FSSC 22000




FOOD SAFETY SYSTEM CERTIFICATION

ANNEX 1: CB CERTIFICATE SCOPE STATEMENTS

Version 6 | April 2023

CONTENTS

1. PURPOSE

This Annex describes the rules for the scope statements on the FSSC 22000 certificate. There are general rules for all categories, and specific rules for individual categories including examples.

2. SCOPE

The food chain categories and related supply chain sectors that fall within the scope of FSSC 22000 certification are defined in Part 1 of the Scheme documents. Manufacturing (sub)categories are assigned based on the end product produced by the organization.

3. GENERAL REQUIREMENTS

The certificate scope statement shall meet the following general requirements:

1) The scope statement shall not be misleading. It shall be a clear, concise, and unambiguous statement that describes the main types of processes/activities, product types and/or services that are supplied/undertaken by the certified organization. The scope of certification shall be within the scope of the Scheme and shall have been audited by the CB. The audit report shall contain sufficient objective evidence to support the full scope of certification;
2) FSSC 22000 is a Management System certification, not a product certification. Therefore, listing all individual products/processes or services is not recommended.
3) Applied technologies that impact food safety shall be included (e.g., sterilization, pasteurization, fermentation, drying) but not all individual process steps (e.g. receiving raw materials, storing raw materials, mixing, proofing, baking).
4) The type of packaging shall be mentioned when it has a vital function in food safety (e.g., vacuum packaging, MAP packaging) and/or when there is a potential impact on food safety (e.g. glass).
5) Not include promotional statements or claims, as per ISO 22003-1:2022, clause 9.1.2.3. Claims being any message or representation, which is not mandatory under legislation, and which suggests that the product or service has particular characteristics. Examples are health claims, nutritional claims, origin claims, free-from claims (e.g. allergen free claims), organic, quality claims;
   Where an organization makes such claims, they shall be investigated when they are part of the FSMS but shall not appear in scope statement;
6) Brand names are not allowed as this might suggest product certification;
7) Be in English, but another language may be added in addition (e.g. the native language of the country of the certified organization);
8) Not include subcontracted or outsourced processes outside the organization's legal responsibility and control. Where products or processes are subcontracted or outsourced, the requirements of ISO 22000:2018 clauses 7.1.6 and 8.1 still apply and objective evidence shall be recorded in the audit report;
9) Not include company names;
10) Not contain terms such as "etcetera" or "etc."
11) Shall not include activities such as trading, broking, unless subcategory FII applies;

12) Not include reference to products, processes or services related to non-food/feed (e.g. shall not refer to pharmaceutical and self-medication products, tobacco, cosmetics, household and personal care products, ink*). *This does not include ink that is applied directly to a foodstuff e.g., ink used to date code the shell of an egg, as this ink may be certified;
13) Not contain exclusions for 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 organizations' activities (ISO 22003-1:2022 9.1.2.3); Where permitted exclusions apply, this shall be motivated in the report and the certificate shall reference the exclusion as part of the scope statement; the scope statement on the certificate shall indicate "Exclusions apply: (excluded product(s)/process(es)/service(s))";
14) Not contain Development and Design as separate activity. These activities are only allowed when part of a processing or manufacturing activity covered by the FSSC 22000 scope of certification and part of the same legal entity;
15) Storage, warehousing, & distribution, delivery, supply, and dispatch operations (on or off site), may only be added to the manufacturing scope (categories BIII, C, D, I and K) statement in cases where these are:

    • dedicated to the company's own production;

    • included within the audited food safety management system; and

    • part of the same legal entity (i.e., owned by the organization).

    Where 3rd party Logistic Services are provided (including logistics services provided to a subsidiary/sister company), category G is applicable.

16) The word "sales" is not allowed: A manufacturer will always have sales activities, as they will need to sell their products (primary reason for being in business). However, there are no provisions or specific requirements in the food manufacturing standard for the sales process, therefore is not auditable and cannot appear in the scope statement. The same requirement applies to words equivalent or similar to sales such as marketing, exporting and or importing.

4. SPECIFIC REQUIREMENTS

The food chain categories and related supply chain sectors that fall within the scope of FSSC 22000 certification are defined in Part 1 of the scheme documents.

4.1 FOOD CHAIN CATEGORY BIII – PRE-PROCESS HANDLING OF PLANT PRODUCTS

Pre-process handling of plant products includes plant products that are not transformed.

The scope statement shall contain the type of plant product handled.

EXAMPLES

Certificate scope statement	Acceptable	Comments and recommendations
Sorting, packing and chilled storage of grapes.	Yes	

4.2 FOOD CHAIN CATEGORY C – FOOD MANUFACTURING

1) Where products are intended for specific vulnerable consumer groups, this shall be indicated in scope statement (e.g., baby food, infant formula, food for special medical purposes, food for special dietary needs, etc.).
2) For pet food production, the type of pet food shall be mentioned (e.g. dry, wet, treats) as well as the target animal group (dogs, cats….)
3) By-products from the food manufacturing process can be included provided they are mentioned in scope statement with the addition “for use in the feed industry” or equivalent wording. This only applies where a small amount of waste products (fit for animal feed) from the food manufacturing process are supplied as a raw material for animal feed.

EXAMPLES

Certificate scope statement	Acceptable	Comments and recommendations
Production of eggs	Partial	In this case it would be better to describe the actual activities such as sorting and packing of eggs.
Production and packing of vegetable oil.	Partial	For a company that produces oil (pressing, extraction) the term production can be appropriate, however for a company that only mixes and fills oil into bottles the term production as such may be misleading and incorrect.
Production (pressing, winterization filtering and filling) of olive oil.	Yes	In this case it is clear what is meant by production, and although generally not recommended here it is necessary to add processing steps.
Development and design of ready-to eat meals.	No	Development and design are not allowed as separate activities. Such activities are only allowed in addition to a processing or manufacturing activity covered by the FSSC 22000 scope of certification and part of the same legal entity.
Production of bakery products (croissants, bread rolls, cakes, and brioche).	Yes	The scope statement shall not only mention bakery products; the main types of products shall be included.
Production of soft drinks packed in cans and glass bottles, and the production of carbon dioxide as an ingredient for these beverages.	Yes	Scope statement correctly describes two types of manufacturing activities (Category C and K).
The blow-molding of plastic bottles from preforms and the bottling of carbonated soft drinks.	Yes	Blow molding from preforms is covered by the food scope and the PRP standard ISO/TS 22002-1 and can be included in the Food scope if part of the same production process.
Manufacturing of dry pet food for rodents.	Yes	

4.3 FOOD CHAIN CATEGORY D - ANIMAL FEED PRODUCTION

- The target animal group shall be mentioned (e.g., cattle, chicken…)

EXAMPLES

Certificate scope statement	Acceptable	Comments and recommendations
Production and transport of dry feed mixtures for cattle.	Yes	Allowed if the transport process is owned by the company.

4.4 FOOD CHAIN CATEGORY E - CATERING

EXAMPLES

Certificate scope statement	Acceptable	Comments and recommendations
Production of ready to eat hot and cold meat and vegetables dishes served at the hotel restaurant	Yes	
Production of food for flight catering: including cold dishes, decorated cakes.	No	This is a manufacturing scope statement under category C. E is only applicable when the actual catering services are delivered to consumers.
Reheating and serving onboard airline meals to passengers	Yes	Included as the meals are being reheated and served for on-site direct consumer consumption.
Production of wraps with different fillings at a food truck, serving food at festivals.	Yes	
Manufacturing of meals at a central kitchen and service at several locations.	No	Offsite catering kitchens and products of industrial kitchens not offered for immediate consumption are included under category CIII.
Production of food for events such as weddings and **conferences. Prepared off-site and delivered to the event location.**	No	

4.5 FOOD CHAIN CATEGORY F – TRADING, RETAIL, WHOLESALE AND E-COMMERCE

Food chain category FI:

1) Category FI is the category for retail and wholesale, and manufacturing processes are not included.
2) In-shop activities that only serve to give pre-prepared food a final process step are allowed in scope (e.g. reheating of ready to eat foods, cutting of meat or fish) and shall be mentioned in the scope statement.
3) It is required to specify which type of activities are conducted (i.e. wholesale or retail).
4) Wholesale activities are organizations that sell goods in large/bulk quantities to other industries and consumers.
5) Category FI includes physical storage of products.

EXAMPLES

Certificate scope statement	Acceptable	Comments and recommendations
Wholesale of canned meat and vegetable products.	Yes	
Washing, cutting, packaging and wholesale of fruit and vegetables.	No	Washing, cutting, and packaging are manufacturing scopes.
Retailing of chilled and frozen packed vegetables, meat, fish, and dairy products to end consumers, including the following in-shop activities: cutting and packing of cheese and fish.	Yes	
Retailing of a supermarket assortment to end-consumers (meat and meat products, fish, beverages, dry products, vegetables and fruits, bakery products, deep frozen products).	Yes	
Wholesale of packaging materials for food use.	Yes	
Retailing of ambient and chilled foodstuffs via the internet	Yes	This is an E-commerce activity.

Food chain category FII:

Category FII is the category for brokering and trading activities.

It does not include physical storage of products, or manufacturing processes. Category FII only includes administrative activities.

EXAMPLES

Certificate scope statement	Acceptable	Comments and recommendations
Trading and brokering of chilled meat products (vacuum packed cuts of beef and pork)	Yes	
Trading of plastic food packaging materials	Yes	
Manufacturing and trading of animal feed	Yes	As long as it includes certification against both category D for manufacturing and category FII for trading.

4.6 FOOD CHAIN CATEGORY G - TRANSPORT AND STORAGE SERVICES

A scope statement in category G shall as a minimum contain following elements:

- Type of service provided (e.g. transport, storage, cross docking),
- The type(s) of product handled (e.g. food product group, packaging materials, animal feed),
- The conditions of the activity (ambient, chilled, frozen) when food and/or feed is stored, and/or transported,
- For transport activities means of transport (e.g., road, air, water, railway, bulk, containers).

EXAMPLES

Certificate scope statement	Acceptable	Comments and recommendations
Ambient storage and road transport of food.	Yes	
Frozen storage of meat and meat products.	Yes	
Storage of fruit and trade in fresh pineapples.	Yes	As long as it includes certification against both category G and category FII.
Arranging of transport, licenses, and export documents.	No	This is not allowed as the organization does not provide physical storage and/or transport.

4.7 FOOD CHAIN CATEGORY I - FOOD PACKAGING MANUFACTURING

The type of material(s) (i.e., plastics, paper and board, metal, glass) shall be mentioned in the certificate scope statement followed by the text "intended for use the food (or feed) industry".

EXAMPLES

Certificate scope statement	Acceptable	Comments and recommendations
Development, press and blow extrusion, gravure printing, laminating, slitting, and converting of flexible packaging for medicinal, chemical- technical, food and hygiene products.	No	Only packaging materials for food products are allowed.
Manufacturing of plastic laminated tubes for food industries.	Yes	
Manufacturing of wooden sticks for the use in lollypop sticks and ice-cream.	Yes	
Manufacture and printing of cardboard boxes to be used in the food industry.	Yes	
Production of preforms from resin and blow molding of plastic bottles.	Yes	The in-line production of bottles using resin to produce a preform and followed by the blowing of bottles is considered a packaging activity and shall additionally be covered by a packaging scope.
The production of paper cups for use in the food industry and intended for sale as part of the food product.	Yes	The intended use and the food industry are included. Paper cups sold only to retail is not allowed.

4.8 FOOD CHAIN CATEGORY K - PRODUCTION OF (BIO) CHEMICALS

The scope statement shall refer to the fact that these products are intended to be used in the food or feed industry.

Where the product produced is legally classified as a food additive in the country of manufacture, then it shall be classified as Category K. If it is legally classified as a food ingredient, and not a food additive, then it shall be classified as Category C (e.g., CIV for ambient stable food ingredient).

EXAMPLES

Certificate scope statement	Acceptable	Comments and recommendations
Production of food-grade solid CO_2 (Dry Ice).	Yes	
The manufacturing of liquid flavors for use in the beverage industry.	Yes	
Manufacturing of cleaning agents to be used in CIP systems in the food industry.	No	Cleaning agents are not within the scope of FSSC 22000.
Production of food gases (Nitrogen, Oxygen, Argon, Nitrogen Dioxide, Carbon Dioxide, Hydrogen) and gas mixtures for use in the food industry.	Yes	
Production of preservatives, antioxidants, and anti-caking agents intended for use in the feed industry.	Yes	

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FOOD SAFETY SYSTEM CERTIFICATION

ANNEX 2: CB AUDIT REPORT REQUIREMENTS

Version 6 | April 2023

INTRODUCTION

This document has been developed to ensure a high caliber of audit reporting and sets out the minimum requirements and expectations in terms of the content and the level of detail required in FSSC 22000 audit reports.

CBs shall only use the mandatory FSSC 22000 audit reports provided by the Foundation. The completed audit report shall clearly demonstrate that the FSSC 22000 Scheme requirements have been addressed by the organization and meet the ISO/IEC 17021-1:2015 as well as the GFSI requirements.

This Annex shall:

1. Be used by all Integrity Program Assessors to determine CB conformance with FSSC 22000 audit reporting requirements;
2. Be used by all CBs to train their auditors and personnel involved in the review and certification decision process on the content requirements of the audit report, to ensure a robust certification process.

ISO/IEC 17021-1:2015, clause 9.4.8.2 and 9.4.5.1 requires: "the audit report shall provide an accurate, concise and clear record of the audit to enable an informed certification decision to be made". In addition, it also requires "audit findings (audit findings summarizing conformity and detailing nonconformity), reference to evidence and conclusions, consistent with the requirements of the type of audit" shall be included.

GFSI Version 2020.1 Part 2 – 5.17: The Certification Program Owner shall ensure that the audit report contains evidence that all the specified requirements of the Certification Program related to the GFSI scope(s) of recognition have been evaluated during the audit and clearly express the outcome of the evaluation.

This document details the minimum audit report content that is required to be included in audit reports.

In the case of multi-site certification, separate report(s) may be produced for the Central function (similar to a head office report), including a consolidated nonconformity report and reports for each of the sites, respectively, in which case the site reports shall meet the content requirements as set out in this Annex.

Alternatively, one audit report may be produced for the multi-site organization, including the Central function information, in which case specific information about each site audited is required and complies with the content of this Annex. The summary sections of the audit report shall clearly reflect what was audited at each site with supporting objective evidence to show that the Scheme requirements were audited at each site. The minimum content of the Central functions shall include a description of the centralized functions, including details on internal audits, how this is managed and controlled by the group, and the competency of the internal auditors. The requirements referenced in the FSSC 22000 Additional requirement 2.5.18 shall be included in the Central function section of the report.

INSTRUCTIONS

1. This document sets out the minimum requirements in each section of the audit report. For the clauses of ISO 22000, the relevant PRP/s, and the additional FSSC 22000 requirements, it explains the minimum content required to be documented in each section.
2. The text in blue font represents an overview of what is expected to be detailed in the audit report, it is not intended to be an exhaustive list and the auditor(s) need to demonstrate that all requirements of the clause(s) have been assessed supported by objective evidence and suitable audit trails.
3. Checklists – summary section per clause shall contain:
    a) An overview of the section, including evidence assessed to demonstrate compliance or non-compliance to the clauses in the section.
    b) Checklist summaries shall be sufficiently detailed to allow insight and an overview and not be oversimplified, or just indicate "conformance with the requirements was noted" or any other vague descriptions of similar effect.
4. In relation to nonconformities raised, the following shall apply:
    a. Nonconformities shall not be reported against more than one clause within FSSC 22000;
    b. The nonconformity shall always be written to the most specific clause and not be grouped unless a systemic issue is identified, in which case the expectation is that in most cases the nonconformity is raised to a higher grade i.e., a major.
    c. Nonconformities shall reference the objective evidence to justify the nonconformity and clearly identify why the requirement is not being met;
    d. The Nonconformity Report issued by the CB shall meet the content requirements of section 3.3 of this Annex. The CBs Nonconformity report shall be uploaded to the Assurance Platform for each audit.
5. In exceptional cases, certain requirements can be deemed not applicable (N/A). Where a requirement is deemed to be N/A then suitable justification shall be recorded in the relevant section of the audit report. Note: this only applies to those clauses in the audit report that have the option to select N/A; all other clauses shall be audited in full.
6. Where Design and Development is permitted to be added to the scope of the certificate as per the requirements of Annex 1, Section 3, then particular attention shall be paid to documenting what was audited, including the interface of the process with the FSMS. This includes detailing the design and development process in the audit plan, the audit program, and the audit report.
7. Where ICT is used during an audit, the details of the type of ICT used and which clauses/departments were audited using ICT must be clearly indicated in the audit report and the audit plan and meet the requirements in Annex 5.
8. CBs are required to issue the full FSSC audit report as supplied by The Foundation, the content of which meets the requirements of this Annex, to clients for all certification audits including surveillance audits. The full audit report consists of the audit checklists for ISO 22000:2018, the relevant PRP standard/s and the additional FSSC 22000 requirements.
9. As per ISO/IEC 17021-1, the audit report must be provided to the organization. Annexes provided to the organization shall include the nonconformity report, audit plan, and the audit program.
10. The complete audit pack shall be uploaded into the Assurance Platform along with attachments in PDF including the final audit report, audit plan, audit program, integrity declaration, attendance register and nonconformity reports. Supporting audit documentation shall be uploaded as a zipped file to facilitate uploading into the Assurance Platform. It is not required to upload supporting evidence for closure of nonconformities into the Assurance

Platform. The mandatory fields and nonconformity details for upload in the Assurance Platform shall always be completed in English.

