an organization has implemented an externally developed combination of control measures, the 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 compliance with the requirements of ISO 22000, and

— is kept up to date.

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

9.2.3.1.3 For FSMS, the stage 1 shall be carried out at the client's premises in order to achieve the objectives stated above.

In exceptional circumstances, part of stage 1 can take place off-site and shall be fully justified. The evidence demonstrating that stage 1 objectives are fully achieved shall be provided. Exceptional circumstances can include very remote location, short seasonal production

9.2.3.1.4 The requirements of ISO/IEC 17021:2011, 9.2.3.1.2, apply.

The client shall be informed that the results of the stage 1 may lead to postponement or cancellation of the stage 2.

9.2.3.1.5 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, may not need to be re-audited during the stage 2 audit. However, the certification body shall ensure that the already audited parts of the FSMS continue to conform to the certification requirements. In this case, the audit report shall include these findings and shall clearly state that conformity has been established during the stage 1 audit.

9.2.3.1.6 The requirements of ISO/IEC 17021:2011, 9.2.3.1.3, apply.

The interval between stage 1 and stage 2 shall not be longer than 6 months. Stage 1 shall be repeated if a longer interval is needed.

9.2.3.2 Stage 2

The requirements of ISO/IEC 17021:2011, 9.2.3.2, apply.

9.2.4 Initial certification audit conclusions

The requirements of ISO/IEC 17021:2011, 9.2.4, apply.

9.2.5 Information for granting initial certification

The requirements of ISO/IEC 17021:2011, 9.2.5, apply.

9.3 Surveillance activities

The requirements of ISO/IEC 17021:2011, 9.3, apply.

9.4 Recertification

The requirements of ISO/IEC 17021:2011, 9.4, apply.

9.5 Special audits

The requirements of ISO/IEC 17021:2011, 9.5, apply.

9.6 Suspending, withdrawing or reducing the scope of certification

The requirements of ISO/IEC 17021:2011, 9.6, apply.

9.7 Appeals

The requirements of ISO/IEC 17021:2011, 9.7, apply.

9.8 Complaints

The requirements of ISO/IEC 17021:2011, 9.8, apply.

9.9 Records of applicants and clients

The requirements of ISO/IEC 17021:2011, 9.9, apply.

10 Management system requirements for certification bodies

The requirements of ISO/IEC 17021:2011, Clause 10, apply.

Annex A
(normative)

Classification of food chain categories

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

a) to define the scope within which it wishes to operate;

b) to identify whether any technical qualification of its auditors is necessary for that particular category;

c) to assess the auditor competence within a particular category;

d) to assess the audit team competence within a particular subcategory;

e) to define the audit duration in accordance with Annex B of this Technical Specification;

f) to identify the appropriate part of the ISO/TS 22002 series, if applicable, for the assessment of compliance with ISO 22000:2005, 7.2;

g) to define the scope of certification document at subcategory level.

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

NOTE 1 When selecting appropriate PRP, reference is first made to the ISO/TS 22002 series; subsequently, reference could be made to other sources, such as Codex Alimentarius Commission. See ISO 22000:2005, 7.2.3.

NOTE 2 Relevant activities within the "services" category: 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 the FSMS. In order to determine which services are within the scope, the following two questions provide a useful filter for determining the relevance to the FSMS:

— Is the organization/service susceptible to introduce a food safety hazard within the food chain?

— Has the organization/service provider decisive influence and authority on the food related processes?

If the answer is affirmative to at least one of the two questions above, the service provider and its operator(s) can be considered within the scope.

