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Food safety —

Part 2: Requirements for bodies providing evaluation and certification of products, processes and services, including an audit of the food safety system

Sécurité des denrées alimentaires —

Partie 2: Exigences pour les organismes procédant à l'évaluation et à la certification de produits, de procédés et de services, incluant un audit du système de 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).

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 system (FSS) 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 FSS can originate from a number of sources. This document has been developed to assist in the certification of the organization's products, processes or services and its FSS, including its management system elements.

This document is intended for use, in combination with ISO/IEC 17065, by bodies that carry out evaluation and certification of products, processes or services including an audit of the FSS. 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.

Certification of an organization's products, processes or services including an audit of the FSS in accordance with this document can involve a number of activities. Because this document is intended for product certification schemes that include a management system element, these activities involve an audit of the organization's FSS. The form of attestation of conformity of an organization's FSS to a specific standard, certification scheme requirements or other specified requirements is normally a certification document or a certificate.

It is for the organization seeking certification to develop its own FSS and related systems according to the scheme requirements. Other than where relevant legislative, customer or certification scheme 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 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 FSS within the wider organization.

This document was developed in conjunction with ISO 22003-1, which is used in combination with ISO/IEC 17021-1.

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 2: Requirements for bodies providing evaluation and certification of products, processes and services, including an audit of the food safety system

1 Scope

This document is supplemental to ISO/IEC 17065. It specifies the rules applicable for the audit of a food safety system (FSS) and certification of products, processes and services complying with requirements of a certification scheme that is based on the internationally accepted principles of food safety (e.g. CODEX *General Principles of Food Hygiene*[8]) and includes management system elements.

This document does not apply to certifications that are solely based on product testing (e.g. performed by an organization applying ISO/IEC 17025) or inspection (e.g. performed by an organization applying ISO/IEC 17020) and does not apply to ISO/IEC 17065-based food safety schemes that do not include both internationally accepted principles of food safety and management system elements.

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

Certification of FSS 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 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 organization's products, processes and services and its FSS comply with the requirements of a certification scheme. 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 organization's FSS complies with a certification scheme's requirements. 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 an FSS with additional criteria.

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

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 17065:2012, *Conformity assessment — Requirements for bodies certifying products, processes and services*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000, ISO/IEC 17065 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 system
FFS
prerequisite programmes (3.2), supplemented with *control measures* (3.16), as appropriate, based on internationally accepted principles of food safety, combined with *management system elements* (3.17), that, when implemented by the organization, provide products and services that are safe, according to their intended use

Note 1 to entry: The prerequisite programmes and control measures of an FSS may be based on either a hazard analysis specific to the organization, its products and processes, or a generic hazard analysis conducted by a competent external body (e.g. competent authority, academia, trade or industry association, certification scheme owner) appropriate to the products and processes of the organization and adapted and tailored by the organization to its operations.

3.2
prerequisite programme
PRP
basic conditions and activities that are necessary within the organization and throughout the food chain to maintain food safety

Note 1 to entry: The PRPs needed depend on the segment of the food chain in which the organization operates and the type of organization. Examples of equivalent terms are good agricultural practice (GAP), good veterinary practice (GVP), good manufacturing practice (GMP), good hygiene practice (GHP), good production practice (GPP), good distribution practice (GDP) and good trading practice (GTP).

[SOURCE: ISO 22000:2018, 3.35]

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

[SOURCE: ISO/IEC 17021-1:2015, 3.7]

3.4
audit
process for obtaining relevant information about an object of conformity assessment and evaluating it objectively to determine the extent to which specified requirements are fulfilled

Note 1 to entry: The specified requirements are defined prior to performing an audit so that the relevant information can be obtained.

Note 2 to entry: In the context of this document, "audit" includes any applicable evaluation activity (in accordance with ISO/IEC 17065), such as inspection, testing and management system audit (in accordance with ISO/IEC 17021-1).

[SOURCE: ISO/IEC 17000:2020, 6.4, modified —Notes 2 and 3 to entry have been deleted and a new Note 2 to entry has been added.]

3.5
audit duration
part of *audit time* (3.6) spent conducting *audit* (3.4) activities from the opening meeting to the closing meeting, inclusive

[SOURCE: ISO/IEC 17021-1:2015, 3.17, modified — The term has been changed from "duration of management system certification audits".]