Notes:

1) This Annex is designed for food manufacturing audits, and the ISO/TS 22002-1:2009 PRP checklist is used in this example. It applies to Food Chain Categories BIII, C and K.
2) For Food Chain Categories A, D, E, FI, G or I the level of detail in the summary sections for the relevant PRP standard shall be aligned with what is reflected in this Annex, even though the content will vary depending on the PRP standard.
3) In all cases, verify the latest FSSC 22000 BoS decision list available on the FSSC website to ensure all audit requirements are covered and reflected in the audit report.
4) Audit attachments: when uploading scans of documents, these must be legible and of good quality.

STAGE 1 AUDIT REPORT

1. ORGANIZATION DETAILS

1.1 ORGANIZATION PROFILE

Registered legal name	Name of organization to be certified
COID	FSSC Certified Organization Identification code
Legal or official company registration number	Applicable reference to legal registration (such as a business registration number)
Location/Address	Full physical address (or other unique identification of site location i.e., GPS, GLN etc. where a physical address is not available)
Technical contact person	Full name: Function/Job role: Email address:
Commercial/marketing contact person	Full name: Function/Job role: Email address:
General description of audited organization	Brief history of company for example, how long in business, purpose built/prior use, main markets (local/international) Overview of products produced/services provided, main processes, number of processing lines, organizational structure including relationship with Head Office or off-site activities where relevant; Level of complexity and risk regarding food safety. **No marketing jargon to be included**
Overview of seasonal activities	Describe what seasonal activities are conducted. (For example: • Processing of stone fruit September - October • Processing of root vegetables March – October) Indicate "None" if not applicable

1.2 HEAD OFFICE (WHERE APPLICABLE)

Registered legal name	Name of Head office to be included in the certification
Location/Address of Head office	Full physical address (or other unique identification of site location i.e., GPS, GLN etc. where a physical address is not available)
Date of head office audit	
Duration of head office audit (in hours)	
Number of sites	Number of sites included under the head office functions

Description of Head office functions	Describe which functions are conducted at Head Office that are common to the certified sites. For example: procurement, human resource management, etc. Indicate if the head office is a separate audit or whether conducted as part of the site audit(s). A separate head office report shall always be generated where the head office is connected to more than one site.

1.3 OFF-SITE ACTIVITIES (WHERE APPLICABLE)

Site name	Name of off-site facility/premises
Location(s)/Address	Full physical address (or other unique identification of site location i.e., GPS, GLN etc. where a physical address is not available)
Date of off-site activity audit/s	
Duration of off-site activity audit/s (in hours)	
Activities at location/s	Describe the activities that are conducted at an off-site location, where they are under the same legal entity and same FSMS (refer FSSC 22000 Scheme requirements Part 3, section 5.2.2). For example: a) Off-site storage b) Off-site manufacturing c) Cross-docking

1.4 MULTI-SITES (WHERE APPLICABLE)

Registered legal name of the Group	Name of the group to be certified
Legal or official company registration number	Applicable reference to legal registration (such as a business registration number)
Location/Address of multi-site organization	Full physical address (or other unique identification of site location i.e., GPS, GLN etc. where a physical address is not available)
Date of Central Functions audit	
Duration of Central Functions audit (in hours)	
Overview of Central Functions	Also, refer to FSSC 22000 Additional Requirement 2.5.18
Number of sites in the group	Number of sites included in the group certification

List of sites included, with addresses, date/s of audit and activity (scope)	

2. AUDIT DETAILS

CB Name and office location (if different from main CB)	CB and office name if local office
Accredited by	Indicate the name of the Accreditation Body here or unaccredited in the case of a provisional license
Audit language	Language audit conducted in – if translator is used provide detail
Audit objectives	Reference ISO 22003-1:2022 – 9.3.2
Audit criteria	Normative documents i.e., ISO 22000:2018, the specific PRP standard/s and the FSSC 22000 additional requirements (Version 6); Defined processes and documentation of the management system of the organization; Legal and regulatory requirements and customer requirements
Audit Delivery	ICT Audit approach/Full On-site/Full remote audit Detail the extent of ICT use as applicable.
Audit dates	Start and end date DD/MM/YYYY
Audit Duration Stage 1	In hours, for example 8 hours (1 MD = 8 hours)

2.1 AUDIT SCOPE

Food chain (sub)-category	Food chain (sub)-categories supporting the scope statement (multiple food chain categories may be applicable, see Scheme Part 1, Table 1)
Scope statement	Scope statement as per Annex 1 requirements. Where exclusions are applicable, the exclusion shall be included in the scope statement (also on the certificate as well as on the Assurance Platform)
Exclusions (when appropriate and detailed)	Describe the exclusions from the scope and provide adequate justification to support the scope exclusion in accordance with the requirements of Annex 1.
Verification of the scope statement	Confirm that the scope statement is an accurate reflection of the organization's activities

2.2 AUDIT PLAN

Deviation from audit plan:	Describe deviations to the audit plan and their reasons where applicable

2.3 AUDIT TEAM

Name	Function	Audit delivery method	Date(s)	Time (in hours)
Auditor name	Includes lead auditor, auditor, translators, technical expert, witnessor, trainees, observers	i.e., remote/onsite	DD/MM/YYYY	e.g., 8 hours

Note: The table shall be completed per audit date and per audit team member in the case of an audit team and reflect the actual time spent auditing. Where this differs from the audit plan, the justification shall be recorded under deviation from audit plan – 2.2

3. AUDIT RESULTS

3.1 OVERVIEW OF CLIENTS' PREPAREDNESS FOR STAGE 2

Management system documentation including the ability to meet statutory, regulatory and customer requirements	Overview of clients FSMS, level of documentation established and applicable legislative and customer requirements, including level of implementation. Detail relevant regulatory approvals/authorizations reviewed, relating to compliance with regulatory aspects.
Client's site-specific conditions (environment; equipment and processes)	Summary description of site environment and any external risks. Short list of principle processes and key equipment used.
Organizational planning and control **Status with regard to:** a) Key performance b) Processes c) Objectives d) Operation of management system	ISO 22000 clauses 4, 5, 6, 7 Status with regard to key performance, processes, objectives, and operation of management system. Detail if the FSMS is designed to achieve the organizations food safety policy, and that the FSMS has arrangements in place to communicate internally and externally. Confirm whether the organization has implemented externally developed elements of the FSMS. If so, whether it is suitable for the organization, developed in conformity to requirements of ISO 22000, relevant PRP standard, and FSSC additional requirements, and is kept up to date.
Operational planning and control including an overview of PRPs, HACCP system and level of controls established	ISO 22000 clause 8 Provide an overview of the HACCP system, by including a summary of: • PRPs appropriate to the business, • Significant food safety hazards identified and their type, • Methodologies used to conduct the hazard assessment and the selection and categorization of control measures (OPRP and CCP), • Overview of OPRP(s) and CCP(s), including their action criteria/critical limits, monitoring systems, and corrective actions for breach of action criteria/critical limits, • Validation process implementation and results, • Verification activities implementation status, • General description of the level of implementation of the hazard control plan, and • Detail the sites controls over any outsourced processes.
Internal Audit	ISO 22000 clause 9 Confirm if a full internal audit has been conducted with dates, general overview of procedure/system, outcomes, effectiveness etc.

Management Review	ISO 22000 clause 9 Confirm if a Management Review has been conducted, indicate date of review, and effectiveness including the input and output requirements.

Review for Stage 2 Preparedness	
Allocation of resources	Confirm if audit duration is appropriate or whether additional time is required.
Planning needs	Detail any particular planning required for Stage 2 (i.e., certain activities taking place during shifts or at different times or locations as applicable).

3.2 AREAS OF CONCERN

Number (#)	Requirement reference (standard)	Clause	Finding details
1	Example: ISO22000: 2018	Example 7.1.6	Detail issue with relation to requirement and provide objective evidence.

3.3 AUDIT CONCLUSION

☐	**Stage 1 audit to be repeated**
☐	**Proceed to Stage 2 audit**

Disclaimer: Auditing is based on a sampling process of the available information at the time of the audit.

STAGE 2 AUDIT REPORT

1. ORGANIZATION DETAILS

1.1 ORGANIZATION PROFILE

Registered legal name	Name of organization to be certified.
COID	FSSC Certified Organization Identification code
Legal or official company registration number	Applicable reference to legal registration (such as a business registration number).
Location/Address	Full physical address (or other unique identification of site location i.e., GPS, GLN etc. where a physical address is not available).
Technical contact person	Full name: Function/Job role: Email address:
Commercial/marketing contact person	Full name: Function/Job role: Email address:
General description of audited organization	Brief history of company for example, how long in business, purpose built/prior use, main markets (local/international). Overview of products produced/services provided, main processes, number of processing lines, organizational structure including relationship with Head Office or off-site activities where relevant; Level of complexity and risk regarding food safety. **No marketing jargon to be included**
Significant changes since the previous audit	Identify any key changes to the organization since the previous audit.
Seasonal activities	Describe what seasonal activities are conducted. (For example: • Processing of stone fruit September – October • Processing of root vegetables March – October) Indicate “None” if not applicable

1.2 HEAD OFFICE (WHERE APPLICABLE)

Registered legal name	Name of Head office to be included in the certification.
Location/Address of Head office	Full physical address (or other unique identification of site location i.e., GPS, GLN etc. where a physical address is not available).
Date of head office audit	
Duration of head office audit (in hours)	
Number of sites	Number of sites included under the head office functions.
Overview of Head office functions	Describe which functions are conducted at Head Office that are common to the certified sites. For example: procurement, human resource management, etc. Indicate if the head office is a separate audit or whether conducted as part of the site audit(s). A separate head office report shall always be generated where the head office is connected to more than one site.

1.3 OFF-SITE ACTIVITIES (WHERE APPLICABLE)

Site name	Name of off-site facility/premises
Location(s)/Address	Full physical address (or other unique identification of site location i.e., GPS, GLN etc. where a physical address is not available).
Date of off-site activity audit/s	
Duration of off-site activity audit/s (in hours)	
Activities at location/s	Describe the activities that are conducted at an off-site location, where they are under the same legal entity and same FSMS (refer FSSC 22000 Scheme requirements Part 3, section 5.2.2). For example: a) Off-site storage b) Off-site manufacturing c) Cross-docking

1.4 MULTI-SITES (WHERE APPLICABLE)

Registered legal name of the Group	Name of the group to be certified
Legal or official company registration number	Applicable reference to legal registration (such as a business registration number)

Location/Address of multi-site organization	Full physical address (or other unique identification of site location i.e., GPS, GLN etc. where a physical address is not available)
Date of Central Functions audit	
Duration of Central Functions audit (in hours)	
Overview of Central Functions	Also, refer to FSSC 22000 Additional Requirement 2.5.18
Number of sites in the group	Number of sites included in the group certification
List of sites included, with addresses, date/s of audit and activity (scope)	

2. AUDIT DETAILS

CB Name and office location (if different from main CB)	CB and office name if local office
Accredited by	Indicate the name of the Accreditation Body here or unaccredited in the case of a provisional license
Audit language	Language audit conducted in – if translator is used provide detail
Audit objectives	Reference ISO17021-1 – 9.3.1.3
Audit criteria	Normative documents i.e., ISO 22000: 2018, the specific PRP standard/s and the FSSC 22000 additional requirements (Version 6); Defined processes and documentation of the management system of the organization; Legal and regulatory requirements and customer requirements
Audit type	Stage 2, surveillance, transition, recertification
Announced/Unannounced	
Audit complexity	Standalone FSSC 22000 audit Combined/Integrated with another standard. Provide details:
Audit delivery	ICT Audit approach/Full On-site/Full remote audit Detail the extent of ICT used during the audit as applicable
Audit dates	Audit start date Audit end date

Audit Duration	In hours, for example 8 hours (1 MD = 8 hours)
Deviation from audit duration	Provide justification where audit duration differs from calculated duration
Addendums included as part of the audit	Indicate Addendum and audit duration if applicable
Product recalls since the previous audit (food safety)	Yes/No If yes, provide details.
Product withdrawals since the previous audit (food safety)	Yes/No If yes, provide details.

2.1 AUDIT SCOPE

Food chain (sub)-category	Food chain (sub)-categories supporting the scope statement (multiple food chain categories may be applicable, see Scheme Part 1, Table 1
Scope statement	Scope statement as per Annex 1 requirements. Where exclusions are applicable, the exclusion shall be included in the scope statement (also on the certificate as well as on the Assurance Platform)
Exclusions (when appropriate, including justification)	Describe the exclusions from the scope and provide adequate justification to support the scope exclusion in accordance with the requirements of Annex 1.
Verification of the scope statement	Confirm that the scope statement is an accurate reflection of the organization's activities

2.2 AUDIT PROGRAM AND PLAN

Deviation from audit program	Describe issues impacting the audit program and their reasons. If none, state "None"
Deviation from audit plan	Describe deviations to the audit plan and their reasons where applicable

2.3 AUDIT TEAM

Name	Function	Audit delivery	Date(s)	Time (in hours)
Auditor name	Includes lead auditor, auditor, translators, technical expert, witnessor, trainees, observers	i.e., remote/onsite	DD/MM/YYYY	i.e., 8 hours

Note: The table shall be completed per audit date and per audit team member in the case of an audit team and reflect the actual time spent auditing. Where this differs from the audit plan, the justification shall be recorded under deviation from audit plan section – 2.2

2.4 PREVIOUS AUDIT

2.4.1 AUDIT DETAILS PREVIOUS AUDIT

Audit type	Stage 1, Stage 2, Surveillance, Recertification, Transition
Announced / Unannounced	
Audit date/s	DD/MM/YYYY
CB conducting previous audit if different to current CB	In case of a transfer, indicate the name of the previous CB
Actions taken on NCs raised at previous audit	Provide comments on the organization's ability to determine the root causes of any previously identified nonconformities, as appropriate, and on the effectiveness of the actions it has taken to correct such situations and prevent their recurrence. It should also comment on the sufficiency of the organization's formal processes for corrective action.

3. AUDIT RESULTS

3.1 EXECUTIVE SUMMARY

Audit summary	High level summary – aimed at senior management of organization to understand how the FSMS is performing and what actions they need to take to address any shortfalls. Provide a statement on the conformity and the effectiveness of the management system together with a summary of the evidence relating to: a) The capability of the management system to meet applicable requirements, food safety objectives and expected outcomes; b) Progress the organization has made against its objectives since the last audit (however, for an initial certification, this section may need to acknowledge that the organization had not yet developed sufficient history of such achievement for auditing purposes) c) Significant food safety issues that senior management need to be aware of (major/critical findings; trends in recalls etc.) d) The internal audit and management review process; e) Detail outcome of previous audit results f) For recertification audit – indicate how the FSMS has evolved over the three-year cycle The structure of the executive summary should follow the order of the main report.
Confirmation that audit objectives have been fulfilled	Positive statement: do not leave blank. If an objective was not met, indicate why
Unresolved issues	Record any unresolved issues (for example disagreement on findings, finding ratings etc.) resulting from the audit.

3.2 SUMMARY OF AUDIT FINDINGS

# Critical nonconformities	
# Major nonconformities	
# Minor nonconformities	

3.3 NONCONFORMITIES

CRITICAL NONCONFORMITIES

#	**Requirement Reference** (std., clause)	**NC statement** (incl objective evidence)	**Root Cause Analysis** (determine why it arose)	**Corrective Action Plan** (action to prevent repeat; person responsible, due date for completion)	**Correction** (to address the immediate issue)	**Acceptance of correction, CAP, and evidence** (auditor and date)
1	For example: ISO 22000:2018 §7.1	Provide a clear statement of the deviation to the requirement. Provide detailed objective evidence. Indicate potential or actual impact on food safety.	Completed by client	Completed by client	Completed by client	Auditor name and date of acceptance of Root cause analysis, CAP, and correction
2						
Date of suspension: DD/MM/YYYY						
Follow-up Audit						
Date of follow-up audit: DD/MM/YYYY						
Objective Evidence reviewed to close out the NC: Provide detail of evidence reviewed to address and close out the NC**.**						
Result of Follow-up audit:				Lift suspension and reinstate certificate/withdraw certificate		

MAJOR NONCONFORMITIES

#	**Requirement Reference** (std., clause)	**NC statement** (incl objective evidence)	**Root Cause Analysis** (determine why it arose)	**Corrective Action Plan** (action to prevent repeat; person responsible; due date for completion)	**Correction** (to address the immediate issue) **& corrective action taken** (to prevent repeat)	**Objective Evidence Reviewed** (to close out the NC)	**Acceptance of correction, CAP, corrective action taken and evidence** (auditor and date)
1	For example: ISO 22000:2018 §7.1	Provide a clear statement of the deviation to the requirement. Provide detailed objective evidence. Indicate potential or actual impact on food safety.	Completed by client	Completed by client	Completed by client	Indicate evidence reviewed to close the NC i.e., document name and number	Auditor name and date of acceptance of Root cause analysis, CAP, correction, corrective action taken including objective evidence
2							
3							
4							
Onsite close out:		Yes/No	**Follow-up onsite audit date (where applicable)**		DD/MM/YYYY		

MINOR NONCONFORMITIES

#	**Requirement Reference** (std., clause)	**NC statement** (incl objective evidence)	**Root Cause Analysis** (determine why it arose)	**Corrective Action Plan** (action to prevent repeat; person responsible; due date for completion)	**Correction** (to address the immediate issue)	**Objective Evidence Reviewed** (relating to the correction)	**Acceptance of correction and CAP** (auditor and date)
1	For example: ISO 22000:2018 §7.1	Provide a clear statement of the deviation to the requirement. Provide detailed objective evidence.	Completed by client	Completed by client	Completed by client	Indicate evidence reviewed for the correction i.e., document name and number	Auditor name and date of acceptance of Root cause analysis, CAP, correction, and objective evidence
2							
3							
4							

The auditor shall obtain written acknowledgement of the nonconformities from the organization at the end of the audit.