Table A.1 — Food chain categories

Cluster [a]	Category		Subcategory		Examples of included activities
Farming	**A**	Farming of Animals	**AI**	Farming of Animals for Meat/ Milk/ Eggs/ Honey	Raising animals (other than fish and seafood) used for meat production, egg production, milk production or honey production Growing, keeping, trapping and hunting (slaughtering at point of hunting) Associated farm packing [b] and storage
			AII	Farming of Fish and Seafood	Raising fish and seafood used for meat production Growing, trapping and fishing (slaughtering at point of capture) Associated farm packing [b] and storage
	B	Farming of Plants	**BI**	Farming 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 Associated farm packing [b] and storage
			BII	Farming of Grains and Pulses	Growing or harvesting of grains and pulses for food Associated farm packing [b] and storage
Food and feed processing	**C**	Food Manufacturing	**CI**	Processing of perishable animal products	Production of animal products including fish and seafood, meat, eggs, dairy and fish products
			CII	Processing of perishable plant products	Production of plant products including fruits and fresh juices, vegetables, grains, nuts, and pulses
			CIII	Processing of perishable animal and plant products(mixed products)	Production of mixed animal and plant products including pizza, lasagne, sandwich, dumpling, ready-to-eat meals
			CIV	Processing of ambient stable products	Production of food products from any source that are stored and sold at ambient temperature, including canned foods, biscuits, snacks, oil, drinking water, beverages, pasta, flour, sugar, food-grade salt
	D	Animal Feed Production	**DI**	Production of Feed	Production of feed from a single or mixed food source, intended for food-producing animals
			DII	Production of Pet Food	Production of feed from a single or mixed food source, intended for non-food producing animals
Catering	**E**	Catering			Preparation, storage and, where appropriate, delivery of food for consumption, at the place of preparation or at a satellite unit
Retail, transport and storage	**F**	Distribution	**FI**	Retail / Wholesale	Provision of finished food products to a customer (retail outlets, shops, wholesalers)
			FII	Food Broking / Trading	Buying and selling food products on its own account or as an agent for others Associated packaging [c]
	G	Provision of Transport and Storage Services	**GI**	Provision of Transport and Storage Services for Perishable Food and Feed	Storage facilities and distribution vehicles for the storage and transport of perishable food and feed Associated packaging [c]
			GII	Provision of Transport and Storage Services for Ambient Stable Food and Feed	Storage facilities and distribution vehicles for the storage and transport of ambient stable food and feed Associated packaging [c]

[a] Clusters are intended to be used for accreditation scope of accredited certification bodies, and for accreditation bodies witnessing certification bodies.
[b] "Farm packing" means packaging without product modification and processing.
[c] "Associated packaging" means packaging without product modification and processing and without altering the primary packaging.

Table A.1 *(continued)*

Cluster [a]	Category		Subcategory	Examples of included activities
Auxiliary services	**H**	Services		Provision of services related to the safe production of food, including water supply, pest control, cleaning services, waste disposal.
	I	Production of Food Packaging and Packaging Material		Production of food packaging material
	J	Equipment manufacturing		Production and development of food processing equipment and vending machines
Biochemical	**K**	Production of (Bio) Chemicals		Production of food and feed additives, vitamins, minerals, bio-cultures, flavourings, enzymes and processing aids Pesticides, drugs, fertilizers, cleaning agents

[a] Clusters are intended to be used for accreditation scope of accredited certification bodies, and for accreditation bodies witnessing certification bodies.
[b] "Farm packing" means packaging without product modification and processing.
[c] "Associated packaging" means packaging without product modification and processing and without altering the primary packaging.

Annex B
(normative)

Minimum audit time

B.1 General

In determining the audit time needed for each site, as required in 9.1.4, the certification body shall consider the minimum on-site duration for initial certification given in Table B.1.

The minimum time includes stage 1 and stage 2 of the initial certification audit (see 9.2.3) but does not include the time for preparation of the audit nor for writing the audit report.

In order to avoid duplication where another relevant management system is in place and certified by the same certification body, additional time is not required (see Table B.1). In the case of a combined audit involving the FSMS, a reduction of the audit time can be implemented if justified and documented.

NOTE 1 Relevant management system means a quality or food safety system which covers the same processes, products and services.

The minimum audit time is established for the audit of an FSMS which includes only one HACCP study. A HACCP study corresponds to a hazard analysis for a family of products/services with similar hazards and similar production technology and, where relevant, similar storage technology.

The minimum time for on-site auditing of the product and/or service realization of the organization shall be 50 % of the total minimum audit time (applies to all type of audits).