3.6
audit time
time needed to plan and accomplish a complete and effective *audit* (3.4) of the client organization's FSS

[SOURCE: ISO/IEC 17021-1:2015, 3.16, modified — "FSS" has replaced "management system" in the definition.]

3.7
nonconformity
non-fulfilment of a requirement

[SOURCE: ISO/IEC 17021-1:2015, 3.11]

3.8
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)

3.9
auditor
person who conducts an *audit* (3.4)

[SOURCE: ISO/IEC 17021-1:2015, 3.6]

3.10
guide
person appointed by the client to assist the audit team

[SOURCE: ISO/IEC 17021-1:2015, 3.8]

3.11
observer
person who accompanies the audit team but does not *audit* (3.4)

[SOURCE: ISO/IEC 17021-1:2015, 3.9]

3.12
technical expert
person who provides specific knowledge or expertise to the audit team

[SOURCE: ISO/IEC 17021-1:2015, 3.14, modified — Note 1 to entry has been deleted.]

3.13
permanent site
location (physical or virtual) where a client organization performs work or provides a service on a continuing basis

[SOURCE: ISO/IEC TS 17023:2013, 3.4]

3.14
temporary site
location (physical or virtual) where a client organization performs specific work or provides a service for a finite period of time and which is not intended to become a *permanent site* (3.13)

[SOURCE: ISO/IEC TS 17023:2013, 3.5]

3.15
audit plan
description of the activities and arrangements for an *audit* (3.4)

[SOURCE: ISO 19011:2018, 3.6]

3.16
control measure
action or activity that can be used to prevent or eliminate a hazard or reduce it to an acceptable level

3.17
management system element
element of a management system (e.g. management commitment, responsibility and review, documented information, internal audit) that supports the production of safe food

4 General requirements

4.1 Legal and contractual matters

4.1.1 ISO/IEC 17065:2012, 4.1, shall be followed.

4.1.2 The certification documents shall identify in detail the categories and subcategories in Table A.1 to which the FSS applies.

4.2 Management of impartiality

ISO/IEC 17065:2012, 4.2, shall be followed.

4.3 Liability and financing

ISO/IEC 17065:2012, 4.3, shall be followed.

4.4 Non-discriminatory conditions

ISO/IEC 17065:2012, 4.4, shall be followed.

4.5 Confidentiality

ISO/IEC 17065:2012, 4.5, shall be followed.

4.6 Publicly available information

ISO/IEC 17065:2012, 4.6, shall be followed.

5 Structural requirements

5.1 Organizational structure and top management

ISO/IEC 17065:2012, 5.1, shall be followed.

5.2 Mechanism for safeguarding impartiality

ISO/IEC 17065:2012, 5.2, shall be followed.

6 Resource requirements

6.1 Certification body personnel

6.1.1 General

ISO/IEC 17065:2012, 6.1.1, shall be followed.

6.1.2 Management of competence for personnel involved in the certification process

6.1.2.1 ISO/IEC 17065:2012, 6.1.2, shall be followed.

In addition to ISO/IEC 17065:2012, 6.1.2.1, the procedure shall require a certification body to apply Annexes A and C in the determination of competencies.

NOTE 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.

6.1.2.2 Determination of personnel competence shall include the individual's ability to apply knowledge, 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 6.1.2.1.

The certification body shall periodically evaluate the performance of each auditor during an on-site audit.

Those responsible for determining personnel competence shall have knowledge of determination methods and shall have demonstrated the ability to apply them and also have equivalent competence to those functions they are evaluating.

6.1.3 Contract with the personnel

ISO/IEC 17065:2012, 6.1.3, shall be followed.

6.2 Resources for audit

6.2.1 Internal resources

ISO/IEC 17065:2012, 6.2.1, shall be followed.

NOTE The applicable requirements of ISO/IEC 17021-1 referred to in ISO/IEC 17065:2012, 6.2.1, have been included in this document.

6.2.2 External resources (outsourcing)

ISO/IEC 17065:2012, 6.2.2, shall be followed.

NOTE The applicable requirements of ISO/IEC 17021-1 referred to in ISO/IEC 17065:2012, 6.2.2, have been included in this document.

7 Process requirements

7.1 General

ISO/IEC 17065:2012, 7.1, shall be followed.

Where a scheme owner has established its own rules for the determination of categories, audit duration and competence, the outcome of the scheme rules shall apply provided the scheme rules are not less than those required in Clause 7 and related annexes as a common basis.

7.2 Application

ISO/IEC 17065:2012, 7.2, 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 in accordance with Annexes A and B.