3.4 AUDIT RECOMMENDATION

Initial certification granted	Yes ☐ No ☐ Not applicable ☐
Certification maintained	Yes ☐ No ☐ Not applicable ☐
Re-certification granted	Yes ☐ No ☐ Not applicable ☐

3.5 AUDIT DURATION

On-site audit time calculation – refer Table B.1 in ISO 22003-1:2022 and V6 Part 3, clause 4.3, 5.2 and 5.3	
Number of HACCP studies (linked to product groups)	Indicate the number of HACCP studies – linked to the product group
Number of employees (FTE) *(Used for audit duration calculation to determine* T_{FTE}*)*	FTE = total number of employees including seasonal workers + non-production staff having an impact on food safety; however, where shifts with similar activities apply, then FTE = number of employees on main shift including seasonal workers and non-production staff having an impact on food safety
Number of shifts	
Description of activities per shift if different from main shift	Where activities are different across shifts, provide short overview of activities per shift
Audit preparation time (in hours)	E.g., 2 hours
Audit reporting time (in hours)	E.g., 8 hours

In addition to completing the above mandatory fields, the audit duration calculation shall be uploaded in the FSSC Assurance Platform as a separate document for each audit. The audit duration calculator that is uploaded to the Assurance Platform shall include the formula, and the calculation with all the steps, for the initial certification audit, surveillance audit and the recertification audit.

Disclaimer: Auditing is based on a sampling process of the available information at the time of the audit.

4. CHECKLISTS

Note: Although the checklists are not recorded to sub-sub clause level in all instances, it is required that where nonconformances are identified, these shall be raised against the relevant sub-sub clause, where applicable and indicated as such in the nonconformity summary section of the report and the CB nonconformity record supplied to the organization.

4.1 ISO 22000:2018

ISO 22000:2018		Conform		Grade	If No – detail NC	NC#
Clause	**Requirement**	**Yes**	**No**	Minor/Major/ Critical		
4	**Context of the organization**					
4.1	Understanding the organization and its context	☐	☐			
4.2	Understanding the needs and expectations of interested parties	☐	☐			
4.3	Determining the scope of the food safety management system	☐	☐			
4.4	Food safety management system	☐	☐			

Summary:

Provide an overview of the context of the organization including examples of internal and external issues identified (positive and negative factors) that impact the ability of the FSMS in achieving its intended results and how this aligns with continual improvement of the FSMS. This section can be cross-referenced with ISO 22000:2018 clause 6.1.2. Detail what mechanisms are in place to stay up to date and meet relevant statutory, regulatory and customer requirements relating to food safety. Summarize the status of any governmental or regulatory inspection findings where relevant and include any significant changes to legislation which impacts the FSMS and whether the site has effectively adopted the changes.

ISO 22000:2018		Conform		Grade	If No – detail NC	NC#
Clause	**Requirement**	**Yes**	**No**	Minor/Major/ Critical		
5	**Leadership**					
5.1	Leadership and commitment	☐	☐			
5.2	Policy	☐	☐			
5.2.1	Establishing the food safety policy	☐	☐			
5.2.2	Communicating the food safety policy	☐	☐			

5.3	Organizational roles, responsibilities, and authorities	☐	☐			
5.3.1	Top management shall ensure that responsibilities and authorities for relevant roles are assigned, communicated, and understood within the organization	☐	☐			
5.3.2	The food safety team leader shall be responsible for: a) - d)	☐	☐			
5.3.3	All persons shall have responsibility to report problem(s) with regards to the FSMS to identified person(s)	☐	☐			

Summary:

Provide an overview including objective evidence assessed:

a) Leadership and commitment of top management with respect to the FSMS, including evidence that the food safety policy and objectives have been established by top management, communicated and are compatible with the strategic direction of the organization and have been integrated into the FSMS;

b) Confirmation that organization has sufficient resources available to maintain the FSMS and are being supported by top management; responsibilities and authority for relevant roles have been established and communicated including responsibility for the FSMS, the food safety team and the FS team leader (incl. job description for food safety team leader meets requirements)

c) Detail reporting mechanisms of the team to top management and how all staff can report food safety issues. How does the organization make the policy available to each individual worker – linked to food safety culture;

d) How continual improvement is promoted within the organization

The summary shall include confirmation that an interview was held with top management, including who was interviewed.

ISO 22000:2018		**Conform**		**Grade**	**If No – detail NC**	**NC #**
Clause	**Requirement**	**Yes**	**No**	Minor/Major/ Critical		
6	**Planning**					
6.1	Actions to address risks and opportunities	☐	☐			
6.1.1	When planning for the FSMS, the organization shall consider the issues referred to in 4.1 and the requirements in 4.2 and 4.3	☐	☐			

	and determine the risks and opportunities that need to be addressed to: a) - d)					
6.1.2	The organization shall plan: a) - b)	☐	☐			
6.1.3	The actions taken by the organization to address risks and opportunities shall be proportionate to: a) - c)	☐	☐			
6.2	Objectives of the food safety management system and planning to achieve them	☐	☐			
6.2.1	The organization shall establish objectives for the FSMS at relevant functions and levels. The objectives of the FSMS shall: a) - f)	☐	☐			
6.2.2	When planning how to achieve its objectives for the FSMS, the organization shall determine: a) - e)	☐	☐			
6.3	Planning of changes	☐	☐			

Summary:

Provide an overview of how risks and opportunities are identified and addressed (including actions) relating to the performance and effectiveness of the FSMS and how the effectiveness of the actions will be evaluated.

That objectives have been established and are SMART; describing the monitoring and review process and communication process (internal and external) with examples to illustrate.

How changes within the FSMS are dealt with, including how the organization plans for changes. Whether the organization applied the process approach when implementing changes, taking into account the PDCA principles. Provide examples of significant changes that have taken place since the previous audit, how they were managed and the effect on the operational FSMS, if applicable.

ISO 22000:2018		**Conform**		**Grade**	**If No – detail NC**	**NC #**
Clause	**Requirement**	**Yes**	**No**	Minor/Major/ Critical		
7	**Support**					
7.1	Resources	☐	☐			
7.1.1	General	☐	☐			
7.1.2	People	☐	☐			
7.1.3	Infrastructure	☐	☐			
7.1.4	Work environment	☐	☐			

7.1.5	Externally developed elements of the FSMS	☐	☐		*This clause may be indicated as N/A where there are no externally developed elements of the FSMS*	
7.1.6	Control of externally provided processes, products, or services	☐	☐			
7.2	Competence	☐	☐			
7.3	Awareness	☐	☐			
7.4	Communication	☐	☐			
7.4.1	General	☐	☐			
7.4.2	External communication	☐	☐			
7.4.3	Internal communication	☐	☐			
7.5	Documented information	☐	☐			
7.5.1	General	☐	☐			
7.5.2	Creating and updating	☐	☐			
7.5.3	Control of documented information	☐	☐			
7.5.3.1	Documented information required by the FSMS and by this document shall be controlled to ensure: a) - b)	☐	☐			
7.5.3.2	For the control of documented information, the organization shall address the following activities as applicable: a) - d)	☐	☐			

Summary:

Provide an overview including objective evidence assessed:

Resources; Competence & Awareness

Detail whether the organization has assessed their resource needs and has sufficient resources in place to support the FSMS. Provide an overview including confirmation that defined and documented competence requirements are available for all personnel conducting work under the organization's control that affects its food safety performance and effectiveness of the FSMS, incl. records of training. For external experts, details of requirements, competency, and scope of work (may be identified in contract). Provide an overview of the food safety team (multidisciplinary, disciplines/areas covered). Detailed evidence of competency for the food safety team and personnel that are responsible for the operation of the hazard control plan.

Control of externally provided processes, products or services

Detail which externally provided elements, processes (incl. outsourced processes), products or services are present. How is the impact on food safety assessed, criteria for control (selection, evaluation, monitoring and re-evaluation) determined, communication managed, and effectiveness verified?

Internal and External Communication

Detail the mechanisms for internal and external communication and how the effectiveness of communication is measured and reinforced.

Documented information

Provide an overview of the document control system, including creating, updating, storage and retention of documents (internal and external) and records; back-up systems for electronic systems and access controls.

ISO 22000:2018		Conform		Grade	If No – detail NC	NC #
Clause	**Requirement**	**Yes**	**No**	Minor/Major/ Critical		
8	**Operation**					
8.1	Operational planning and control	☐	☐			
8.2	Prerequisite programs (PRPs)	☐	☐			
8.2.1	The organization shall establish, implement, maintain and update PRPs to facilitate the prevention and/or reduction of contaminants (incl food safety hazards) in the products, product processing and work environment	☐	☐			
8.2.2	The PRPs shall be: a) - d)	☐	☐			
8.2.3	When selecting and/or establishing PRPs, the organization shall ensure that applicable statutory, regulatory, and mutually agreed customer requirements are identified. The organization should consider: a) - b)	☐	☐			
8.2.4	When establishing PRPs the organization shall consider: a) - l)	☐	☐			
8.3	Traceability system	☐	☐			
8.4	Emergency preparedness and response	☐	☐			
8.4.1	General	☐	☐			
8.4.2	Handling of emergencies and incidents	☐	☐			

8.5	Hazard control	☐	☐			
8.5.1	Preliminary steps to enable hazard analysis	☐	☐			
8.5.1.1	General	☐	☐			
8.5.1.2	Characteristics of raw materials, ingredients, and product contact materials	☐	☐			
8.5.1.3	Characteristics of end products	☐	☐			
8.5.1.4	Intended use	☐	☐			
8.5.1.5	Flow diagrams and description of processes	☐	☐			
8.5.1.5.1	Preparation of the flow diagrams	☐	☐			
8.5.1.5.2	On-site confirmation of the flow diagrams	☐	☐			
8.5.1.5.3	Description of processes and process environment	☐	☐			
8.5.2	Hazard analysis	☐	☐			
8.5.2.1	General	☐	☐			
8.5.2.2	Hazard identification and determination of acceptable levels	☐	☐			
8.5.2.2.1	The organization shall identify and document all food safety hazards that are reasonably expected to occur in relation to the type of product, type of process and process environment. The identification shall be based on: a) -e)	☐	☐			
8.5.2.2.2	The organization shall identify step(s) (e.g., receiving raw materials, processing, distribution and delivery) at which each food safety hazard can be present, be introduced, increase of persist. When identifying hazards, the organization shall consider: a) - c)	☐	☐			

8.5.2.2.3	The organization shall determine the acceptable level in the end product of each food safety hazard identified, whenever possible. When determining acceptable levels, the organization shall: a) - c)	☐	☐			
8.5.2.3	Hazard assessment	☐	☐			
8.5.2.4	Selection and categorization of control measure(s)	☐	☐			
8.5.2.4.1	Based on the hazard assessment, the organization shall select an appropriate control measure or combination of control measures that will be capable of preventing or reducing the identified significant food safety hazard to defined acceptable levels	☐	☐			
8.5.2.4.2	In addition, for each control measure, the systematic approach shall include an assessment of the feasibility of: a) - c)	☐	☐			
8.5.3	Validation of control measure(s) and combination of control measures	☐	☐			
8.5.4	Hazard control plan (HACCP/OPRP plan)	☐	☐		*This clause may be indicated as N/A where there are no CCP(s) or OPRP(s)*	
8.5.4.1	General	☐	☐			
8.5.4.2	Determination of critical limits and action criteria	☐	☐			
8.5.4.3	Monitoring systems at CCPs and for OPRPs	☐	☐			
8.5.4.4	Actions when critical limits or action criteria are not met	☐	☐			
8.5.4.5	Implementation of the hazard control plan	☐	☐			
8.6	Updating the information specifying the PRPs and the hazard control plan	☐	☐			

8.7	Control of monitoring and measuring	☐	☐			
8.8	Verification related to PRPs and the hazard control plan	☐	☐			
8.8.1	Verification	☐	☐			
8.8.2	Analysis of results of verification activities	☐	☐			
8.9	Control of product and process nonconformities	☐	☐			
8.9.1	General	☐	☐			
8.9.2	Corrections	☐	☐			
8.9.2.1	The organization shall ensure that when critical limits at CCPs and/or action criteria for OPRPs are not met, the products affected are identified and controlled with regard to their use and release	☐	☐			
8.9.2.2	When critical limits at CCPs are not met, affected products shall be identified and handled as potentially unsafe products (see 8.9.4)	☐	☐			
8.9.2.3	Where action criteria for an OPRP are not met, the following shall be carried out: a) - c)	☐	☐			
8.9.2.4	Documented information shall be retained to describe corrections made on nonconforming products and processes, including a) - c)	☐	☐			
8.9.3	Corrective actions	☐	☐			
8.9.4	Handling of potentially unsafe products	☐	☐			
8.9.4.1	General	☐	☐			
8.9.4.2	Evaluation for release	☐	☐			
8.9.4.3	Disposition of nonconforming products	☐	☐			
8.9.5	Withdrawal/recall	☐	☐			

Summary:

Provide an overview of Operational planning and control including how actions determined in 6.1 have been implemented and how the organization manages the consequences of any unintended changes. Detail the controls in place for any subcontracted or outsourced processes.

Prerequisite Programs (PRPs): Do not list all the individual PRP documents here. Reference in this summary section that the details relating to PRPs are reflected in the relevant PRP checklist (ISO/TS 22002-x as applicable). Comment on the effectiveness of the implementation and verification of PRP's across the site in a general sense.

Traceability System: Define how the organization ensures traceability (one up- one down principle) and that it meets any relevant legislative and customer requirements. Reference the frequency of traceability testing (incl. mass balance) and when the last test was conducted and which product. Detail the traceability exercise conducted by the auditor during this audit and report results (detail product tested, whether speed of completion was in accordance with the organizations procedures, and the outcome of test/mass balance). Where the organization undertakes rework, define how traceability is maintained.

Emergency preparedness and response: Detail the document that addresses the management of potential emergency situations. Detail if there have been any emergency situations since the last audit, how the organization handled these, including actions taken and whether requirements were met. Document the frequency (e.g., annually), date, nature and outcome of the periodic test and any changes to the procedures following the occurrence of any incident, emergency situations or tests. Detail whether the procedure addresses the management of interruptions of essential services including for example the disruption of water, electricity, or refrigeration supply.

Hazard control: Brief overview of preliminary information collected, including product descriptions, intended use and vulnerable groups. Reference the flowcharts, indicate when the flowcharts were last updated and if they have been revised following changes to the process. Reference flowchart/s verified during audit by the auditor and whether the requirement has been met.

Confirmation that the relevant types of hazards (chemical, physical, microbiological, allergens) have been considered in the hazard analysis. Describe the methodology used to assess significant hazards, control measures and determining OPRPs and CCPs. Confirm that all CCPs and OPRPs have been validated and the effectiveness there-of. Complete the below table and add additional rows if needed.

Auditor verification of CCP(s) and OPRP(s)*			
CCP#/ OPRP#	*Description of process step:*	*Critical limits or action criteria*	*Monitoring procedure, correction, and corrective action*
E.g., CCP 1	*E.g., Heat treatment*	*E.g., 121°C for 3 minutes*	*E.g., Monitoring: XX* *Correction: XX* *Corrective action: XX*

**All CCPs and OPRPs are required to be verified by the auditor during the audit. Where a line is not operational at the time of the audit, and physical verification cannot be undertaken, the records shall still be verified.*

Detail the CCP(s) and OPRP(s) records checked as part of the audit.

*Where packaging is used to impart or provide a functional effect on food (e.g., shelf-life extension) the organization has specified requirements in place. **Reference may be made to the FSSC additional requirement 2.5.11 to avoid duplication.*

HACCP review – detail process and when last update was made and how this ties back to the management review.

Control of monitoring and measuring: Detail the processes in place for control of monitoring and measuring equipment.

Verification related to PRPs and the hazard control plan: Detail verification activities undertaken, and detail documented evidence sampled including testing results of end product samples.

Control of product and process nonconformities: where the critical limits or action criteria have not been met since the last audit, detail if the procedure was followed and if the effectiveness of corrective actions was verified. Document examples there-of. Detail how the organization prevents potentially unsafe products from entering the food chain and positive release procedure. Detail examples of nonconforming products that have occurred since the last audit and the actions taken based on records reviewed. Establish whether an effective recall system has been implemented and shall include the details of the last mock recall conducted and the effectiveness thereof. Document any actual withdrawals/recalls since last audit, the outcome and how this was reviewed, and any amendments made as a result of the recall/withdrawal. Further details on recalls in ISO/TS 22002-1: clause 15.