NOTE 2 Product and service realization processes do not include activities related to FSMS development, training, control, audit, review and improvement.

The number of auditors per audit day shall take into consideration the effectiveness of the audit, the resources of the organization being audited as well as the resources of the certification body.

Where additional meetings are necessary, e.g. review meetings, coordination, audit team briefing, an increase in audit time may be required.

The number of employees involved in any aspect of food safety shall be expressed as the number of full-time equivalent employees (FTE). 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 office workers.

Certain categories are subject to multi-site sampling (see 9.1.5.2) and this may be taken into account when calculating the audit time.

Where sampling of sites is allowed, the sample of sites shall be selected before applying the audit duration calculation. Therefore audit duration calculations shall be applied to each site in accordance with the requirements of this annex and Table B.1.

If the scope of one specific client organization covers more than one category, the audit-time calculation shall be taken from the highest recommended basic audit time. Additional time is required for each HACCP study (i.e. a minimum of 0,5 audit day for each HACCP study).

Other factors may necessitate increasing the minimum audit time (e.g. number of product types, number of product lines, product development, number of critical control points, number of operational pre-requisites programmes, building area, infrastructure, in-house laboratory testing, need for a translator).

B.2 Calculation of minimum initial certification audit time

B.2.1 The minimum audit time for a single site, T_S, expressed in days, is calculated as follows:

$$T_S = (T_D + T_H + T_{MS} + T_{FTE}) \quad \text{(B.1)}$$

where

T_D is the basic on-site audit time, in days;

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

T_{MS} is the number of audit days for absence of relevant management system;

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

B.2.2 The audit time for each site in addition to the main site, is calculated according to Table B.1 with a minimum of 1 audit day per site. When properly documented and justified, a reduction can be made for a less complex organization measured by number of employees, size of the organization and/or product volume or within categories having a T_S time of less than 1,5 audit days.

Table B.1 — Minimum initial certification audit time

Category [a]	Basic on-site audit time, in audit days T_D	Number of audit days for each additional HACCP study T_H	Number of audit days for absence of certified relevant management system T_{MS}	Number of audit days per number of employees T_{FTE}	For each additional site visited
A	0,75	0,25	0,25	1 to 19 = 0	50 % of minimum on-site audit time
B	0,75	0,25		20 to 49 = 0,5	
C	1,50	0,50		50 to 79 = 1,0	
D	1,50	0,50		80 to 199 = 1,5	
E	1,00	0,50		200 to 499 = 2,0	
F	1,00	0,50		500 to 899 = 2,5	
G	1,00	0,25		900 to 1 299 = 3,0	
H	1,00	0,25		1 300 to 1 699 = 3,5	
I	1,00	0.25		1 700 to 2 999 = 4,0	
J	1,00	0,25		3 000 to 5 000 = 4,5	
K	1,50	0,50		> 5 000 = 5,0	

[a] See Annex A.

B.3 Calculation of minimum surveillance and recertification audit time

The minimum surveillance audit time shall be one-third of the initial certification audit time, with a minimum of 1 audit day (0,5 audit day for categories A and B). The minimum recertification audit time shall be two-thirds of the initial certification audit time, with a minimum of 1 audit day (0,5 audit day for categories A and B). When properly documented and justified, a reduction to the minimum can be made in a less complex organization measured by number of employees, size of the organization and/or product volume or within categories having an initial minimum audit time of less than 1,5 audit days.

Annex C
(normative)

Required food safety management system (FSMS) competence

Table C.1 specifies the FSMS competence for certification body personnel for specific certification functions. This specific competence is additional to the generic competence identified in ISO/IEC 17021:2011, Table A.1.

The certification body shall identify specific knowledge and skills in relation to the food chain categories consistent with the general competence identified in Table C.1, i.e. specific knowledge in terms of products, processes and services relevant to the food chain category. Personnel involved in competence evaluation shall have, as a minimum, equivalent competence to the functions being evaluated.