7.3 Application review

7.3.1 The certification body shall conduct a review of the information obtained (see 7.2) to ensure that:

a) the information about the client its products/processes/services and its FSS, including the sites of the client's operations, and any other points influencing the certification activity (language, safety conditions, etc.), is sufficient for the conduct of the certification process;

b) any known difference in understanding between the certification body and the client is resolved, including agreement regarding standards or other normative documents;

c) the scope of certification sought is defined;

d) the means are available to conduct audits;

e) the certification body has the competence and capability to perform the certification activity.

7.3.2 ISO/IEC 17065:2012, 7.3.2, shall be followed.

7.3.3 ISO/IEC 17065:2012, 7.3.3, shall be followed.

7.3.4 ISO/IEC 17065:2012, 7.3.4, shall be followed.

7.3.5 ISO/IEC 17065:2012, 7.3.5, shall be followed.

7.3.6 The certification body shall determine the relevant scope of certification for the organization applying for certification using Annex A unless the scheme provides specific categories or subcategories. The certification body shall identify the category(s) or subcategory(s) in scope of certification for each site or sites by briefly describing the main types of products and processes for the products and/or services that are evaluated by the certification body.

7.3.7 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 that are not in the scope of the certification scheme.

7.4 Evaluation

NOTE ISO/IEC 17065 refers to "evaluation" and is applicable to the various types of product, process and services certification schemes which incorporate conformity assessment activities including inspection, testing, audit, verification and validation. In the context of this document, the evaluation activity is audit, and therefore the terminology used under this subclause is audit only.

7.4.1 Activities prior to the audit

7.4.1.1 Audit programme

NOTE 1 The "audit programme" is identified as equivalent to the "evaluation plan" required in ISO/IEC 17065:2012, 7.4.1.

The certification body shall have a programme for the audit activities, including audit activities conducted remotely, to allow for the necessary arrangements for each audit to be managed. The programme shall be clear with respect to the individual activities (e.g. audit, testing and inspection) but shall take into account that the individual activities are not always distinguishable from each other when conducted on-site.

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 products and processes covered by the scope using the criteria of the certification scheme, if any.

NOTE 2 Depending on the characteristics of the certification scheme and the FSS requirements, the audit programme can be either a generic plan applicable to all activities, including auditing of the relevant management system elements (e.g. quality or food safety management system or an integration thereof), when applicable, or a specific one for a particular activity, or a combination of both.

7.4.1.2 Determining audit time

7.4.1.2.1 The certification body shall have documented procedures for determining the audit time. For each client, the certification body shall determine the time needed to plan and accomplish a complete and effective audit of the FSS. 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.

7.4.1.2.2 In determining and documenting the 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.2 and B.3 and Table B.1;

c) the time for reporting and, if applicable, conducting post-audit activities;

d) the number of auditors per audit day balanced with the organization's resources;

e) where additional meetings are necessary (e.g. review meetings, coordination, audit team briefing), an increase in audit time can be required;

f) where applicable and agreed, the time needed to ensure effective remote auditing or use of information and communication technology (ICT).

7.4.1.3 Multi-site sampling

7.4.1.3.1 A multi-site organization is an organization having an identified central function at which certain FSS 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.

A multi-site organization has multiple locations at different addresses with or without different ownership involved.

NOTE The concept of a multi-site organization in the context of this document does not include farming operations (i.e. categories A and B in Annex A) that have a number of production sites (e.g. fields, barns, paddocks, pastures) within their operation. Farming operations that have storage facilities or packing facilities in several locations associated with their production sites are not typically considered multi-site operations, unless those facilities are clearly run independently of other functions (i.e. with separate crews, which can be the case with some multi-commodity farming operations). Multi-site can include producer groups managed by a central function.

7.4.1.3.2 When the certification body is required to audit the FSS of a multi-site organization (see 7.4.1.3.1), it may adopt a sampling approach. Sampling of multi-site organizations shall cover all activities of the organization within the scope of certification. See 7.4.1.5 for categories within which sampling is allowed.

NOTE Sampling is not permitted for some specific certification schemes.

7.4.1.3.3 Where multi-site sampling is permitted for the audit of a client's FSS, the certification body shall have a sampling programme to ensure achievement of the audit objectives. The rationale for the sampling programme for each client shall be documented.