ISO 22000:2018		Conform		Grade	If No – detail NC	NC #
Clause	**Requirement**	**Yes**	**No**	Minor/Major/ Critical		
9	**Performance evaluation**					
9.1	Monitoring, measuring, analysis and evaluation	☐	☐			
9.1.1	General	☐	☐			
9.1.2	Analysis and evaluation	☐	☐			
9.2	Internal audit	☐	☐			
9.2.1	The organization shall conduct internal audits at planned intervals to provide information on whether the FSMS conforms to: a) - b)	☐	☐			
9.2.2	The organization shall a) - g)	☐	☐			
9.3	Management review	☐	☐			
9.3.1	General	☐	☐			
9.3.2	Management review input	☐	☐			
9.3.3	Management review output	☐	☐			

Summary:

Monitoring, measuring, analysis and evaluation: Detail what is monitored/measured and whether the requirements of 9.1 are met in support of the evaluation and performance of the FSMS. Provide an overview of the analysis of information from the monitoring and measuring activities, including the results and trends of verification activities related to PRPs, the Hazard control plan and internal and external

audits. Confirmation that analysis achieves 9.1.2 a-e and is used as an input for management review and updating the FSMS.

Internal audit: Provide an overview of the internal audit program, including frequency, competency and impartiality of internal auditors and how corrective actions are dealt with. The audit program shall confirm that the frequency of internal audits is based on risk, in accordance with 9.2.1 (a). Indicate whether the audit program includes all aspects of FSSC 22000 (ISO 22000, PRP's, FSSC 22000 part 2 and BoS decisions as applicable) as part of the audit criteria and is sufficiently reflected in the internal audit reports. Detail records of internal audit reports sampled. Indicate status of corrective actions for NCs identified during internal audits (link to improvement), follow-up actions/verification and escalation mechanisms should NCs not be addressed, or audit program falls behind.

Management review: Provide an overview of the management review process and its effectiveness including frequency of meetings (minimum once per annum) and participation of senior management (goes to leadership). Reference any significant issues raised at the management review (internal/external risks/opportunities, and significant changes planned/occurred) and whether the organization is effectively handling these issues. *Provide an overview of the output of the management review and any changes to the FSMS, Food Safety Policy, and/or objectives, and any resource requirements. Indicate whether all aspects (inputs, 9.3.2 and outputs, 9.3.3) are addressed in the documented information retained as evidence of the results of the management reviews e.g., agenda and meeting minutes, and detail the date of the last Management Review. Confirm that suitable decisions and actions have been taken to ensure continual improvement and maintenance of the FSMS in line with the Scheme, as a result of the output of the management review.*

ISO 22000:2018		Conform		Grade	If No – detail NC	NC #
Clause	**Requirement**	**Yes**	**No**	Minor/Major/ Critical		
10	**Improvement**					
10.1	Nonconformity and corrective action	☐	☐			
10.1.1	When a nonconformity occurs, the organization shall: a) - e)	☐	☐			
10.1.2	The organization shall retain documented information as evidence of: a) - b)	☐	☐			
10.2	Continual improvement	☐	☐			
10.3	Update of the food management system	☐	☐			

Summary:

Provide an overview of the nonconformity and corrective action system, including customer complaints. Detail how corrective actions are handled incl. root cause, whether similar NCs exist, implementing correction, and corrective action, follow-up/verification (review effectiveness of CA). Detail the NCs/CAs sampled during the audit.

Describe mechanisms or actions taken by management to ensure continual improvement relating to the suitability, adequacy and effectiveness of the FSMS.

Updating the FSMS – confirm that FSMS is continually updated and how this is monitored and achieved taking into consideration the requirements in 10.3.

4.2 ISO/TS 22002-1:2009

ISO/TS 22002-1:2009		Conform			Grade	If No – detail NC If N/A – provide justification	NC #
Clause	**Requirement**	**Yes**	**No**	**N/A**	**Minor/Major/ Critical**		
4	**Construction and layout of buildings**						
4.1	General requirements	☐	☐				
4.2	Environment	☐	☐				
4.3	Locations of establishments	☐	☐				

Summary:

General Requirements: Describe types of buildings (i.e., production, offices, storage, workshops, warehousing etc.), their state of repair and any updates or changes.

Environment: Describe what activities take place in adjacent areas to the site (i.e., industrial units, open paddocks etc.), and whether risks have been considered. Detail the last review date and outcome of the effectiveness of measures to protect against potential contamination.

Location of establishment: Describe site boundaries (fencing, adjacent buildings etc.). Access details can be referred to clause 18.2 of the Food PRP to avoid duplication. Comment on general maintenance of site (vegetation, roads, yards, parking areas, and standing water).

ISO/TS 22002-1:2009		Conform			Grade	If No – detail NC If N/A – provide justification	NC #
Clause	**Requirement**	**Yes**	**No**	**N/A**	**Minor/Major/ Critical**		
5	**Layout of premises and workspace**						
5.1	General requirements	☐	☐				
5.2	Internal design, layout, and traffic patterns	☐	☐				
5.3	Internal structures and fittings	☐	☐				
5.4	Location of equipment	☐	☐				
5.5	Laboratory facilities	☐	☐	☐			
5.6	Temporary or mobile premises and vending machines	☐	☐	☐			
5.7	Storage of food, packaging materials, ingredients, and non-food chemicals	☐	☐				

Summary:

Comment on adequacy of design, layout, equipment, and traffic patterns with respect to impact on food safety, including facilitating cleaning and maintenance activities. Zoning (physical separation of raw from processed areas), materials and human flow patterns mapped.

Comment on the maintenance of floors, walls, ceilings, overhead structures, drains, and other internal structures and fittings. Indicate if there is standing water (i.e., drains not sufficient) and risk to product from potential broken windows (glass, dust, insects etc.) and roof vents/fans etc. Comment on whether doors were closed or screened when not used.

Where Laboratory facilities are present on the site, document location and if micro/chemical testing conducted and risks controlled. Detail how in-line/on-line testing facilities are controlled.

Where there are any temporary or mobile structures, vending machines used, detail how the hazards are assessed and controlled.

Provide an overview of the storage of raw materials (incl. bulk), ingredients, intermediate products, packaging materials, finished products, and non-food chemicals, and how the organization meets the requirements. Detail the temperature controls in place for chilled or frozen storage areas.

ISO/TS 22002-1:2009		Conform			Grade	If No – detail NC If N/A – provide justification	NC#
Clause	Requirement	Yes	No	N/A	Minor/Major/ Critical		
6	**Utilities – air, water, energy**						
6.1	General requirements	☐	☐				
6.2	Water supply	☐	☐				
6.3	Boiler chemicals	☐	☐	☐			
6.4	Air quality and ventilation	☐	☐				
6.5	Compressed air and other gases	☐	☐	☐			
6.6	Lighting	☐	☐				

Summary:

Water supply: Detail the water type (potable, non-potable), their use (e.g., ingredient, ice, steam, cleaning, hand washing, etc.), their source (i.e., municipal, bore water, in-house treated water plants) and controls in place. Indicate if quality (incl. chemical) and microbiological specifications for water (various uses) are defined and if water meets specifications (type of testing, frequency, results) and any legislative requirements that might apply. Detail examples of records looked at.

Where Boiler chemicals are used, provide information on approval for use, storage, security measures and any areas of concern where steam comes in direct contact with product.

Air quality and ventilation: Detail if air is used as an ingredient or is in direct product contact, how the organization ensures such air meets requirements (testing, specifications, quality monitoring program etc. document records reviewed). Detail records of maintenance of air systems including air filter replacement program. Indicate whether adequate ventilation was in place.

Provide an overview of compressed air and other gases if used (type, purpose etc.) If used, and is in contact with product, equipment etc. detail approved sources, use, and controls in place including if filtered.

Comment if there is sufficient lighting in all areas (production, storage etc.) to facilitate hygienic operations; if light fixtures are suitably protected, and where UV lights are in use.

ISO/TS 22002-1:2009		Conform			Grade	If No – detail NC If N/A – provide justification	NC #
Clause	Requirement	Yes	No	N/A	Minor/Major/ Critical		
7	**Waste disposal**						
7.1	General requirements	☐	☐				
7.2	Containers for waste and inedible or hazardous substances	☐	☐				
7.3	Waste management and removal	☐	☐				
7.4	Drains and drainage	☐	☐				

Summary:

Provide an overview of the waste management system in place and if any hazardous substances have to be removed, how this is managed and controlled including destruction/removal.

Where trademarked materials are discarded or destroyed how the risk of re-use is being managed. Verify contract with waste removal company, and records of destruction.

Drains – comment on their design, location, direction of flow, capacity and appropriate for the size of the premises.

ISO/TS 22002-1:2009		Conform			Grade	If No – detail NC If N/A – provide justification	NC #
Clause	Requirement	Yes	No	N/A	Minor/Major/ Critical		
8	**Equipment suitability, cleaning, and maintenance**						
8.1	General requirements	☐	☐				
8.2	Hygienic design	☐	☐				
8.3	Product contact surfaces	☐	☐				
8.4	Temperature control and monitoring equipment	☐	☐				
8.5	Cleaning plant, utensils, and equipment	☐	☐				
8.6	Preventive and corrective maintenance	☐	☐				

Summary:

Provide a general overview of the suitability of equipment, product contact surfaces and hygienic design requirements including the general condition of equipment. Where temperature control and monitoring equipment are in use, comment on thermal process equipment regarding type, monitoring and temperature control measures, also in terms of meeting product specifications (temp gradient and holding conditions). Detail the plant, utensil and equipment cleaning frequencies (refer to procedure/cleaning schedule, suitability of cleaning equipment etc.). Provide an overview of the preventive and corrective maintenance program, including how corrective maintenance is carried out and temporary fixes are addressed. Indicate if lubricants are used and if they are food grade. Detail

whether the site had post-maintenance cleaning procedures in place. Detail documented evidence of maintenance sampled, including training of maintenance personnel.

ISO/TS 22002-1:2009		Conform			Grade	If No – detail NC If N/A – provide justification	NC #
Clause	**Requirement**	**Yes**	**No**	**N/A**	**Minor/Major/ Critical**		
9	**Management of purchased materials**						
9.1	General requirements	☐	☐				
9.2	Selection and management of suppliers	☐	☐				
9.3	Incoming material requirements (raw/ ingredients/ packaging)	☐	☐				

Summary:

Provide an overview of the supplier approval program including supplier risk assessment, and how this is controlled, monitored, and reviewed to ensure suppliers meet the specified requirements.

Has requirements for incoming materials been established including delivery vehicle inspection and incoming materials inspection requirements and frequency and how to deal with non-compliances (including dealing with and identification of products on hold or rejected, and prevention of unintended use). Where bulk receiving lines are present, these shall be identified, capped, and locked and approval/discharge systems in place.

ISO/TS 22002-1:2009		Conform			Grade	If No – detail NC If N/A – provide justification	NC #
Clause	**Requirement**	**Yes**	**No**	**N/A**	**Minor/Major/ Critical**		
10	**Measures for prevention of cross contamination**						
10.1	General requirements	☐	☐				
10.2	Microbiological cross contamination	☐	☐				
10.3	Allergen management	☐	☐				
10.4	Physical contamination	☐	☐				

Summary:

Microbiological cross-contamination: Describe separation measures taken, zoning, access controls and traffic patterns as applicable.

*Allergen management: Detail if there are allergens in the product(s) and which ones are present, if there are none indicate such. Reference specific training including allergen awareness training. Where allergen declarations are made (on label or accompanying documentation), are these verified and validated and meeting any specific legislative/customer requirements. Detail cleaning, line change-over practices/product sequencing and how rework is addressed. **Reference may be made to the FSSC additional requirements for allergen management to avoid duplication.*

*Physical contamination: Detail brittle (glass/hard plastic) material inspections and breakage procedures in place. Detail any breakage records sampled. **Reference may be made to the FSSC additional requirements for foreign matter management to avoid duplication.*

ISO/TS 22002-1:2009		Conform			Grade	If No – detail NC If N/A – provide justification	NC #
Clause	**Requirement**	**Yes**	**No**	**N/A**	**Minor/Major/ Critical**		
11	**Cleaning and sanitizing**						
11.1	General requirements	☐	☐				
11.2	Cleaning and sanitizing agents and tools	☐	☐				
11.3	Cleaning and sanitizing programs	☐	☐				
11.4	Cleaning in place (CIP) systems	☐	☐	☐			
11.5	Monitoring sanitation effectiveness	☐	☐				

Summary:

Provide an overview of the cleaning and sanitation procedure/program, including whether it is suitable/appropriate to the relevant processes (incl. cleaning agents and tools), what validation of methods has been conducted and what monitoring is in place to check the effectiveness of cleaning.

Where CIP systems are used, provide detail on the CIP program including parameters and monitoring measures and requirements. Confirm lines are separated from active product lines.

Detail records reviewed to demonstrate parameters are met.

ISO/TS 22002-1:2009		Conform			Grade	If No – detail NC If N/A – provide justification	NC #
Clause	**Requirement**	**Yes**	**No**	**N/A**	**Minor/Major/ Critical**		
12	**Pest Control**						
12.1	General requirements	☐	☐				
12.2	Pest control programs	☐	☐				
12.3	Preventing access	☐	☐				
12.4	Harborage and infestations	☐	☐				
12.5	Monitoring and detection	☐	☐				
12.6	Eradication	☐	☐				

Summary:

Describe pest control program and how it covers the requirements of this section. Reference the pest control contract when external companies are being used, licensing of operators, approved chemicals used, monitoring frequency and how follow up actions are monitored and implemented – also referencing

where eradication has been required and related action taken. Detail any trends identified in pest activity and how this was addressed.

ISO/TS 22002-1:2009		Conform			Grade	If No – detail NC If N/A – provide justification	NC #
Clause	**Requirement**	**Yes**	**No**	**N/A**	**Minor/Major/ Critical**		
13	**Personnel hygiene and employee facilities**						
13.1	General requirements	☐	☐				
13.2	Personnel hygiene facilities and toilets	☐	☐				
13.3	Staff canteens and designated eating areas	☐	☐				
13.4	Workwear and protective clothing	☐	☐				
13.5	Health status	☐	☐				
13.6	Illness and injuries	☐	☐				
13.7	Personal cleanliness	☐	☐				
13.8	Personal behavior	☐	☐				

Summary:

Detail the procedure on personal hygiene for employees, visitors, and contractors and how this is implemented and managed. Comment on level of implementation and personal behavior of employees, also linked to internal communication of the procedures/policies.

Comment on whether the number and location of hygiene facilities (incl. hand washing, drying, and sanitizing facilities, etc.) and toilets are adequate, and whether they meet requirements. Detail if there are designated eating areas, located away from production/packing/storage areas. Where there are catering facilities on site, detail how hygienic conditions are maintained, and controls in place for storage, cooking and holding incl. temperature.

Workwear and protective clothing - detail type of workwear and protective clothing used and how it is used/maintained/laundered (incl. frequency), specific requirements for different zones i.e., high-risk areas where relevant, and glove management as appropriate.

Health status – describe the company system used (e.g., medicals) and how illnesses and injuries (incl. wounds/burns/cuts) are reported and managed.

ISO/TS 22002-1:2009		Conform			Grade	If No – detail NC If N/A – provide justification	NC #
Clause	**Requirement**	**Yes**	**No**	**N/A**	**Minor/Major/ Critical**		
14	**Rework**						
14.1	General requirements	☐	☐	☐			
14.2	Storage, identification, and traceability	☐	☐	☐			
14.3	Rework usage	☐	☐	☐			

Summary:

Where an organization has rework, detail how these requirements are met in terms of storage, identification, and traceability. Detail how rework is recorded when used and records reviewed. Indicate if specifications for rework use are followed.

ISO/TS 22002-1:2009		Conform			Grade	If No – detail NC If N/A – provide justification	NC #
Clause	**Requirement**	**Yes**	**No**	**N/A**	**Minor/Major/ Critical**		
15	**Product Recall Procedures**						
15.1	General requirements	☐	☐				
15.2	Product recall requirements	☐	☐				

Summary:

*Describe the process/procedure the organization has to manage a recall situation. Indicate whether the site has a list of key contacts in place. Where an actual recall occurred, provide details, actions taken, whether public warnings were considered and indicate whether similar products or products produced under the same conditions were evaluated. ** Reference may be made to clause 8.9.5 of ISO 22000:2018 to avoid duplication.*

ISO/TS 22002-1:2009		Conform			Grade	If No – detail NC If N/A – provide justification	NC#
Clause	**Requirement**	**Yes**	**No**	**N/A**	**Minor/Major/ Critical**		
16	**Warehousing**						
16.1	General requirements	☐	☐				
16.2	Warehousing requirements	☐	☐				
16.3	Vehicles, conveyances, and containers	☐	☐				

Summary:

Provide an overview of warehousing activities on the site and how requirements in the standard are met, including FIFO, FEFO, temperature & humidity requirements and any specific product or storage requirements. Where controlled atmosphere is used, how it is monitored (testing, frequency, records etc.)

Detail areas for waste materials, chemicals and nonconforming materials if not covered in cl. 5.7 and 7.3 of ISO/TS 22002-1.