Table C.1 — Required FSMS competence

Competence (knowledge and skills)	Function				
	Application review	Audit team selection	Audit planning activities	Auditing activities	Certification decision
1. Ability to apply the application review requirements in ISO/IEC 17021, this Technical Specification, specific scheme rules and certification body procedures, including: — multisite sampling requirements and their application; — audit duration requirements and their application; — evaluate number of applicable HACCP studies; — ability to categorize an organization into a food category and subcategory, in accordance with Annex A.			X	X	X
2. Ability to identify relevant to food chain category(ies): — PRP; — food safety hazards; — legal requirements;	X	X	X	X	X
3. Ability to determine if there are: — 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	X	X
4. Ability to identify the competence required for the audit team, in accordance with this table and certification body procedures.		X			
5. Ability to develop an audit plan that ensures: — audit team members audit those product and processes that they are technically competent to audit; — audit time is optimized; — audit objectives defined in this Technical Specification can be realized; — specific FSMS scheme requirements are met.			X	X	

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

Table C.1 *(continued)*

Competence (knowledge and skills)	Function				
	Application review	**Audit team selection**	**Audit planning activities**	**Auditing activities**	**Certification decision**
6. Ability to interpret and apply normative documents relevant to the scope of certification sought and the food chain category (see Annex A), e.g. ISO 22000, ISO/TS 22002 and/or other scheme certification standards. Knowledge shall include all normative references and their technical terms and definitions.				X	
7. Ability to identify: — food-borne microbiological 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	
[a] It is not expected that the certification decision function requires competence specific to the food chain category.					

Table C.1 *(continued)*

Competence (knowledge and skills)	Function				
	Application review	**Audit team selection**	**Audit planning activities**	**Auditing activities**	**Certification decision**
8. Ability to apply FSMS, HACCP, hazard assessment and hazard analysis principles as interpreted by ISO 22000, in the food chain category, including:					
— Food safety policy requirements;					
— Hazard analysis methodologies;					
— Verification of the effectiveness of hazard analysis;					
— FSMS planning requirements;					
— The role of customer specification and government regulation as an input into hazard analysis;					
— Food safety team formation and function, including competence and authorities required;					
— Selection of appropriate control measures;					
— Establishment of acceptable limits;					
— Validation methodologies;					
— Verification measures;					
— FSMS updating requirements;					
— Food testing methodologies, and the role of laboratory accreditation in providing confidence in laboratory test results;				X	X [a]
— Management of non-conforming product;					
— Withdrawal and Recall procedures (country of production, country of destination), including any regulatory reporting requirements;					
— Calibration requirements for measurement equipment;					
— Traceability requirements (e.g. standard, customer, regulatory);					
— Communication (internal and external);					
— Management responsibility;					
— Emergency preparedness;					
— Intentional contamination;					
— Competence of personnel;					
— Training;					
— Supplier selection and management;					
— Complaints.					

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

Table C.1 *(continued)*

Competence (knowledge and skills)	Function				
	Application review	**Audit team selection**	**Audit planning activities**	**Auditing activities**	**Certification decision**
9. Ability to apply food chain category and subcategory practices and vocabulary in relation to: — Food chain relationships; — Best practice with respect to PRP, OPRP, CCP; — 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	
10. Ability to apply the requirements for reporting in ISO/IEC 17021 and this Technical Specification, and any CAB and/or FSMS scheme reporting requirements.				X	X
[a] 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 17021:2011, 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 proposed certification (contract) fits within scope of the certification body's scope of operations (e.g. accreditation, regulatory authorization, etc.).

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

— Determine if there are multisite 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 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 history of facility to be audited

— Confirm resource needs

— Confirm travel plans

— Develop or confirm audit strategy and methodology

— Assign audit team roles, responsibilities and activities

— Develop audit plan, including sampling plan

— Review audit logistics

— Consider 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 program documentation

— Review documentation against requirements

— Verify the organization's management system

— Determine if organization's documents meet requirements or identify non-conformities