7.4.1.3.4 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 used for determining the sampling, based on the following conditions:

a) sites are operating under one centrally controlled and administered FSS;

b) sites subject to sampling are similar (e.g. 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 FSS;

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 FSS 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 FSS is subject to central management review;

j) the central function has authority to initiate continual improvement of the FSS.

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.

7.4.1.3.5 The use of multi-site sampling is permitted for categories A and B. Sampling may be applied to multi-site organizations and producer groups, with the minimum sample size being the square root of the total number of other sites or group members, $\sqrt{(x)}$, rounded up to the next whole number. The square root sample shall be taken per risk category based on production complexity of the sites/members (e.g. open field plant production, perennial plant production, indoor production, open field livestock production, indoor livestock production). The scheme owner may define the risk categories and increase the minimum sample size.

The use of multi-site sampling is permitted for categories F and G, and for category E 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.

For all categories for which multi-site sampling is permitted, the certification body shall increase the size of the sample or terminate the site sampling where the FSS does not indicate the ability to achieve the intended results.

The use of multi-site sampling is not permitted for any other categories identified in Annex A.

7.4.1.3.6 Where multi-site sampling is permitted, the certification body shall define and utilize a sampling programme to ensure an effective audit of the FSS where the following conditions apply.

a) At least annually, an audit of the central function for the FSS shall be performed by the certification body prior to performing the majority of 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 FSS 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 FSS, corrective actions shall be implemented accordingly.

7.4.1.3.7 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, and other relevant aspects of corrective action;

c) variations in the site characteristics;

d) other relevant changes since the last audit.

7.4.1.3.8 The certification body shall increase the size of sample or terminate the site sampling where the FSS subject to certification does not indicate the ability to achieve the intended results.

7.4.2 Planning audit

7.4.2.1 Determining audit objectives, scope and criteria

7.4.2.1.1 The audit objectives shall be determined by the certification body. The audit scope and criteria, including any changes, shall be established by the certification body after discussion with the client and according to any applicable scheme requirements.

7.4.2.1.2 The audit objectives shall describe what is to be accomplished by the audit. They shall include the following:

a) determination of the conformity of the client's FSS, or parts of it, with audit criteria;

b) determination of the ability of the FSS to ensure the client meets applicable statutory, regulatory and contractual requirements;

c) determination of the effectiveness of the FSS to ensure the client can reasonably expect to achieve its specified objectives;

d) as applicable, identification of areas for potential improvement of the effectiveness of the FSS.

7.4.2.1.3 The audit scope shall describe the extent and boundaries of the audit, such as sites, organizational units, activities and processes to be audited. Where the certification process consists of more than one audit (e.g. covering different sites), the scope of an individual audit may not cover the full certification scope, but the totality of audits shall be consistent with the scope in the certification documentation.

7.4.2.2 Audit team selection and assignments

7.4.2.2.1 The certification body shall have a process for selecting and appointing the audit team, including the audit team leader and technical experts as necessary, taking into account the competence needed to achieve the objectives of the audit and requirements for impartiality. If there is only one auditor, the auditor shall have the competence to perform the duties of an audit team leader applicable for that audit. The audit team shall have the totality of the competences identified by the certification body as set out in 6.1.2 for the audit.

7.4.2.2.2 In deciding the size and composition of the audit team, consideration shall be given to the following:

a) audit objectives, audit scope, criteria and estimated audit time;

b) whether the audit is combined, joint or integrated;

c) the overall competence of the audit team needed to achieve the objectives of the audit;

d) certification requirements (including any applicable scheme, statutory, regulatory or contractual requirements);

e) language and culture.

7.4.2.2.3 The necessary knowledge and skills of the audit team leader and auditors may be supplemented by technical experts, translators and interpreters who shall operate under the direction

of an auditor. Where translators or interpreters are used, they shall be selected such that they do not unduly influence the audit.

NOTE The criteria for the selection of technical experts are determined on a case-by-case basis by the needs of the audit team and the scope of the audit.

7.4.2.2.4 Auditors-in-training may participate in the audit, provided an auditor is appointed to supervise. The supervising auditor shall be competent to take over the duties and have final responsibility for the activities and findings of the auditor-in-training.

7.4.2.2.5 The audit team leader, in consultation with the audit team, shall assign to each team member responsibility for auditing specific processes, functions, sites, areas or activities. Such assignments shall take into account the need for competence, and the effective and efficient use of the audit team, as well as different roles and responsibilities of auditors, auditors-in-training and technical experts. Changes to the work assignments may be made as the audit progresses to ensure achievement of the audit objectives.