Vehicles, conveyances and containers: summary and extent to which these are used, how it is managed and maintained (cleanliness, state of repair, etc.), including control over contracted vehicles, and specific temperature and/or humidity requirements.

ISO/TS 22002-1:2009		Conform			Grade	If No – detail NC If N/A – provide justification	NC#
Clause	**Requirement**	**Yes**	**No**	**N/A**	**Minor/Major/ Critical**		
17	**Product information/consumer awareness**						

17.1	Product information and consumer awareness	☐	☐				

Summary:

Document the sample(s) reviewed (labels, packaging, websites, and advertisements) and report on whether information was presented to consumers in such a way as to enable them to make informed choices.

ISO/TS 22002-1:2009		Conform			Grade	If No – detail NC If N/A – provide justification	NC#
Clause	**Requirement**	**Yes**	**No**	**N/A**	**Minor/Major/ Critical**		
18	**Food defense, biovigilance and bioterrorism**						
18.1	General requirements	☐	☐				
18.2	Access controls	☐	☐				

Summary:

Food defense: can refer to Additional FSSC 22000 requirements to reduce duplication in report.

Access controls: Provide an overview of access control measures, site security and any reported breaches.

4.3 FSSC 22000 ADDITIONAL REQUIREMENTS

FSSC 22000 Additional Requirement		Conform			Grade	If No – detail NC If N/A – provide justification	NC#
Clause	**Requirement**	**Yes**	**No**	**N/A**	**Minor/Major/ Critical**		
2.5.1	Management of services and purchased materials (All Food Chain Categories)	☐	☐				

Summary:

Detail which testing is being conducted by external or internal laboratories, which laboratories are used for verification/validation of food safety elements, and how they are competent and have the capability to conduct the analysis (i.e., ISO17025). Where a laboratory does not have ISO 17025, document how they meet the competency/capability requirements e.g., proficiency testing programs, regulatory approved programs.

Describe the process followed in the case of procurement under emergency situations to ensure that products still conform to specified requirements and the supplier has been evaluated, including reference to the documented procedure. Detail if any instance of emergency use of non-approved suppliers has occurred since the previous audit (date, supplier, material) and confirm if procedure was followed effectively.

Where animals, fish and seafood are procured that are subject to control of prohibited substances (e.g., pharmaceuticals, veterinary medicines, heavy metals, and pesticides), describe how the organization has included this in their supplier approval process and the controls established;

Provide an overview of the review process for product specifications (raw material and finished product) to ensure continued compliance with food safety, quality, legal and customer requirements with examples.

Food chain category I only: provide an overview of criteria established for the use of recycled packaging material as a raw material input into the production of finished packaging material, meeting legal and customer requirements.

FSSC 22000 Additional Requirement		Conform			Grade	If No – detail NC If N/A – provide justification	NC#
Clause	**Requirement**	**Yes**	**No**	**N/A**	**Minor/Major/ Critical**		
2.5.2	Product Labelling and Printed Materials (All Food Chain Categories)	☐	☐				

Summary:

Detail site relevant legislation for final product labelling in the country of intended sale. Provide an overview of the system followed to ensure correct and accurate labelling, meeting both legislative and customer requirements and requirements around allergen labelling where applicable. Document which product labels were reviewed and whether the samples meet requirements. In the case of bulk or unlabeled products – describe the labelling process or method of communication on product information to ensure the safe use of the food by the customer or consumer.

Where claims are made on product label or packaging, detail evidence of validations and verifications in place to ensure product integrity is maintained incl. traceability and mass balance. Also, reference evidence sampled such as:

- *A valid certificate supporting e.g., Halal, Kosher, or Organic claims, etc.;*
- *Laboratory testing results (meeting the requirements of 2.5.1 and which conform to legal requirements) for nutritional content claims, such as high in omega 3 fatty acids, etc.*

Food chain category I only: provide overview of artwork management and print control procedures in place to ensure printed materials meet customer and legal requirements.

FSSC 22000 Additional Requirement		Conform			Grade	If No – detail NC If N/A – provide justification	NC#
Clause	**Requirement**	**Yes**	**No**	**N/A**	**Minor/Major/ Critical**		
2.5.3	Food Defense (All Food Chain Categories)	☐	☐				
2.5.3.1	Threat Assessment	☐	☐				
2.5.3.2	Plan	☐	☐				

Summary:

Reference procedure that addresses this requirement and detail:

a) Confirmation that a threat assessment has been conducted using a defined methodology and relevant threats addressed - both internal and external threats and control measures are suitable/sufficient.
b) The significant threats identified, as well as the mitigation measures implemented incl. verification procedures.
~~c)~~ Any relevant legislation (e.g., Food Defense Acts) and the organization's conformance to it. If there are no legislative requirements, then note this fact.
d) Training and communication strategy for employees and site security measures
e) Food chain category FII only: confirmation that the supplier(s) had a food defense plan in place.

Statement on effectiveness of implementation of Food Defense Plan, that it is supported by the organization's FSMS and how kept up to date.

FSSC 22000 Additional Requirement		Conform			Grade	If No – detail NC If N/A – provide justification	NC#
Clause	**Requirement**	**Yes**	**No**	**N/A**	**Minor/Major/ Critical**		
2.5.4	Food Fraud Mitigation (All Food Chain Categories)	☐	☐				
2.5.4.1	Vulnerability Assessment	☐	☐				
2.5.4.2	Plan	☐	☐				

Summary:

Reference procedure that addresses this requirement. Detail

a) Confirmation that food fraud vulnerability assessment has been conducted using a defined methodology, breadth of assessment (supply chain and not only at site level) and relevant vulnerabilities addressed, and control measures are suitable/sufficient.
b) The significant vulnerabilities, as well as the mitigation measures implemented incl. verification procedures.
c) Any relevant legislation and the organization's conformance to it. If there are no legislative requirements, then note this fact.
d) Food chain category FII only: confirmation that the supplier(s) had a food fraud mitigation plan in place.

Statement on effectiveness of implementation of Food Fraud Plan and that it is included in the performance evaluation of the FSMS.

FSSC 22000 Additional Requirement		Conform			Grade	If No – detail NC If N/A – provide justification	NC#
Clause	**Requirement**	**Yes**	**No**	**N/A**	**Minor/Major/ Critical**		
2.5.5	Logo use (All Food Chain Categories)	☐	☐	☐			

Summary:

Where the logo is used, document how/where it is used and confirm it is used correctly.

FSSC 22000 Additional Requirement		Conform			Grade	If No – detail NC If N/A – provide justification	NC#
Clause	**Requirement**	**Yes**	**No**	**N/A**	**Minor/Major/ Critical**		
2.5.6	Management of allergens (All Food Chain Categories)	☐	☐				

Summary:

Reference allergen management plan and detail which allergens are present. Confirm whether the site had a list of all the allergens handled including for raw materials and finished products. Confirm that the allergen risk assessment covers all potential sources, including cross contamination.

Detail control measures used to prevent cross-contamination including storage, production and potential cross contamination and training of personnel. Where there are allergens on site that are out of scope (included in products that are excluded from scope, or not part of the scope of FSSC 22000 certification), detail type and whether the potential risks and cross contamination is controlled in relation to the products included in the scope of certification.

Detail evidence of validation and verification of control measures including testing (where necessary). Detail whether precautionary or warning labels are used and whether it is in accordance with the requirement. Indicate the date of the last review of the allergen management plan including trending of verification data.

FSSC 22000 Additional Requirement		Conform			Grade	If No – detail NC If N/A – provide justification	NC#
Clause	**Requirement**	**Yes**	**No**	**N/A**	**Minor/Major/ Critical**		
2.5.7	Environmental monitoring (Food Chain Categories BIII, C, I & K)	☐	☐	☐		*This clause may only be indicated as N/A for FCC A, D, E, F, and G*	

Summary:

Provide evidence that the organization has implemented a risk-based environmental monitoring program, covering the relevant pathogen, spoilage, and indicator organisms, supported by a documented procedure for the evaluation of the effectiveness of all controls on preventing contamination from the manufacturing environment.

The environmental monitoring program shall include as a minimum, the evaluation of microbiological controls present and provide evidence that the organization collects and analyses data of the environmental monitoring activities including regular trend analysis. Describe what monitoring activities are undertaken (microbiological), frequency, general overview of results of testing (trend analysis etc.) and corrective actions or adjustments to the program as needed. Indicate the date of the last annual review of the environmental monitoring program, as well as any reviews due to triggers that have occurred.

Please note that this is not a section on cleaning – Cleaning is covered in PRP clause 11.

FSSC 22000 Additional Requirement		Conform			Grade	If No – detail NC If N/A – provide justification	NC#
Clause	**Requirement**	**Yes**	**No**	**N/A**	**Minor/Major/ Critical**		
2.5.8	Food safety and quality culture (All Food Chain Categories)	☐	☐				

Summary:

Provide an overview of how food safety and quality culture objectives are addressed within the organization with specific reference to communication, training, employee feedback and engagement, and performance measurement of defined activities, covering all sections of the organization impacting on food safety and quality.

Reference the food safety and quality culture plan, including confirmation that the organization has set targets and timelines, and that food safety and quality culture has been addressed in the management review for continuous improvement.

FSSC 22000 Additional Requirement		Conform			Grade	If No – detail NC If N/A – provide justification	NC#
Clause	**Requirement**	**Yes**	**No**	**N/A**	**Minor/Major/ Critical**		
2.5.9	Quality control (All Food Chain Categories)	☐	☐				

Summary:

- *Reference the quality policy and confirm that the organization has defined measurable quality objectives.*
- *Confirmation that quality control parameters have been defined for finished product specifications and include example/s verified during the audit.*
- *Provide an overview of the product release procedure addressing quality control and testing.*
- *Provide overview of analysis and evaluation of the results of quality control parameters as well as whether it was included as an input to the management review.*
- *Detail how quality aspects as per the requirements of 2.5.9 have been included in the internal audit program.*
- *Reference quality control procedures and documented evidence (records) sampled for unit, weight, and volume control.*
- *Reference line start-up and change-over procedures and documented evidence (records) sampled, including addressing that labelling and packaging from previous runs have been removed from the line(s).*

FSSC 22000 Additional Requirement		Conform			Grade	If No – detail NC If N/A – provide justification	NC#
Clause	**Requirement**	**Yes**	**No**	**N/A**	**Minor/Major/ Critical**		
2.5.10	Transport, storage, and warehousing (all Food Chain Categories)	☐	☐				

Summary:

a) Provide an overview of the specified stock rotation system that includes FEFO principles in conjunction with the FIFO requirements.

b) Food chain category C0 only: Where slaughtering is applicable and relevant, what controls are in place linked to post-slaughter time and temperature in relation to chilling or freezing of the products?

c) Food chain category FI only: Provide an overview of the transport and delivery services involved. Detail conditions/systems that are aimed at minimizing potential contamination during transport and delivery.

d) Detail whether the organization uses transport tankers for their final product or receives raw materials in tankers. If so, provide an overview of how the organization meets the Scheme requirements.

FSSC 22000 Additional Requirement		Conform			Grade	If No – detail NC If N/A – provide justification	NC#
Clause	**Requirement**	**Yes**	**No**	**N/A**	**Minor/Major/ Critical**		
2.5.11	Hazard control and measures for preventing cross-contamination (All Food Chain Categories)	☐	☐				

Summary:

a) Food chain category BIII, C and I: Where packaging is used to impart or provide a functional effect on food (e.g., shelf-life extension), detail what packaging is being used and whether this has been assessed as part of the hazard analysis. Reference applicable measures taken.

b) Food chain category C0 only: Provide an overview of the inspection process at lairage and/or at evisceration to ensure animals are fit for human consumption where applicable.

c) Food chain category D only: Reference the procedure that addresses this requirement. Provide an overview of the formulated products and the relevant customer and legislative requirements. Detail which ingredients/additives are used that contain components that can have adverse animal health impact(s), and how these are controlled.

d) All food chain categories, excluding FII: Provide an overview of the foreign matter management in place including reference to the risk assessment to determine the need for and type of foreign body detection equipment and the procedure for the management and use of the equipment. Where the risk assessment deems no foreign body detection equipment is necessary, reference the justification that was maintained as documented evidence. Detail whether the site has procedures in place for management of breakages (metal, ceramic, hard plastic, etc.).

FSSC 22000 Additional Requirement		Conform			Grade	If No – detail NC If N/A – provide justification	NC#
Clause	**Requirement**	**Yes**	**No**	**N/A**	**Minor/Major/ Critical**		
2.5.12	PRP Verification (Food Chain Categories BIII, C, D, G, I & K)	☐	☐	☐		*This clause may only be indicated as N/A for FCC A, E, and F*	

Summary:

Provide an overview of the site inspections/PRP checks conducted to verify that the site (internal and external), production environment and processing equipment are maintained in a suitable condition to ensure food safety, including the frequency and how findings are addressed.

Confirmation that the site inspections covered the PRPs required by the relevant PRP standard(s) and whether it served as an input for the internal audit.

FSSC 22000 Additional Requirement		Conform			Grade	If No – detail NC If N/A – provide justification	NC#
Clause	**Requirement**	**Yes**	**No**	**N/A**	**Minor/Major/ Critical**		
2.5.13	Product Design and Development (Food Chain Categories BIII, C, D, E, F, I & K)	☐	☐	☐		*This clause may only be indicated as N/A for FCC A, and G*	

Summary:

Reference the product design and development procedure. Provide an overview of the process to incorporate new products and changes into the product or manufacturing processes. This shall cover any potential hazards introduced (update to hazard analysis), impact on the process, resource & training, equipment and maintenance and any shelf-life and production trials conducted. Reference any new product developments since the previous audit.

Detail the process in place for on-going shelf-life verification at a frequency based on risk and provide examples of evidence sampled.

Where ready-to-cook products are produced and cooking instructions are provided on the product label/packaging, confirm that the organization has conducted validation and reference validations sampled.

FSSC 22000 Additional Requirement		Conform			Grade	If No – detail NC If N/A – provide justification	NC#
Clause	**Requirement**	**Yes**	**No**	**N/A**	**Minor/Major/ Critical**		
2.5.14	Health Status (Food Chain Category D)	☐	☐	☐		*This clause may not be indicated as N/A for FCC D*	

Summary:

Provide an overview of the procedure the organization has in place to monitor the health status of employees, the process for visitors and contractors and if any restrictions apply, including legislative requirements/restrictions.

FSSC 22000 Additional Requirement		Conform			Grade	If No – detail NC If N/A – provide justification	NC#
Clause	**Requirement**	**Yes**	**No**	**N/A**	**Minor/Major/ Critical**		
2.5.15	Equipment Management (All Food Chain Categories, excluding FII)	☐	☐	☐		*This clause may only be indicated as N/A for FCC FII*	

Summary:

a) *Identify if the organization has commissioned any new equipment or any significant changes to existing equipment since the previous audit. If so, provide an overview of the equipment purchase specifications in place and detail how it meets the requirements of the Scheme including evidence thereof.*

b) *Provide an overview of the change management process for new equipment/changes to existing equipment including evidence sampled of successful commissioning, as applicable.*

FSSC 22000 Additional Requirement		Conform			Grade	If No – detail NC If N/A – provide justification	NC#
Clause	**Requirement**	**Yes**	**No**	**N/A**	**Minor/Major/ Critical**		
2.5.16	Food loss and waste (All Food Chain Categories, excluding category I)	☐	☐	☐		*This clause may only be indicated as N/A for FCC I*	

Summary:

a) Provide an overview of organizations' strategy to reduce food loss and waste, reference the documented policy, and that specific objectives and targets have been set.

b) Detail the controls in place to manage donated products and to ensure the products are safe for consumption.

*c) Detail the controls in place to manage contamination of surplus product**s** or by-products intended for animal feed/food.*

d) Confirmation that these processes comply with legal requirements and were kept up to date.

FSSC 22000 Additional Requirement		Conform			Grade	If No – detail NC If N/A – provide justification	NC#
Clause	**Requirement**	**Yes**	**No**	**N/A**	**Minor/Major/ Critical**		
2.5.17	Communication requirements (All Food Chain Categories)	☐	☐				

Summary:

Detail how the organization has included the communication requirements into their FSMS.

a) Confirm whether the organization had any serious events since the previous audit, and if so, reference evidence thereof regarding communication of the serious event to the CB and what suitable measures were implemented; and*

*b) Confirm whether the organization had any serious situations** since the previous audit, and if so, reference evidence thereof regarding communication of the serious situation to the CB and what suitable measures were implemented.*

**Serious events that impact the FSMS, legality and/or the integrity of the certification including situations that pose a threat to food safety, or certification integrity.*

***Serious situations where the integrity of the certification was at risk and/or where the Foundation can be brought into disrepute.*

FSSC 22000 Additional Requirement		Conform			Grade	If No – detail NC If N/A – provide justification	NC#
Clause	**Requirement**	**Yes**	**No**	**N/A**	**Minor/major/ critical**		
2.5.18	Requirements for Organizations with Multi-site Certification (Food Chain Category E, F & G)	☐	☐	☐		*This clause may not be indicated as N/A for multi-site groups*	
2.5.18.1	Central Functions	☐	☐	☐			
2.5.18.2	Internal Audit Requirements	☐	☐	☐			

Summary:

Centralized Function:

Provide an overview of the central function and how commitment to the food safety system is managed and ensured across all the sites. Describe how roles and responsibilities have been defined for key roles and whether sufficient resources are available to manage the FSMS.