— Establish investigative lines for Stage 2 audit

— Confirm readiness for Stage 2 audit

D.5.2 Conduct opening meeting

— Confirm certification scope

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

— Establish communication channels

— Identify guides/escorts

— Confirm reporting method

— Identify food safety and security requirements

— Confirm audit plan

— Reaffirm time of closing meeting

— Complete meeting records

D.5.3 Collecting and verifying information

— Verify process flow chart

— Assess effectiveness of implementation of control measures and processes

— Verify effectiveness of corrective actions of previous non-conformities/deficiencies

— Perform process approach audit

D.5.4 Preparation for closing meeting

— Hold audit team preparatory meeting (if required)

— Analyse audit findings and compare to requirements

— Confirm completion of audit plan

— Categorize, review and finalize any non-conformities and opportunities for improvement and relate them to the process and the system

— Prepare preliminary audit report

D.5.5 Conduct closing meeting

— Present and review audit findings (non-conformities and/or opportunities for improvement)

— Confirm objectives of audit have been met

— Provide positive feedback

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

— Obtain written acknowledgement of non-conformities

— Complete meeting records

D.5.6 Finalize audit report

— Describe findings against certification standard 's requirements (e.g. non-conformities, opportunities for improvement)

— Incorporate comments of competence and conformity

— Describe final audit conclusions

— Judge effectiveness of corrective actions (when required)

— Finalize audit report

D.5.7 Conducting post-audit activities

— Deliver audit report

— Communicate information regarding nonconformity resolution timing

— Report any unusual circumstances that occurred during the audit

— Review corrective actions for appropriateness

— Determine requirements for verification of corrective actions

— Verify effectiveness of implementation of corrective actions

— Report any necessary adjustment of audit programme, as appropriate

D.6 Certification decision

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

— **I**nteract 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 decision

— Provide feedback to 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 CB or other auditor calibration activities

— Undertake self-study or training activities

Annex E
(informative)

Food safety management systems and product certification

E.1 General

The ISO Committee on conformity assessment (CASCO) is responsible for the standards relating to all aspects of conformity assessment, such as the certification of management systems and the certification of products, processes and services, inspection and laboratory.

In recent years, CASCO has harmonized conformity assessment standards in order to ensure that requirements common to several standards are based on common definitions and that appropriate common text is used. A single user needing to refer to (or meet the requirements in) several standards can thus more easily demonstrate conformity, e.g. a management system and product certification body.

This Technical Specification is based on ISO/IEC 17021:2011, which sets out the requirements for a management systems certification body. However, it is recognized that in many instances in the food safety sector, the emphasis is on "safe product", and that some certification schemes therefore use the product certification standard, ISO/IEC 17065, as their basis.

E.2 Comparison of ISO/IEC 17065 and ISO/IEC 17021

Table E.1 compares the contents of ISO/IEC 17021:2011 and ISO/IEC 17065:2012. Additional text of ISO/IEC 17065, which is not contained in ISO/IEC 17021, is highlighted.

Table E.1 — Comparison of ISO/IEC 17021:2011 and ISO/IEC 17065:2012

ISO/IEC 17021:2011		ISO/IEC 17065:2012	
4	**Principles**	**4.5, 4.6 and Annex A**	
5	**General requirements**		
5.1	**Legal and contractual matters**	**4.1**	**Legal and contractual matters**
			4.1.2 [a]
5.2	**Management of impartiality**	**4.2**	**Management of impartiality**
			4.2.1 [a] 4.2.6 bullets e) to g) [a] 4.2.7 [a]
5.3	**Liability and financing**	**4.3**	**Liability and financing**
			4.4.1 to 4.4.3 [a]
6	**Structural requirements**	**5**	**Structural requirements**
6.1	**Organizational structure and top management**	**5.1**	**Organizational structure and top management**
			5.1.1 [a] 5.1.3 bullets f) and g) [a]
6.2	**Committee for safeguarding impartiality**	**5.2**	**Mechanism for safeguarding impartiality**
			5.2.1 [a] 5.2.3 [a]
7	**Resource requirements**	**6**	**Resource requirements**
7.1	**Competence of management and personnel**	**6.1**	**Certification body personnel**

[a] Additional text of ISO/IEC 17065, not contained in ISO/IEC 17021.