7.4.2.3 Observers, technical experts and guides

7.4.2.3.1 Observers

The presence and justification of observers during the audit activities shall be agreed to by the certification body and client prior to the conduct of the audit. The audit team shall ensure that observers do not unduly influence or interfere in the audit process or outcome of it.

NOTE Observers can be members of the client's organization, consultants, witnessing accreditation body personnel, regulators or other justified persons.

7.4.2.3.2 Technical experts

The role of technical experts during audit activities shall be agreed to by the certification body and client prior to the conduct of the audit. A technical expert shall not act as a member of the audit team (e.g. auditor). The technical experts shall be accompanied by a member of the audit team.

NOTE The technical experts can provide advice to the audit team for the preparation, planning or conducting of the audit.

7.4.2.3.3 Guides

Each audit team member shall be accompanied by a guide, unless otherwise agreed to by the team leader and the client. Guide(s) are assigned to the audit team to facilitate the audit. The team shall ensure that guides in their role as guide do not influence or interfere with the audit process or outcome of it.

NOTE The responsibilities of a guide can include:

a) establishing contacts and timing for interviews;

b) arranging visits to specific parts of the site or organization;

c) ensuring that rules concerning site safety and security procedures are known and respected by the audit team members;

d) witnessing the audit on behalf of the client;

e) providing clarification or information as requested by an audit team member.

7.4.2.4 Audit plan

7.4.2.4.1 General

For each audit identified in the audit programme (see 7.4.1.1), the certification body shall ensure that an audit plan is established to provide the basis for agreement regarding the conduct and scheduling of the audit activities.

7.4.2.4.2 Preparing the audit plan

The audit plan shall be appropriate to the objectives and the scope of the audit. The audit plan shall at least include or refer to the following:

a) the audit objectives according to the scheme;

b) the audit criteria according to the scheme;

c) the audit scope, including identification of the organizational and functional units or processes to be audited;

d) the dates and sites where the on-site audit activities will be conducted, including visits to temporary sites and remote auditing activities, if not contained in the audit programme;

e) the expected duration of on-site audit activities, if not contained in the audit programme;

f) the roles and responsibilities of the audit team members and accompanying persons, such as observers or interpreters.

NOTE The audit plan information can be contained in more than one document.

7.4.2.4.3 Communication of audit team tasks

The tasks given to the audit team as part of the audit team shall be defined. They shall require the audit team to:

a) examine and verify the structure, policies, processes, procedures, records and related documents of the client relevant to the FSS;

b) determine whether these meet all the requirements relevant to the intended scope of certification;

c) determine that the processes and procedures are established, implemented and maintained effectively, to provide a basis for confidence in the client's FSS;

d) communicate to the client, for its action, any inconsistencies between the client's policy and objectives.

7.4.2.4.4 Communication of audit plan

The audit plan shall be communicated and the dates of individual audit activities shall be agreed upon, in advance, with the client. This does not apply to unannounced audits if specified by the scheme.

7.4.2.4.5 Communication concerning audit team members

The certification body shall provide the name of and, when requested, make available background information on, each member of the audit team, with sufficient time for the client to object to the appointment of any particular audit team member and for the certification body to reconstitute the team in response to any valid objection.

7.4.3 Conducting audits

7.4.3.1 General

The audit shall be conducted according to the minimum process steps specified in 7.4.3.4 to 7.4.3.9. The applicable scheme may provide additional specified requirements related to other evaluation activities such as inspection or testing.

The certification body shall have a process for conducting on-site audits. This process shall include an opening meeting and a closing meeting.

Where any part of the audit is made by electronic means or where the site to be audited is virtual, the certification body shall ensure that such activities are conducted by personnel with appropriate competence. The evidence obtained during such an audit shall be sufficient to enable the auditor to take an informed decision on the conformity with the requirement in question.

NOTE "On-site" audits can include remote access to electronic site(s) that contain(s) information that is relevant to the audit of the FSS. Consideration can also be given to the use of electronic means for conducting audits.

7.4.3.2 The audit shall include a documentation review which shall determine whether:

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

b) the FSS 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 or combinations thereof;

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

d) the FSS is designed to achieve the organization's food safety objectives;

e) the validation of control measures, verification that the activities and improvement programmes conform to the requirements of the FSS;

f) the FSS documents and arrangements are in place to communicate internally and externally;

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

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

7.4.3.3 Where an organization has implemented a HACCP-based system, the documentation review shall determine if the PRPs and the combination of control measures:

— are suitable for the organization;

— were developed in compliance with the internationally accepted principles of HACCP;

— are kept up to date.