Internal Audits:

Provide an overview of the internal audit program (incl. frequency), confirmation that all sites, the central function and FSMS have been included and audited prior to the certification audit. How are nonconformities addressed and are there any escalation mechanisms in place? Are sufficient numbers of internal auditors available to cover the number of sites and do they meet the internal auditor requirements? Provide examples of competency records checked. Describe the technical review process

and whether the technical reviewers meet the competency requirements. How is performance monitoring and calibration of internal auditors and technical reviewers managed?

FSSC 22000

FOOD SAFETY SYSTEM CERTIFICATION

ANNEX 3: CB CERTIFICATE TEMPLATES

Version 6 | April 2023

INTRODUCTION

The FSSC 22000 certificates shall be based on the templates in this Annex.

The content of the certificate shall match the template contained in this Annex, the requirements of ISO/IEC 17021-1, and section 7.2 in Part 3 of the Scheme.

The layout of the certificate is at the discretion of the CB.

Where the certified organization requires a copy of the FSSC 22000 certificate in another language, the following requirements shall be met:

a) The English certificate remains the original and valid version of the certificate and is the one uploaded to the Assurance Platform;
b) The translated copy of the certificate shall be a complete and true representation of the English version and meet the requirements of this Annex;
c) The CB shall have a process in place to manage translated copies of certificates and ensure translations are correct and accurate.

Where a full remote audit is delivered, and the outcome of the full remote audit is to maintain certification, the certificate shall be updated to add the following reference "Audit delivery: Full Remote Audit due to serious event". Following the next onsite audit (full on-site or via the ICT Audit Approach), the certificate shall be updated, and the reference to the Full Remote Audit removed.

Templates in this Annex:

1. FSSC 22000 for single sites
2. FSSC 22000 with head office (refer Part 3, section 5.2.1)
3. FSSC 22000 with off-site activities (refer Part 3, section 5.2.2)
4. FSSC 22000 for multi-site certification (refer Part 3, section 5.3)

Note: for Organizations with off-site activities the list of locations and activities may be listed on an addendum to the certificate.

1. FSSC 22000 – SINGLE SITE

The Food Safety Management System of

Name of Organization

at

Location, Country

has been assessed and determined to comply with
the requirements of

FSSC 22000

Certification scheme for food safety management systems consisting of the following elements: ISO 22000: 2018, "name of applicable PRP standard(s)" (e.g., ISO/TS 22002-1:2009) and Additional FSSC 22000 requirements (Version 6).

This certificate is applicable for the scope of:

Scope Statement [process/activities, product and/or service description]

Food Chain Subcategory [see table in section 3 of Part 1]

Exclusions apply [excluded product(s)/process(es)/service(s) description] (if applicable)

Audit Delivery: Full Remote Audit due to serious event (if applicable)
COID code:
Certificate registration number:
Certification decision date:
Initial certification date: Authorized by:
Issue date: Position of signatory AB Symbol
Valid until:

Issued by:
Name and address of certification body CB Mark

QR Code

The authenticity of this certificate can be verified in the FSSC 22000 database of Certified Organizations available on www.fssc.com.

2. FSSC 22000 WITH HEAD OFFICE

The Food Safety Management System of

Name of Organization

at

Location, Country

has been assessed and determined to comply with
the requirements of

FSSC 22000

Certification scheme for food safety management systems consisting of the following elements: ISO 22000: 2018, "name of applicable PRP standard(s)" (e.g., ISO/TS 22002-1:2009) and Additional FSSC 22000 requirements (Version 6).

This certificate is applicable for the scope of:

Scope Statement [process/activities, product and/or service description]

Food Chain Subcategory [see table in section 3 of Part 1]

This audit included the following central FSMS processes managed by (name and location of head office): (describe FSMS processes managed at the head office)

Exclusions apply [excluded product(s)/process(es)/service(s) description] (if applicable)

Audit Delivery: Full Remote Audit due to serious event (if applicable)
COID code:
Certificate registration number:
Certification decision date:
Initial certification date: Authorized by:
Issue date: Position of signatory AB Symbol
Valid until:

Issued by:
Name and address of certification body CB Mark

QR Code

The authenticity of this certificate can be verified in the FSSC 22000 database of Certified Organizations available on www.fssc.com.

3. FSSC 22000 WITH OFF-SITE ACTIVITIES

The Food Safety Management System of

Name of Organization

at

Location, Country

has been assessed and determined to comply with
the requirements of

FSSC 22000

Certification scheme for food safety management systems consisting of the following elements: ISO 22000: 2018, "name of applicable PRP standard(s)" (e.g., ISO/TS 22002-1:2009) and Additional FSSC 22000 requirements (Version 6).

This certificate is applicable for the scope of:

Scope Statement [process/activities, product and/or service description]

Food Chain Subcategory [see table in section 3 of Part 1]

This audit included the following off-site activities at (locations):

(name, address, and scope at each location) or can be included as an addendum similar to the multi-site certification template.

Exclusions apply [excluded product(s)/process(es)/service(s) description] (if applicable)

Audit Delivery: Full Remote Audit due to serious event (if applicable)
COID code:
Certificate registration number:
Certification decision date:
Initial certification date: Authorized by:
Issue date: Position of signatory AB Symbol
Valid until:
Issued by:
Name and address of certification body CB Mark

QR Code

The authenticity of this certificate can be verified in the FSSC 22000 database of Certified Organizations available on www.fssc.com.

4. FSSC 22000 MULTI-SITE CERTIFICATION

The Food Safety Management System of

Name of Organization

at

Location, Country

has been assessed and determined to comply with
the requirements of

FSSC 22000

Certification scheme for food safety management systems consisting of the following elements: ISO 22000: 2018, "name of applicable PRP standard(s)" (e.g., ISO/TS 22002-1:2009) and Additional FSSC 22000 requirements (Version 6).

This certificate is applicable for the scope of:

Scope Statement [process/activities, product and/or service description]

Food Chain Subcategory [see table in section 3 of Part 1]

This audit included multi-site activities as detailed in Addendum 1

Exclusions apply [excluded product(s)/process(es)/service(s) description] (if applicable)

Audit Delivery: Full Remote Audit due to serious event (if applicable)
COID code:
Certificate registration number:
Certification decision date: AB Symbol
Initial certification date: Authorized by:
Issue date: Position of signatory
Valid until:
Issued by:
Name and address of certification body CB Mark

QR Code

The authenticity of this certificate can be verified in the FSSC 22000 database of Certified Organizations available on www.fssc.com.

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ADDENDUM 1

Not valid as a stand-alone document and shall only be used with the main certificate.

Name of multi-site organization:
COID code:
Certificate registration number: Valid until:

Name of site	
Address of site	
Scope of the site	

Name of site	
Address of site	
Scope of the site	

Name of site	
Address of site	
Scope of the site	

Name of site	
Address of site	
Scope of the site	

Name of site	
Address of site	
Scope of the site	

Name of site	
Address of site	
Scope of the site	

Name of site	
Address of site	
Scope of the site	

Name of site	
Address of site	
Scope of the site	

Issued by:
Name and address of certification body CB Mark

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FSSC 22000




FOOD SAFETY SYSTEM CERTIFICATION

ANNEX 4: AB ACCREDITATION CERTIFICATE

Version 6 | April 2023

INTRODUCTION

The accreditation certificate issued to the Certification Body shall be based on the requirements of this Annex.

The content of the certificate shall match the requirements in this Annex, but the layout of the certificate is at the discretion of the AB.

ISO standards and ISO Technical Specifications referenced as normative documents shall refer to the latest versions linked to the Version of the Scheme.

The scope of accreditation is given below:

Normative documents	Certification scheme
ISO 22000, ISO/TS 22002-1, Additional FSSC 22000 requirements	Food Safety System Certification 22000 (FSSC 22000) Version 6 for the following cluster and categories: Cluster Primary Production - Category B, Farming or handling of plants BIII: Pre-process handling of plant products. Accreditation granted in accordance with ISO/IEC 17021-1: 2015 and ISO 22003-1:2022
ISO 22000, ISO/TS 22002-1, Additional FSSC 22000 requirements	Food Safety System Certification 22000 (FSSC 22000) Version 6 for the following clusters and categories: Cluster Processing food for humans and animals - Category C, Food, ingredient, and pet food processing C0: Animal – primary conversion CI: Processing of perishable animal products CII: Processing of perishable plant-based products CIII: Processing of perishable animal and plant - Products (mixed products) CIV: Processing of ambient stable products Accreditation granted in accordance with ISO/IEC 17021-1: 2015 and ISO 22003-1:2022.
ISO 22000, ISO/TS 22002-6, Additional FSSC 22000 requirements	Food Safety System Certification 22000 (FSSC 22000) Version 6 for the following cluster and categories: Cluster Processing food for humans and animals - Category D, Feed, and animal food processing Accreditation granted in accordance with ISO/IEC 17021-1: 2015 and ISO 22003-1:2022.
ISO 22000, ISO/TS 22002-2, Additional FSSC 22000 requirements	Food Safety System Certification 22000 (FSSC 22000) Version 6 for the following cluster and category: Cluster Catering/food service - Category E, Catering/food service Accreditation granted in accordance with ISO/IEC 17021-1: 2015 and ISO 22003-1:2022.
ISO 22000, BSI/PAS 221, Additional FSSC 22000 requirements	Food Safety System Certification 22000 (FSSC 22000) Version 6 for the following cluster and category: Cluster Retail, transport, and storage: - Category F, Trading, retail, and e-commerce FI: Retail / Wholesale Accreditation granted in accordance with ISO/IEC 17021-1: 2015 and ISO 22003-1:2022.

Normative documents	Certification scheme
ISO 22000, Additional FSSC 22000 requirements	Food Safety System Certification 22000 (FSSC 22000) Version 6 for the following cluster and category: Cluster Retail, transport, and storage: - Category F, Trading, retail, and e-commerce FII: Brokering / trading. Accreditation granted in accordance with ISO/IEC 17021-1: 2015 and ISO 22003-1:2022.
ISO 22000, ISO/TS 22002-5, Additional FSSC 22000 requirements	Food Safety System Certification 22000 (FSSC 22000) Version 6 for the following cluster and categories: Cluster Retail, transport, and storage - Category G, Transport, and storage services Accreditation granted in accordance with ISO/IEC 17021-1: 2015 and ISO 22003-1:2022.
ISO 22000, ISO/TS 22002-4, Additional FSSC 22000 requirements	Food Safety System Certification 22000 (FSSC 22000) Version 6 for the following cluster and category: Cluster Packaging Material - Category I, Production of packaging material Accreditation granted in accordance with ISO/IEC 17021-1: 2015 and ISO 22003-1:2022.
ISO 22000, ISO/TS 22002-1, Additional FSSC 22000 requirements	Food Safety System Certification 22000 (FSSC 22000) Version 6 for the following cluster and category: Cluster Bio/chemical - Category K, Chemical and bio-chemical Accreditation granted in accordance with ISO/IEC 17021-1: 2015 and ISO 22003-1:2022.

FSSC 22000




FOOD SAFETY SYSTEM CERTIFICATION

ANNEX 5: CB REQUIREMENTS FOR THE USE OF INFORMATION AND COMMUNICATION TECHNOLOGY (ICT)

Version 6 | April 2023

CONTENTS

1. PURPOSE

This Annex describes the requirements for the use of Information and Communication Technology (ICT) by Certification Bodies linked to FSSC 22000 audit activities.

2. SCOPE

The scope of this document covers the following:

- Conducting FSSC 22000 audits using Information and Communication Technology (ICT)
- CB Auditor requirements and activities

ICT is the use of technology for gathering, storing, retrieving, processing, analyzing, and transmitting information. It includes software and hardware such as smartphones, handheld devices, laptop computers, desktop computers, drones, video cameras, wearable technology, artificial intelligence, and others. The use of ICT may be appropriate for auditing/assessment both locally and remotely.

As technology evolves and time constraints on businesses increase, there is a need to consider alternative methods of delivering auditing activities while still achieving the audit objectives and ensuring a robust audit process.

The IAF Mandatory Document (MD) 4 for the *Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes* (latest version) shall be used by CBs as a normative document in conjunction with the requirements as set out in this Annex.

3. CONDUCTING AUDITS USING ICT

The standard method for conducting FSSC 22000 audits is via full on-site audits as described in Part 3 of the scheme. An alternative, voluntary option can now be applied where the criteria are met, by delivering the FSSC 22000 audit as a split process utilizing ICT. This is referred to as the ICT audit approach, which is voluntary and shall be mutually agreed upon between the CB and the certified organization prior to the audit.

The ICT audit approach consists of two (2) components, which should be delivered in the following order:

Step 1: Remote audit component consisting of a document review and interviews with key personnel using ICT.

Step 2: On-site audit component focusing on the implementation and verification of the FSMS (including HACCP), PRPs, the physical inspection of the production process, and any remaining requirements not covered during the remote audit.

Although it is preferred to conduct the remote audit component first, it is possible to reverse the sequence and start with the onsite audit component. Where the sequence is reversed, the auditor may be required to (re)verify a product/process activity onsite, based on the outcome of the remote audit component, which could result in the auditor needing to return to the site to verify this activity. In this case, the CB and the organization shall accept this risk in writing prior to the

delivery of the ICT Audit Approach Audit in this order. Where the auditor needs to return onsite for the verification activity, this is still considered to be part of the regular audit and must be completed within the overall 30-day timeframe. The audit is not considered to be complete until all components have been delivered.

The audit components (remote + onsite) may also be delivered at the same time when an audit team is utilized.

During the **remote audit**, assessment activities are performed from a location other than the physical location of the audited organization, while during the **on-site audit**, assessment activities are performed at the physical location of the audited organization.

The CB shall conduct a feasibility assessment to determine, in conjunction with the certified organization, whether the ICT audit approach is a viable option. The CB shall have documented procedures, including criteria for assessing and approving the ICT Audit Approach. This feasibility assessment shall be conducted and documented prior to the audit, taking into consideration the members of the audit team and the audited organization.

The following shall be considered when conducting the feasibility assessment:

a) Maturity of the certified organization's FSMS and performance history;
b) Whether the certified organization permits and accommodates remote audit activity (i.e., availability of records in electronic format or document reader), including data protection and security measures;
c) The ICT tools to be utilized;
d) Whether the certified organization and/or the CB have representatives capable of communicating in the same language;
e) Whether the CB and the certified organization have the capability and ability to conduct the remote audit in the chosen medium/forum of the remote audit; and
f) Impact on audit duration and audit planning e.g. where more time might be required due to the use of ICT.

4. GENERAL PRINCIPLES

a) If the ICT audit approach is deemed to be a viable option, ICT means to be used shall be tested with the certified organization before the planned remote audit to confirm that the ICT is appropriate, suitable, and effective. Feasibility also depends on the online connection quality. A weak bandwidth or limited hardware capability may slow the process to the point of inefficiency.
b) Suitable support/training shall be provided on the use of ICT to the auditor and any other members of the audit team, prior to the remote audit. Records of these trainings shall be kept by the CB and uploaded on the auditor's register on the Assurance Platform.
c) The requirements of IAF MD4 shall be followed. This mandatory document defines the rules that Certification Bodies and their auditors shall follow to ensure that ICT is used to optimize the efficiency and effectiveness of the audit/assessment, while supporting and maintaining the integrity of the audit process.
d) The CB shall include the requirements of IAF MD4 in their procedures for the use of ICT and personnel competence.
e) Data security and confidentiality: to prepare for the use of ICT, all certification legal and customer requirements related to confidentiality, security and data protection should be

identified and actions taken to ensure their effective implementation. This implies that both the auditor and the auditee agree to the use of ICT and with the measures taken to fulfil these requirements.

f) Both the remote audit and the on-site audit shall be conducted by an FSSC 22000 qualified auditor(s). The audit team shall have the combined competence for the food chain sub-categories supporting the scope of the audit. The auditor delivering the onsite component of the audit, as well as any product/process-related activities (evaluating the product/process activities, HACCP studies, etc.) shall hold the competence for the food chain sub-categories, or category where no sub-category exists, linked to the scope of the audit.

g) The remote audit component will typically be 0.5 - 1 day and the on-site verification audit the remainder of the total duration of the regular annual audit. The on-site audit component cannot be less than 1 day and shall at least be 50% of the total audit duration. When determining the amount of time spent on-site and remotely, the outcome of the feasibility assessment and the historical performance of the organization (including complaints and recalls) shall be taken into consideration. For example, if the feasibility assessment demonstrated that a remote audit is possible, but the historical performance of the organization has been of concern, then the proportion of time spent on-site is expected to be increased.

h) The total audit duration based on the calculation in Part 3 of the Scheme rules shall be met between the remote audit component and the on-site audit component. Where rounding is applied, durations shall be rounded upwards to the nearest half day taking into account that additional time might be required to conduct the remote audit component. Total audit duration does not include preparation activities or reporting, and additional time is required for these activities as defined in Part 3 of the Scheme.

i) When compiling the audit plan for the remote audit component, consideration should be given to appropriate durations and allow for more frequent breaks to enhance attention and reduce eye strain. These breaks cannot be counted towards audit duration.

j) If time is consumed on issues such as network downtime, unexpected interruptions or delays, accessibility problems, or other ICT challenges, this time shall not be counted towards audit duration. Provisions for ensuring audit duration must be established.

k) It is recommended that the remote and the on-site audit components take place as close together as possible, but in all cases the maximum timeline for completion of the audit (remote + on-site) shall not exceed 30 calendar days.

l) As an exception, and only in the case of serious events as defined by the Scheme, the timeline for completion of the audit may be extended to a maximum of 90 calendar days, based on a clear and documented concession process and risk assessment by the CB. The risk assessment shall consider the elements in section 3 of IAF Information Document (ID) 3 *Management of Extraordinary Events or Circumstances Affecting ABs, CABs and Certified Organizations* as a minimum. The extension is only allowed where the efficiency and integrity of the audit will not be compromised. Where concessions are granted by the CB and the 90-day timeline is applied, the risk assessment shall be uploaded to the Assurance Platform as part of the audit documentation.

m) In all instances where the ICT utilized is not functioning properly or preventing/hampering a robust audit, the audit shall be aborted, and suitable follow-up actions determined.

n) Where a serious event occurs after an ICT audit approach audit has commenced, and the audit needs to be converted to a full remote audit, the CB shall apply for an exemption with the Foundation. In the case an exemption is granted, the CB shall follow the requirements of the Full Remote Audit Addendum, including conducting a risk assessment (refer to Part 3, Section 5.10 of the Scheme) and is required to undertake a further

feasibility assessment to ensure the ICT is suitable to deliver the full remote audit, including auditing of the production processes.