Table E.1 *(continued)*

ISO/IEC 17021:2011		ISO/IEC 17065:2012	
			6.1.2.2 bullets f) to h) [a]
7.2	**Personnel involved in the certification activities**	**6.1**	**Certification body personnel**
7.3	**Use of individual external auditors and external technical experts**	**6.2**	**Resources for evaluation**
			6.1.3 bullet c) [a] 6.2.1 [a] 6.2.2.1 to 6.2.2.3 [a] 6.2.2.4 bullets d) to f) [a]
7.4	**Personnel records**	**6.1**	**Certification body personnel**
7.5	**Outsourcing**	**6.2**	**Resources for evaluation**
8	**Information requirements**	**4.6**	**Publicly available information**
			4.6 bullet b) [a]
8.1	**Publicly accessible information**	**4.6**	**Publicly available information**
8.2	**Certification documents**	**7.7**	**Certification documentation**
8.3	**Directory of certified clients**	**7.8**	**Directory of certified products**
8.4	**Reference to certification and use of marks**		
			4.1.3 Use of license, certificates and marks of conformity [a]
8.5	**Confidentiality**	**4.5**	**Confidentiality**
8.6	**Information exchange between a certification body and its clients**	**4.6**	**Publicly available information**
9	**Process requirements**	**7**	**Process requirements**
9.1	**General requirements**	7.1	**General**
			7.1.1 to 7.1.3 [a] 7.3.2 [a]
9.2	**Initial audit and certification**	**7.4**	**Evaluation**
			7.4.4 to 7.4.5 [a] 7.4.7 to 7.4.8 [a] 7.6.3 to 7.6.5 [a] 7.7.2 [a] 7.7.3 bullets a) to c) [a]
9.3	**Surveillance activities**	**7.9**	**Surveillance**
			7.9.1 to 7.9.4 [a] 7.10.3 [a]
9.4	**Recertification**	**N/A**	
9.5	**Special audits**	**N/A**	
9.6	**Suspending, withdrawing or reducing the scope of certification**	**7.11**	**Termination, reduction, suspension or withdrawal of certification**
			7.11.2 to 7.11.6 [a]
9.7	**Appeals**	**7.13**	**Complaints and appeals**
9.8	**Complaints**	**7.13**	**Complaints and appeals**
			7.13.6 [a] 7.13.9 [a]
9.9	**Records of applicants and clients**	**7.12**	**Records**
			7.12.1 [a] 7.12.3 [a]
10	**Management system requirements for certification bodies**	**8**	**Management system requirements**
10.1	**Options**		
10.2	**Option 1: Management system requirements in accordance with ISO 9001**	**8.1**	**Option B**

[a] Additional text of ISO/IEC 17065, not contained in ISO/IEC 17021.

Table E.1 *(continued)*

ISO/IEC 17021:2011		ISO/IEC 17065:2012	
10.3	**Option 2: General management system requirements**	**8.2 to 8.8**	**Option A**
			8.2.4 to 8.2.5 [a] 8.5.1.2 [a] 8.6.3 [a]
[a] Additional text of ISO/IEC 17065, not contained in ISO/IEC 17021.			

E.3 Food scheme use of these standards

E.3.1 FSMS certification

For management system certification bodies that issue certifications in accordance with ISO 22000, the requirements for their operations is straightforward and identified in this Technical Specification, with reference back to the requirements in ISO/IEC 17021.

ISO/IEC 17021 and this Technical Specification describe together the systems that the certification body should have in place in order to deliver effective certification.

The set of requirements is shown in Table E.2.

Table E.2 — Requirements for FSMS certification in accordance with ISO 22000

Type of requirements	ISO/IEC 17021:2011	This Technical Specification
General requirements	Clause 5	5.2
Structural requirements	Clause 6	none
Resource requirements	Clause 7	7.1.1, 7.12, 7.1.3, Annex C
Information requirements	Clause 8	Annex A
Process requirements	Clause 9	9.1.1, 9.1.2, 9.1.4, 9.1.5, 9.1.7, 9.2.1, 9.2.3, Annex A, Annex B
Management system requirements for certification bodies	Clause 10	none

E.3.2 FSMS certification scheme specific requirements

As stated in the Introduction, this Technical Specification is intended for use by anybody involved in the assessment of FSMS, but 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.