NOTE Further information is provided by CODEX *General principles of food hygiene*[8] or by a certification scheme. Usually this activity is done by an audit team member.

7.4.3.4 Conducting the opening meeting

The opening meeting is usually conducted by the audit team leader with the client's management or those responsible for the functions or processes to be audited. The purpose of the opening meeting is to

provide a short explanation of how the audit activities will be undertaken. The degree of detail shall be consistent with the familiarity of the client with the audit process and may include the following:

a) introduction of the participants, including an outline of their roles;

b) confirmation of the scope of audit;

c) confirmation of the audit plan (including type and scope of audit, objectives and criteria), any changes, and other relevant arrangements with the client, such as the date and time for the closing meeting, interim meetings between the audit team and the client's management;

d) confirmation of formal communication channels between the audit team and the client;

e) confirmation that the resources and facilities needed by the audit team are available;

f) confirmation of matters relating to confidentiality;

g) confirmation of relevant work safety, emergency and security procedures for the audit team;

h) confirmation of the availability, roles and identities of any guides and observers;

i) the method of reporting, including any grading of audit findings;

j) information about the conditions under which the audit can be prematurely terminated;

k) confirmation that the audit team leader and audit team representing the certification body is responsible for the audit and shall be in control of executing the audit plan including audit activities and audit trails;

l) confirmation of the status of findings of the previous review or audit, if applicable;

m) methods and procedures to be used to conduct the audit based on sampling;

n) confirmation of the language to be used during the audit;

o) confirmation that, during the audit, the client will be kept informed of audit progress and any concerns;

p) opportunity for the client to ask questions.

7.4.3.5 Communication during the audit

7.4.3.5.1 During the audit, the audit team shall periodically assess audit progress and exchange information where appropriate also to the other audit team members. The audit team leader shall reassign work as needed between the audit team members and periodically communicate the progress of the audit and any concerns to the client.

7.4.3.5.2 Where the available audit evidence indicates that the audit objectives are unattainable or suggests the presence of an immediate and significant risk (e.g. food safety), the audit team leader shall report this to the client and, if possible, to the certification body to determine appropriate action. Such action may include reconfirmation or modification of the audit plan, changes to the audit objectives or audit scope, or termination of the audit. The audit team leader shall report the outcome of the action taken to the certification body.

7.4.3.5.3 The audit team leader shall review with the client any need for changes to the audit scope which becomes apparent as auditing activities progress and report this to the certification body.

7.4.3.6 Obtaining and verifying information

7.4.3.6.1 During the audit, information relevant to the audit objectives, scope and criteria (including information relating to interfaces between functions, activities and processes) shall be obtained by appropriate sampling and verified to become audit evidence.

7.4.3.6.2 Methods to obtain information shall include, but are not limited to:

a) interviews;

b) observation of processes and activities;

c) review of documentation and records.

7.4.3.7 Identifying and recording audit findings

7.4.3.7.1 A finding of nonconformity shall be recorded against a specific requirement, and shall contain a clear statement of the nonconformity, identifying in detail the objective evidence on which the nonconformity is based. Nonconformities shall be discussed with the client to ensure that the evidence is accurate and that the nonconformities are understood. The auditor however shall refrain from suggesting the cause of nonconformities or their solution.

7.4.3.7.2 The audit team leader shall attempt to resolve any diverging opinions between the audit team and the client concerning audit evidence or findings, and unresolved points shall be recorded.

7.4.3.8 Preparing audit conclusions

The audit team shall under the responsibility of the audit team leader and prior to the closing meeting:

a) review the audit findings, and any other appropriate information obtained during the audit, against the audit objectives and audit criteria and, where applicable classify the nonconformities according to the scheme requirement;

b) agree upon the audit conclusions, taking into account the uncertainty inherent in the audit process;

c) agree on any necessary follow-up actions;

d) confirm the appropriateness of the audit planning or identify any modification required for future audits (e.g. scope of certification, audit time or dates, surveillance frequency, audit team competence).

7.4.3.9 Conducting the closing meeting

7.4.3.9.1 A formal closing meeting shall be held with the client's management and, where appropriate, those responsible for the functions or processes audited. The purpose of the closing meeting, usually conducted by the audit team leader, is to present the audit conclusions. Any nonconformities shall be presented in such a manner that they are understood, and the time frame for responding shall be agreed.