4.1 APPLICABILITY

The ICT audit approach may be applied in the case of the regular, annual FSSC 22000 audits (surveillance and recertification audits) as part of the routine certification process and is additional to Part 3 of the Scheme.

The use of ICT may be applied to Stage 1 audits in exceptional circumstances or events as described below, and for Head Office audits where the corporate functions are controlled separately.

In the year where an unannounced audit is due, the ICT audit approach outlined in this Annex may be used, whilst still applying the requirements of Part 3, section 5.4 of the Scheme. The prerequisite would be that the on-site component of the audit shall be conducted first, followed directly by the remote audit component with a maximum period of 48 hours between the two audit components.

4.1.1 INITIAL AUDITS

In exceptional circumstances or events, all or part of stage 1 can take place off-site or remotely through the use of ICT and shall be fully justified (ISO 22003-1:2022, cl. 9.3.5). The objectives of the Stage 1 audit as per ISO17021-1 (9.3.1.2.2) shall be met, and to this end, ICT (i.e. live video) shall be included to also observe the production processes, work environment and facilities. The Stage 1 audit report shall reference that the audit was completed remotely, which ICT tools were used, and include confirmation that the objectives were achieved.

The Stage 2 audit shall be conducted as a full on-site audit within 6 months of the Stage 1, or the Stage 1 shall be repeated. It is not permitted to use the ICT audit approach for the Stage 2 audit.

4.1.2 SURVEILLANCE AUDITS

Annual surveillance audits may be conducted using the ICT audit approach. The full audit (remote + on-site) shall be completed within the calendar year.

Where the ICT audit approach is applied to the first surveillance audit following an initial certification, the process shall be planned to ensure that the full audit (remote + on-site) takes place before or not later than 12 months after the date of certification decision for the initial audit. Where the full audit has not been delivered within the 12 months, the certificate shall be suspended.

4.1.3 RE-CERTIFICATION AUDITS

The re-certification audit may be conducted using the ICT audit approach. The remote audit component combined with the on-site audit component constitutes a complete re-certification audit and both components shall be completed prior to the expiry of the existing certificate. The requirements in ISO/IEC 17021-1: 2015 – 9.6.3.2 apply.

4.2 AUDIT PROCESS

The audit (remote + on-site) shall be conducted by qualified FSSC 22000 auditor/s meeting the competency requirements linked to the scope of certification. In all instances, the on-site audit shall be conducted by an FSSC 22000 qualified lead auditor with the sub-category. When the remote and onsite components are delivered at different times by different auditors, the CB shall have a proper handover/communication process in place.

4.2.1 REMOTE AUDIT COMPONENT

The remote audit component shall include a document review and interviews with key personnel.

The following are examples of what may be included as part of the document review undertaken during the remote audit component:

- Document/procedure reviews;
- Key changes since the last audit (where applicable);
- Product recalls and significant complaints;
- Status with regard to FSMS objectives and key process performance, management review and internal audits;

4.2.2 ON-SITE AUDIT COMPONENT

The on-site audit component serves as the verification audit for Food Safety Management System (FSMS) implementation with a focus on the production processes and environment, as well as the remainder of the clauses not covered as part of the remote audit component.

The on-site audit component shall include as a minimum inspection/physical verification of PRPs, the traceability test, and implementation of the FSMS. The latter includes, but is not limited to, the HACCP system, for example, the effective operation of PRPs, verification of the process flow diagram, OPRP, and CCP monitoring and verification. It might be necessary to review parts of the remote audit again to ensure the implementation of requirements.

All the requirements of the Scheme shall be covered between the remote audit and the on-site audit components and be clearly reflected in the audit plans, audit program, and the final audit report.

4.2.3 NONCONFORMITY MANAGEMENT

Any nonconformities identified during the audit (remote and on-site) shall be addressed in line with the Scheme requirements, including grading and timelines, and recorded on the NC report (refer to Annex 2).

i. Where the audit (remote + on-site) is completed within 30 calendar days, one nonconformity report is completed, and the timeline for nonconformity closure starts at the end of the last audit component. Any nonconformities identified during the course of the audit shall be communicated to the organization in a timely manner. The CB may opt to provide a provisional NC report to the organization at the end of the first audit component delivered.

ii. In the case of a serious event and where the 30 calendar days for audit completion is exceeded (refer to the exception in 3.1(l)), any non-conformities identified as part of the first audit component shall be recorded, and a copy of the nonconformity report left with the certified organization at the end of the first audit component. The timeline for closure of these nonconformities starts at the end of the first audit component. The NC report produced following the last audit component shall contain an overview of all the nonconformities raised, including the nonconformities raised at the first audit component, to provide a consolidated record. The timeline for the closure of NCs identified at the last audit component starts at the end of the last audit component.

iii. Where a critical nonconformity is identified at any time during the audit (remote or on-site), the certificate shall be suspended, and a full new on-site audit will be required to lift the suspension within 6 months.

ICT tools may be used to close out minor and/or major non-conformities, depending on the nature of the nonconformity and the reliability of the ICT. The CB shall be able to demonstrate that the methods used are suitable for the resulting action. Critical nonconformities require an on-site follow-up audit in all instances.

4.2.4 AUDIT REPORT

One audit report is produced covering both the remote and the on-site audit components. The audit report shall clearly identify the extent to which any ICT has been used in carrying out the audit and the effectiveness of ICT in achieving the audit objectives. The audit report shall include all summarized information, findings, and nonconformity details of both the remote and on-site audit components, covering all Scheme normative requirements and meeting the requirements as set out in Annex 2 of the Scheme. The report shall also reference the dates and the duration of the on-site and remote audits components, and the auditor/s involved in both components.

The full audit pack, consisting of the remote and the on-site audit documentation, shall be uploaded to the Assurance Platform within 2 months of the last day of the full audit. Instructions will be provided separately by the Foundation on the process and requirements for uploading audit information and nonconformities in the Assurance Platform.

The certification audit is only concluded once both the remote and the on-site components have been successfully completed. Following completion of the full audit (remote & onsite components) and a positive certification decision by the CB, the audit process is complete and where applicable a new certificate may be issued.

5. AUDIT TEAM

5.1 WITNESSING OF AUDITORS

Where appropriate ICT tools are available, this technology may also be utilized for the remote witnessing of existing qualified FSSC 22000 auditors as part of the maintenance of competency requirements (3 yearly witness audit) and the requalification process.

The same applies to already qualified FSSC 22000 auditors moving to another CB. Where the new CB deems the remote witnessing to be sufficiently robust, the new CB may use a remote witness audit to approve the FSSC 22000 auditor. Remote witnessing is not allowed for initial auditor approval of FSSC 22000 (auditors new to FSSC 22000).

In all cases where remote ICT tools are used, the CB needs to ensure that the technology is appropriate and enables the witnessor to observe the full FSSC 22000 certification audit, including the opening meeting, document review, on-site facility audit, and the closing meeting. It needs to be clearly reflected in the witness audit report that the witness was conducted remotely and which remote technology was used. Permission will be required from the certified organization to conduct the witness audit in this manner, and the normal confidentiality requirements apply. The technology needs to be tested beforehand, and the witnessor and the auditor trained in the use of the technology as required in IAF MD4. In all instances where the technology utilized is not functioning properly or preventing/hampering a robust audit, the witness audit shall be aborted, and suitable follow-up actions determined by the CB.

5.2 USE OF TECHNICAL EXPERTS

Technical experts are permitted to join the audit remotely using ICT tools, if the CB has determined that ICT tools are appropriate and sufficient to meet the audit objectives and the certified organization agrees to the remote audit activity. The technology needs to be tested beforehand and the technical expert and the auditor shall be trained in the use of the technology as required by IAF MD4. In all instances where the technology utilized is not functioning properly or preventing/hampering a robust audit, the CB shall make alternative arrangements to ensure the full audit process can be completed or the audit shall be aborted.

FSSC 22000

FSSC 22000

BOARD OF STAKEHOLDERS DECISION LIST

VERSION 6

April 2023

BOARD OF STAKEHOLDERS DECISION LIST FSSC 22000 VERSION 6

The Board of Stakeholders (BoS) Decision list is a document which contains decisions applicable to FSSC 22000 Scheme Version 6. The decisions overrule or provide further clarification on existing Scheme rules and have to be implemented and applied within the defined transition period. The decision list is dynamic and can be adjusted by the BoS when deemed necessary.

The Board of Stakeholders is composed of representatives of the food sectors covered by the FSSC 22000 Scheme. The BoS is responsible for approval of the content and functioning of the FSSC 22000 scheme. The Board has the possibility to provide binding decisions and voluntary recommendations for the associated Certification Bodies and Accreditation Bodies with respect to the FSSC 22000 Scheme.

Number	Reference	Description	Nature	Decision date	Effective date	Transition period
#1	Requirements for Version 6 Upgrade Process	The V6 Upgrade Process sets out the requirements for CBs and ABs on the transition process, including how to transition organizations from FSSC 22000 Version 5.1 to Version 6.	Mandatory	15 Feb 2023	01 April 2024	12 months

FSSC 22000

FSSC 22000 SCHEME FOOD SAFETY MANAGEMENT SYSTEM CERTIFICATION

www.fssc.com

Version 6.0 | April 2023

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TRANSLATIONS

Please be aware that in the case of translations of the FSSC 22000 Scheme documents, the English version is the official and binding version.

GENERAL CONTENTS

INTRODUCTION

With a growing world population, there is an increasing need for affordable, safe, and good quality food products. To fulfill this need, FSSC 22000 provides a trusted brand assurance platform to the food industry. Key in this mission is the availability of the FSSC 22000 certification Scheme for food safety management systems. This document contains the new Version 6.0 of the FSSC 22000 Scheme published in April 2023. The main factors that initiated the development of this version have been:

- Incorporating the requirements of ISO 22003-1:2022
- Strengthening the requirements to support organizations in their contributions to meeting the Sustainable Development Goals (SDGs)
- Editorial changes and amendments as part of continuous improvement

ABOUT THE SCHEME

The Scheme consists of five Parts and two Appendices that are bundled in this document. Furthermore, there are five Annexes. All these documents also contain mandatory Scheme requirements. Lastly, there are guidance documents on several topics to provide additional support. All documents can be downloaded for free from the FSSC website.

HOW THE SCHEME IS ORGANIZED

PART 1 SCHEME OVERVIEW

This part describes the Scheme context and details including its certification scopes.

PART 2 REQUIREMENTS FOR ORGANIZATIONS TO BE AUDITED

This part describes the Scheme requirements against which licensed Certification Bodies shall audit the Food Safety Management System of the organization in order to achieve or maintain certification for FSSC 22000.

PART 3 REQUIREMENTS FOR THE CERTIFICATION PROCESS

This part describes the requirements for the execution of the certification process to be conducted by licensed Certification Bodies.

PART 4 REQUIREMENTS FOR CERTIFICATION BODIES

This part describes the requirements for licensed Certification Bodies that provide Scheme certification services to organizations.

PART 5 REQUIREMENTS FOR ACCREDITATION BODIES

This part describes the requirements for recognized Accreditation Bodies that provide accreditation services to licensed Certification Bodies.

APPENDIX 1 DEFINITIONS

This appendix contains definitions for terms that have been used throughout all the Scheme documents.

APPENDIX 2 NORMATIVE REFERENCES

This appendix contains all references that have been used throughout all the Scheme documents.

ANNEXES

There are five Annexes that are mandatory and necessary for proper implementation of the Scheme:

- Annex 1 CB Certificate scope statements
- Annex 2 CB Audit report requirements
- Annex 3 CB Certificate templates
- Annex 4 AB Accreditation certificate
- Annex 5 CB Requirements for the use of information and communication technology (ICT)

ADDENDA

Foundation FSSC has voluntary Addenda and Modules that can be undertaken together with FSSC 22000 certification audits. Refer to the FSSC website for details on the Addenda and Modules currently offered by the Foundation, including the related conditions and requirements.

PART 1
SCHEME OVERVIEW

CONTENTS PART 1 SCHEME OVERVIEW

1 INTRODUCTION

1.1 THE SCHEME

The FSSC 22000 certification scheme (hereafter the Scheme) outlines the requirements for the audit and certification of food safety management systems of organizations in the food supply chain. The certificate confirms that the organization's management system is in conformance with the Scheme requirements.

The Scheme is based on the publicly available standards/technical specifications:

- ISO 22000:2018 requirements for any organization in the food chain;
- Relevant prerequisite programs (PRPs) based on technical specifications for the sector (e.g., ISO/TS 22002-x; PAS xyz); and
- FSSC 22000 Additional Requirements as determined by our stakeholders.

When the Foundation decides that updates or changes to the Scheme are necessary, requirements for communication and implementation will be published separately.

The Scheme provides a voluntary certification model that can be applied across various sectors in the food supply chain. Where sector-specific prerequisite programs (PRPs) have been developed and accepted, these form part of the normative documents of the Scheme. The food chain category description used by this Scheme is defined according to ISO 22003-1:2022 (see Chapter 3).

As of February 2010, the Scheme has been benchmarked and recognized by the Global Food Safety Initiative (GFSI) confirming global food industry recognition and acceptance.

As of March 2021, the Scheme has been endorsed as a sub-scope of the IAF MLA which is a demonstration of the technical rigor and consistency of the Scheme.

1.2 OWNERSHIP AND GOVERNANCE

The Foundation FSSC (hereafter the Foundation) retains the ownership and the copyright of all Scheme related documentation and also holds the agreements for all involved Certification Bodies and Accreditation Bodies.

The Foundation's Statutes contain additional provisions and requirements regarding the ownership of and governance over the Foundation and the Scheme. These Statutes are publicly available in the Register of the Chamber of Commerce in Gorinchem, the Netherlands, under number 64112403. Such additional provisions and requirements are part of the Scheme in as far as they may relate to the rights and obligations of direct and indirect stakeholders in the Scheme.

1.3 LANGUAGE

English is the official and valid version of the Scheme.

2 FEATURES

2.1 AIM AND OBJECTIVES

The aim of the Scheme is to ensure that it continuously meets international food industry requirements resulting in a certification that assures that organizations provide safe food to their customers.

The specific Scheme objectives are to:

a) Provide recognition for organizations that have demonstrated compliance to the Scheme requirements by establishing and maintaining an accurate and reliable public register of certified organizations;
b) Promote the accurate application, recognition, and general acceptance of food safety management systems within the Consumer Goods industry;
c) Provide information on and support for the auditing and certification of food safety management systems within the scope of the Scheme;
d) Create impact through setting public goals linked to the UN Sustainable Development Goals.

The Foundation endeavors to achieve these objectives by:

a) Entering into agreements with strategic partners;
b) Providing governance and oversight of certification through the Foundation's Integrity Program;
c) Providing continued support to our licensed partners through training, knowledge management and data sharing;
d) Managing and taking appropriate action in events that could bring the Foundation into disrepute or impact the Foundation's business continuity, certification and/or brand integrity;
e) Supporting other organizations that strive to achieve similar or partially similar objectives as those mentioned in Article 2.1.

2.2 NATURE OF THE SCHEME

The Scheme provides an independent ISO-based Scheme for third party auditing and certification.

The Scheme:

a) Incorporates ISO standards, sector specific technical specifications for PRPs, market driven additional requirements as well as statutory and regulatory requirements;
b) Is recognized by the Global Food Safety Initiative;
c) Allows the integration with ISO-based management system standards such as those for quality, environmental, health and safety etc.;
d) Is governed by a non-profit Foundation and managed by an independent Board of Stakeholders;
e) Increases transparency throughout the food supply chain by maintaining an "FSSC 22000 Register of certified organizations" which is publicly available.

3 SCOPE

The Scheme is intended for the audit and certification of organizations for the following food chain (sub)categories as set out in Table 1 and is aligned with the categories as defined in ISO 22003-1:2022.