This Technical Specification is intended for use by scheme owners wishing to use the audit of an FSMS as part of a food safety scheme, whether it is a management system or product certification scheme.

A scheme owner may wish to develop scheme specific requirements in addition to those in ISO 22000. These may include additional information in relation to the PRP requirements, or additional modules to cover other issues that customers want addressed. This may lead to a scheme owner setting additional requirements for the certification bodies that are certifying to these standards.

Table E.3 shows how the scheme owner may add some additional requirements relating to the requirements of either ISO/IEC 17021 or this Technical Specification, or both.

Table E.3 — FSMS certification scheme specific requirements

FSMS certification scheme		Scheme rules
ISO/IEC 17021:2011	This Technical Specification	
5. General requirements	5.2	none
6. Structural requirements	none	none
7. Resource requirements	7.1.1, 7.1.2, 7.1.3 and Annex C	Could add competence requirements or auditor certification requirement
8. Information requirements	Annex A	Could add specific format for certification documents
9. Process requirements	9.1.1, 9.1.2, 9.1.4, 9.1.5, 9.1.7, 9.2.1, 9.2.3, Annex A and Annex B	Could add specific reporting requirements or duration
10. Management system requirements for certification bodies	none	none

E.3.3 Product certification scheme including FSMS audit

For a food safety scheme that complies with ISO/IEC 17065 and that incorporates FSMS auditing as part of its evaluation activities, the audit activities (and related competence requirements) need to meet the applicable requirements of ISO/IEC 17021, in accordance with ISO/IEC 17065:2012, 6.2.1.

The certification body shall outsource evaluation activities only to bodies that meet the applicable requirements of the relevant International Standards and, as specified by the certification scheme, of other documents. For testing, it shall meet the applicable requirements of ISO/IEC 17025; for inspection, it shall meet the applicable requirements of ISO/IEC 17020; and for management system auditing, it shall meet the applicable requirements of ISO/IEC 17021. The impartiality requirements of the evaluation personnel stipulated in the relevant standard shall always be applicable.

For those bodies that include the auditing of an FSMS, the applicable requirements referenced above should also include the requirements of this Technical Specification, as referenced in ISO/IEC 17021.

NOTE This is only the case where the product certification scheme includes auditing of the food safety management system as part of the certification: there are many product certification schemes available within the food industry where this is not the case. For example, some product certification schemes use inspection as part of the conformity assessment activity: in this case, the above reference of ISO/IEC 17065 would guide the reader to meet the applicable requirements of ISO/IEC 17020.

Table E.4 illustrates how a product certification scheme incorporating FSMS auditing could build scheme requirements based on the requirements of ISO/IEC 17065:2012, 6.2.1. In doing so, the scheme owner shall identify the applicable requirements of ISO/IEC 17021 and this Technical Specification and then add any additional requirements that they may consider necessary to meet the objectives (and stakeholder needs) of the scheme. Additional requirements are usually identified in a set of scheme rules.

Table E.4 — Product certification scheme including FSMS audit

Product certification scheme including FSMS audit			Scheme rules
ISO/IEC 17065:2012	ISO/IEC 17021:2011	This Technical Specification	
4. General Requirements	none	5.2	none
5. Structural requirements	none	none	none
6. Resource requirements	Competence requirements for auditing of FSMS: 7.1 to 7.3	7.1.1, 7.1.2, 7.1.3 and Annex C	Additional specific competence requirements
7. Process requirements	Auditing requirements: 9.1 to 9.4	9.1.1, 9.1.2, 9.1.4, 9.1.5, 9.1.7, 9.2.1, 9.2.3, Annex A and Annex B	Report format, additional certification requirements
8. Management system requirements	none	none	none

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[6] ISO/IEC 17030:2003, *Conformity assessment — General requirements for third-party marks of conformity*

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