NOTE "Understood" does not necessarily mean that the nonconformities have been accepted by the client.

7.4.3.9.2 The closing meeting shall also include the following elements where the degree of detail shall be consistent with the familiarity of the client with the audit process:

a) advising the client that the audit evidence obtained was based on a sample of the information; thereby introducing an element of uncertainty;

b) the method and time frame of reporting audit findings;

c) the certification body's process for handling nonconformities including any consequences relating to the status of the client's certification, taking into consideration results of other audit activities;

d) the time frame for the client to present a plan for correction and corrective action for any nonconformities identified during the audit;

e) the certification body's post audit activities;

f) information about the complaint and appeal handling processes.

7.4.3.9.3 The client shall be given the opportunity to ask questions. Any diverging opinions regarding the audit findings or conclusions between the audit team and the client shall be discussed and resolved where possible. Any diverging opinions that are not resolved shall be recorded and referred to the certification body.

7.4.4 Accepting external results

ISO/IEC 17065:2012, 7.4.5, shall be followed.

7.4.5 Audit report

7.4.5.1 The audit team leader shall ensure that the audit report is prepared and shall be responsible for its content. The audit report shall provide an accurate, concise and clear record of the audit to contribute to the making of an informed certification decision. Depending on the scheme, the audit report shall include or refer to the following:

a) identification of the certification body;

b) the name and address of the client and the client's representative;

c) the type of audit;

d) the audit criteria;

e) the audit objectives;

f) the audit scope, particularly identification of the organizational or functional units or processes audited and the time of the audit;

g) identification of the audit team leader, audit team members and any accompanying persons;

h) the dates and places where the audit activities (on-site or offsite, permanent or temporary sites) were conducted;

i) audit findings, reference to evidence and conclusions, consistent with the requirements of the type of audit;

j) verification of effectiveness of taken corrective actions regarding previously identified nonconformities, if applicable.

Depending on the scheme, the audit report may include or refer to the following:

— any deviation from the audit plan and their reasons;

— any significant issues impacting on the audit plan;

— significant changes, if any, that affect the FSS of the client since the last audit took place;

— any unresolved issues, if identified;

— where applicable, whether the audit is combined, joint or integrated;

— a disclaimer statement indicating that auditing is based on a sampling process of the available information;

— opinion as to whether the certification requirements have been fulfilled;

— whether the audited client is effectively controlling the use of the certification documents and marks, if applicable.

7.4.5.2 The report of the audit shall also contain amongst further items (as defined by the certification scheme):

a) a statement on the conformity and the effectiveness of the FSS together with a summary of the evidence relating to the capability of the FSS to meet applicable requirements and expected outcomes;

b) a conclusion on the appropriateness of the certification scope.

7.4.6 Nonconformities

7.4.6.1 General

ISO/IEC 17065:2012, 7.4.6, shall be followed.

7.4.6.2 Cause analysis of nonconformities

The certification body shall require the client to analyse the cause and describe the specific correction and corrective actions taken, or planned to be taken, to eliminate detected nonconformities, within a defined time.

7.4.7 Resolving nonconformities

7.4.7.1 General

ISO/IEC 17065:2012, 7.4.7, shall be followed.

7.4.7.2 Effectiveness of corrections and corrective actions

7.4.7.2.1 The certification body shall review the corrections, identified causes and corrective actions or corrective actions plans submitted by the client to determine if these are acceptable. The certification body shall verify the effectiveness of any correction and corrective actions taken. The evidence obtained to support the resolution of nonconformities shall be recorded. The client shall be informed of the result of the review and verification. The client shall be informed if any additional audit activities [e.g. full audit, an additional limited audit, or documented evidence (to be confirmed during future audits)] will be needed to verify effective correction and corrective actions.

7.4.7.2.2 If a nonconformity was identified and not satisfactorily corrected in the agreed time frame, certification shall not be granted or maintained. This applies also to situations where a nonconformity was identified at one of the sites in a multi-site organization.

NOTE Verification of effectiveness of correction and corrective actions can be carried out based on a review of documented information provided by the client, or where necessary, through verification on-site.

7.4.8 ISO/IEC 17065:2012, 7.4.2, shall be followed.

7.4.9 ISO/IEC 17065:2012, 7.4.3, shall be followed.

7.4.10 ISO/IEC 17065:2012, 7.4.4, shall be followed.

7.4.11 ISO/IEC 17065:2012, 7.4.5, shall be followed.

7.4.12 ISO/IEC 17065:2012, 7.4.8, shall be followed.

7.4.13 ISO/IEC 17065:2012, 7.4.9, shall be followed.

7.5 Review

ISO/IEC 17065:2012, 7.5, shall be followed.

7.6 Certification decision

ISO/IEC 17065:2012, 7.6, shall be followed.

7.7 Certification documentation

ISO/IEC 17065:2012, 7.7, shall be followed.

The certification documents shall identify in detail the scope of certification (see ISO/IEC 17065:2012, 3.10), i.e. the certified products and key processes and the applicable sub-categories (and/or category if no sub-categories) (see Table A.1).

7.8 Directory of certified products

ISO/IEC 17065:2012, 7.8, shall be followed.

7.9 Surveillance

ISO/IEC 17065:2012, 7.9, shall be followed.

7.10 Changes affecting certification

ISO/IEC 17065:2012, 7.10, shall be followed.

7.11 Termination, reduction, suspension or withdrawal of certification

ISO/IEC 17065:2012, 7.11, shall be followed.

7.12 Records

ISO/IEC 17065:2012, 7.12, shall be followed.

7.13 Complaints and appeals

ISO/IEC 17065:2012, 7.13, shall be followed.

7.14 Special audits

7.14.1 Expanding scope

The certification body shall, in response to an application for expanding the scope of a certification already granted, undertake a review of the application and determine any audit activities necessary to decide whether or not the extension may be granted. This may be conducted in conjunction with surveillance activities if applicable.

7.14.2 Short-notice or unannounced audits

Where the certification body conducts short-notice or unannounced audits the certification body shall:

a) describe and make known in advance to the certified clients the conditions under which such audits will be conducted;

b) exercise additional care in the assignment of the audit team because of the lack of opportunity for the client to object to audit team members.

8 Management system requirements

ISO/IEC 17065:2012, Clause 8 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) 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 part of the sector 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 the certification of products, process and services including an audit of the FSS. 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. If the answer is affirmative, 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 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 expose 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, workplaces (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.
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.

[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
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 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 FSS;

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 FSS;

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 FSS, 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 FSS;

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

n) any language and interpretation needs.

B.3 Calculation of minimum audit duration

B.3.1 General

FSS audits shall meet the minimum audit duration calculation given in B.3.3 using the requirements of Annexes A and B. FSS schemes may design their own categories and audit duration calculations in excess of Annex B. Where a scheme owner has established their own rules for the determination of 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.

When determining the number of employees involved in any aspect of food safety, it shall be expressed as the number of fulltime 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 processes, 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, 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, report writers).

B.3.2 Audit duration calculation for categories A and B

The minimum certification audit duration for FSS certification audits of categories A and B shall be:

— 3 h in the simple situation per subcategory;

— when category BI is combined with category BIII, 4 h in the simple situation.

The minimum of 3 h duration shall apply to the simple circumstances (one location, one or few crops, simple machinery, few workers, subsequent audit, documentation is well organized, etc.). In exceptional circumstances, the scheme owner may define additional criteria for further reductions of audit duration where justified.

In addition to the factors given in Clause B.2, primary production factors that can increase the minimum of 3 h are different types of growing, harvesting or handling methods.

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

In the case of producer group members certification, the minimum duration of the management system audit for the group (i.e. central function) shall be 6 h. It is possible that producer group members have audits of shorter duration than 3 h depending on the complexity of the farming situation.

NOTE "Group certification" entails certification of group of individual producers who are members of the group. The certificate holder is a single legal entity, which operates as a central function overseeing the group members. The members of the group are individual producers who are each responsible for their own farming operations. As members of the group, the individual producers have a contractual relationship with the legal entity that holds certification for the group.

B.3.3 Audit duration calculation for categories C through K

For categories C through K, the minimum certification audit duration for FSS certification audits shall be D_S, expressed in days, which is calculated, considering Table B.1:

$$D_S = (T_D + T_H + T_{FTE})/2$$

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 site audit days for additional HACCP studies;

T_{FTE} is the number of site 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}
CO	2,0	0,50	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
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	00,5	
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.

The resulting audit duration using the factors in Clause B.3 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 Operational food safety planning does not include activities related to FSS development, training, internal audit, management review and improvement.