Table 1. Overview of (Sub)Categories

Category	Subcategory	Description	Example of included activities and products	Normative Documents
B	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.	ISO 22000:2018 ISO/TS 22002-1:2009 FSSC 22000 Additional requirements
C	C0	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.	ISO 22000:2018, ISO/TS 22002-1:2009 FSSC 22000 Additional requirements
	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 pet food from animal products only.	ISO 22000:2018, ISO/TS 22002-1:2009, FSSC 22000 Additional requirements
C	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.	ISO 22000:2018, ISO/TS 22002-1:2009, FSSC 22000 Additional requirements
	CIII	Processing of perishable animal and plant products (mixed products)	Processing and packaging including pizza, lasagna, sandwiches, dumplings, and ready-to-eat meals. Includes off-site catering kitchens. Includes products of industrial kitchens not offered for immediate consumption. Processing perishable pet food from mixed products.	ISO 22000:2018, ISO/TS 22002-1:2009, FSSC 22000 Additional requirements

Category	Subcategory	Description	Example of included activities and products	Normative Documents
	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.	ISO 22000:2018, ISO/TS 22002-1:2009, FSSC 22000 Additional requirements
D	D	Processing of feed and animal food	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.	ISO 22000:2018, ISO/TS 22002-6:2016, FSSC 22000 Additional requirements
E	E	Catering / food service	Open exposed food activities such as cooking, mixing, and blending, preparation of components and products for on-site direct consumer consumption or take away. Examples include restaurants, hotels, food trucks, institutions, 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.	ISO 22000:2018, ISO/TS 22002-2:2013, FSSC 22000 Additional requirements
F	FI	Retail /Wholesale/ E-commerce	Storage and provision of finished products to customers and consumers (retail outlets, shops, wholesalers). Includes minor processing activities, e.g., slicing, portioning, reheating.	ISO 22000:2018, BSI/PAS 221:2013, FSSC 22000 Additional requirements
F	FII	Brokering /Trading /E-commerce	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.	ISO 22000:2018, FSSC 22000 Additional requirements
G	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.	ISO 22000:2018, ISO/TS 22002-5:2019, FSSC 22000 Additional requirements

Category	Subcategory	Description	Example of included activities and products	Normative Documents
I	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.	ISO 22000:2018, ISO/TS 22002-4:2013, FSSC 22000 Additional requirements
K	K	Production of Bio/chemicals	Production of food and feed processing aids, additives (e.g., flavorings, vitamins), gases and minerals. Production of bio-cultures and enzymes.	ISO 22000:2018, ISO/TS 22002-1:2009, FSSC 22000 Additional requirements

3.1 HANDLING OF PLANTS (CATEGORY B)

Food chain subcategory BIII refers to the handling of plants that do not transform the product from the original whole form e.g., fruit and vegetable packhouses, where only minimal processing which does not alter the form of the product may occur such as washing, sorting, grading, trimming, waxing, drenching, etc. Processing such as cutting and dicing, which changes the form of the product, is excluded from subcategory BIII and is included under subcategory CII.

3.2 FOOD MANUFACTURING (CATEGORY C)

Food chain category C involves the following food processing activities:

a) C0: Conversion of animal carcasses including processes such as lairage, slaughter, evisceration, bulk chilling & freezing, bulk storage.
b) CI: Processing of perishable animal products. Processing and packaging of animal products including fish, seafood, meat, poultry, eggs, dairy requiring chilled or frozen temperature control and processing of pet food from animal products only.
c) CII: Processing and packaging of perishable plant-based products including fruits and fresh juices, vegetables, grains, nuts, and pulses, frozen water-based products (e.g., ice), plant-based meat and dairy substitutes and the processing of pet food from plant products only.
d) CIII: Processing of perishable animal and plant products (mixed products) including pizza, lasagna, sandwiches, dumplings, ready-to-eat meals, and pet food from mixed (animal and plant) products. Off-site catering kitchens, and products of industrial kitchens that are not offered for immediate consumption.
e) CIV: Processing of ambient stable products. Production of food products from any source that is stored and sold at ambient temperature, including canned foods, biscuits, bread, snacks, oil, drinking water, beverages, pasta, flour, sugar, food-grade salt, and ambient stable pet food.

Foods for special dietary needs and food for special medical purposes, where legally classified as food within the country of manufacture, may be included under food chain category C. If the product is classified as a pharmaceutical or medical product under the legislation then it is outside the scope of FSSC 22000 certification.

3.3 ANIMAL FEED PRODUCTION (CATEGORY D)

Food chain category D covers the production of animal feed:

a) Processing of 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.
b) Processing of feed mixtures, with or without additives, intended for food-producing animals, e.g., premixes, medicated feed, compound feeds.

3.4 CATERING (CATEGORY E)

Food chain category E applies when the catering service is delivered directly to consumers. The food is prepared for on-site consumption or take away.

Examples include:

- Units that serve food directly to the consumer or offer food for immediate consumption, e.g., restaurants, hotels, cafeterias and onboard passenger service;
- Catering sites handling foods with direct serving to consumers, e.g., canteens, coffee shops, food trucks and event catering.

3.5 TRADING, RETAIL, WHOLESALE AND E-COMMERCE (CATEGORY F)

Food chain category FI applies to retail and wholesale activities, and related E-commerce activities.

- Retail is defined as selling goods to the final customer (i.e., consumer), in small quantities for consumption and not for the purpose of resale. Retailers shall have physical buildings and facilities (i.e., shops, warehouses).
- Wholesale is defined as the buying of goods from manufacturers or other sellers and selling of goods to other businesses such as retailers, industries, and occasionally end consumers.
- The retailer or wholesaler may offer internet sales or deliveries (E-commerce) that may be included in the scope only when linked to the physical location but not as a stand-alone activity.
- Wholesalers always take ownership of the products and activities may include food, feed and/or packaging products for food and feed.
- For both retail and wholesale, minor processing activities that only serve to give pre-prepared food a final processing step may be included (e.g., reheating of ready to eat foods, cutting or portioning of meat or fish).

Food chain category FII applies to Food brokering, trading, and E-commerce activities.

- Food brokering and trading is the buying and selling of products on its own account without physically handling, or as an agent for others, of any item that enters the food chain.
- Food E-commerce is the buying and selling of food products over an electronic network (internet) without physical handling.

3.6 TRANSPORT AND STORAGE (CATEGORY G)

Food chain category G applies to third-party logistics service providers who physically store and/or transport food, feed, or food/feed packaging materials, regardless of legal product ownership. It may include additional activities such as re-packing or relabeling of packed products, freezing and thawing activities.

Manufacturers, caterers, or retailers/wholesalers that only store and/or transport their own product(s) and do not provide a service to others shall be audited under the category linked to their production activities.

Manufacturers, caterers, or retailers/wholesalers who also provide storage and/or transport activities to organizations other than their own site, shall also require category G in addition to the relevant manufacturing category. Other organizations also refer to subsidiaries or sister companies.

3.7 PRODUCTION OF FOOD PACKAGING AND PACKAGING MATERIALS (CATEGORY I)

Food chain category I covers packaging (including plastic, carton, paper, metal, glass, wood and other materials) that includes the production of food/feed packaging, food/feed packaging materials and intermediate products for:

a) Direct food contact surfaces or materials (i.e., physically touching the food or in contact with headspace) that will be in contact with the food during normal use of the food packaging, including labels and food desiccants with direct food contact and/or;
b) Indirect food contact surfaces or materials that are not in direct contact with the food during normal use of the food packaging, but there is the possibility for substances to be transferred into the food, including labels applied to primary packaging.
c) Closing packaging materials such as tape, plastic strips, or other can be included in Category I when the manufacturer can prove that it will be applied to a food or feed primary packaging material;
d) Disposable tableware can only be certified when it is sold together (and as part of) the food product. Examples are spoons that are packed with yoghurt, forks or chopsticks packed with ready-to-eat food. The intended use, including that it is sold together (and as part of) the food product, shall be clearly specified in the scope statement. Disposable tableware that is intended for domestic (home) use is outside the scope of certification.
e) Napkins/serviettes can only be certified where they are supplied specifically for use in food service. This intended use shall be clearly specified in the scope statement.
f) Packaging materials, such as aluminum foil, baking paper and plastic wrap, which are intended to be used in the preparation of foodstuffs within the food industry may be certified, in which case the scope statement shall indicate that it is for use within the food industry. Packaging materials of this nature that are not for use within the food industry or are intended for domestic (home) use, are excluded from the scope of FSSC 22000 certification.
g) Packaging activities limited to (inline) unfolding of packaging, blowing of bottle preforms, printing etc. are not considered as food packaging activities and are included in the food scope of certification and therefore category I does not apply.
h) The in-line production of primary packaging, such as bottles using resin to produce a preform and followed by the blowing of bottles, is considered a packaging activity and shall additionally be covered by the packaging scope. Therefore, category I shall apply.

i) Packaging material used for personal care, pharmaceutical products or other non-food uses are outside the scope of the Scheme.

3.8 PRODUCTION OF BIO/CHEMICALS (CATEGORY K)

Food chain category K involves the production of Chemical and Bio-Chemical products and applies to the production of food and feed additives, vitamins, minerals, bio-cultures, flavorings, enzymes, gases, and processing aids.

Food supplements, where legally classified as food within the country of manufacture, may be included under food chain category K. If the product is classified as a pharmaceutical or medical product under the legislation, then it is outside the scope of FSSC 22000 certification.

PART 2 REQUIREMENTS FOR ORGANIZATIONS TO BE AUDITED

CONTENTS PART 2 REQUIREMENTS FOR ORGANIZATIONS TO BE AUDITED

1 PURPOSE

This part describes the Scheme requirements against which licensed Certification Bodies shall audit the Food Safety Management System of the organization to achieve or maintain certification for FSSC 22000.

2 REQUIREMENTS

2.1 GENERAL

Organizations shall develop, implement, and maintain all the requirements outlined below and shall be audited by a licensed Certification Body in order to receive a valid FSSC 22000 certificate.

The audit requirements for FSSC 22000 certification consist of:

1) ISO 22000:2018 Food Safety Management System requirements;
2) Sector specific prerequisite program (PRPs) requirements (ISO/TS 22002-x series or other specified PRP standard) and;
3) FSSC 22000 Additional requirements.

2.2 SCHEME CHANGES AND INTERPRETATION

The Board of Stakeholders (BoS) Decision list is a document which contains decisions applicable to FSSC 22000 Scheme. The decisions overrule or provide further clarification on existing Scheme rules and shall be implemented and applied within the defined transition period. The decision list is dynamic and can be adjusted by the BoS when deemed necessary.

The Foundation publishes interpretation articles related to Scheme requirements that include further clarification on requirements and the application and/or implementation thereof. Certification bodies and Certified Organizations need to adhere to these interpretation articles as applicable. It is the responsibility of the FSSC 22000 contact person to keep up to date with the interpretation articles and communicate it to the relevant parties within the CB or to Certified Organizations as appropriate.

2.3 ISO 22000

The requirements for the development, implementation, and maintenance of the Food Safety Management System (FSMS) are laid down in the standard ISO 22000:2018 “Food safety management systems - Requirements for any organization in the food chain”.

2.4 PREREQUISITE PROGRAMS

The Scheme specifies mandatory application of technical specifications detailing the pre-requisite programs (PRPs) as referenced in clause 8.2 of ISO 22000:2018, with the exception of sub-category FII. These PRP requirements are specified in the ISO/TS 22002-x series and/or the BSI/PAS 221 standards. Refer to Part 1, Table 1 of the Scheme.

2.5 FSSC 22000 ADDITIONAL REQUIREMENTS

2.5.1 MANAGEMENT OF SERVICES AND PURCHASED MATERIALS (ALL FOOD CHAIN CATEGORIES)

a) In addition to clause 7.1.6 of ISO 22000:2018, the organization shall ensure that where laboratory analysis services are used for the verification and/or validation of food safety, these shall be conducted by a competent laboratory (including both internal and external laboratories as applicable) that has the capability to produce precise and repeatable test results using validated test methods and best practices (e.g. successful participation in proficiency testing programs, regulatory approved programs or accreditation to international standards such as ISO 17025).
b) For food chain categories C, D, I, FII, G and K, the following additional requirement applies to ISO 22000:2018 clause 7.1.6: The organization shall have a documented procedure for procurement in emergency situations to ensure that products still conform to specified requirements and the supplier has been evaluated.
c) For food chain categories C0, CI, CIII and CIV: In addition to ISO/TS 22002-1:2009 clause 9.2, the organization shall have a policy for the procurement of animals, fish and seafood that are subject to control of prohibited substances (e.g., pharmaceuticals, veterinary medicines, heavy metals, and pesticides);
d) For food chain categories C, D, I, FII, G and K, the following additional requirement applies: The organization shall establish, implement, and maintain a review process for raw material and finished product specifications to ensure continued compliance with food safety, quality, legal and customer requirements.
e) For food chain category I, in addition to clause 7.1.6 of ISO 22000:2018, the organization shall establish criteria related to the use of recycled packaging as a raw material input into the production of finished packaging material and ensure that relevant legal and customer requirements are being met.

2.5.2 PRODUCT LABELING AND PRINTED MATERIALS (ALL FOOD CHAIN CATEGORIES)

a) In addition to clause 8.5.1.3 of ISO 22000:2018, the organization shall ensure that finished products are labelled according to all applicable statutory and regulatory requirements in the country of intended sale, including allergen and customer specific requirements.
b) Where a product is unlabeled, all relevant product information shall be made available to ensure the safe use of the food by the customer or consumer.
c) Where a claim (e.g., allergen, nutritional, method of production, chain of custody, raw material status, etc.) is made on the product label or packaging, the organization shall maintain evidence of validation to support the claim and shall have verification systems in place, including traceability and mass balance, to ensure product integrity is maintained.
d) For food chain category I, artwork management and print control procedures shall be established and implemented to ensure the printed material meets applicable customer and legal requirements. The procedure shall address the following as a minimum:

    i. Approval of artwork standard or master sample;
    ii. Process to manage changes to artwork and print specifications, and to manage obsolete artwork and printing materials;
    iii. Approval of each print run against the agreed standard or master sample;
    iv. Process to detect and identify printing errors during the run;
    v. Process to ensure effective segregation of differing print variants; and

vi. Process to account for any unused printed product.

2.5.3 FOOD DEFENSE (ALL FOOD CHAIN CATEGORIES)

2.5.3.1 THREAT ASSESSMENT

The organization shall:

a) Conduct and document the food defense threat assessment, based on a defined methodology, to identify and evaluate potential threats linked to the processes and products within the scope of the organization; and
b) Develop and implement appropriate mitigation measures for significant threats.

2.5.3.2 PLAN

a) The organization shall have a documented food defense plan, based on the threat assessment, specifying the mitigation measures and verification procedures.
b) The food defense plan shall be implemented and supported by the organization's FSMS.
c) The plan shall comply with applicable legislation, cover the processes and products within the scope of the organization and be kept up to date.
d) For food chain category FII, in addition to the above, the organization shall ensure that their suppliers have a food defense plan in place.

2.5.4 FOOD FRAUD MITIGATION (ALL FOOD CHAIN CATEGORIES)

2.5.4.1 VULNERABILITY ASSESSMENT

The organization shall:

a) Conduct and document the food fraud vulnerability assessment, based on a defined methodology, to identify and assess potential vulnerabilities; and
b) Develop and implement appropriate mitigation measures for significant vulnerabilities. The assessment shall cover the processes and products within the scope of the organization.

2.5.4.2 PLAN

a) The organization shall have a documented food fraud mitigation plan, based on the output of the vulnerability assessment, specifying the mitigation measures and verification procedures.
b) The food fraud mitigation plan shall be implemented and supported by the organization's FSMS.
c) The plan shall comply with the applicable legislation, cover the processes and products within the scope of the organization and be kept up to date.
d) For food chain category FII, in addition to the above, the organization shall ensure that their suppliers have a food fraud mitigation plan in place.

2.5.5 LOGO USE (ALL FOOD CHAIN CATEGORIES)

a) Certified organizations shall use the FSSC 22000 logo only for marketing activities such as the organization's printed matter, website, and other promotional material.
b) In case of using the logo, the certified organization shall request a copy of the latest FSSC logo from their Certification Body, and comply with the following specifications:

Color	PMS	CMYK	RGB	#
Green	348 U	82/25/76/7	33/132/85	218455
Grey	60% black	0/0/0/60	135/136/138	87888a

Use of the logo in black and white is permitted when all other text and images are in black and white.

c) The certified organization is not allowed to use the FSSC 22000 logo, any statement or make reference to its certified status on:
   i. a product;
   ii. its labelling;
   iii. its packaging (primary, secondary or any other form);
   iv. certificates of analysis or certificates of conformance (CoA's or CoC's);
   v. in any other manner that implies FSSC 22000 approves a product, process, or service and
   vi. where exclusions to the scope of certification apply.

2.5.6 MANAGEMENT OF ALLERGENS (ALL FOOD CHAIN CATEGORIES)

The organization shall have a documented allergen management plan that includes:

a) A list of all the allergens handled on site, including in raw materials and finished products;
b) Risk assessment covering all potential sources of allergen cross-contamination;
c) Identification and implementation of control measures to reduce or eliminate the risk of cross-contamination, based on the outcome of the risk assessment; and
d) Validation and verification of these control measures shall be implemented and maintained as documented information. Where more than one product is produced in the same production area that have different allergen profiles, verification testing shall be conducted at a frequency based on risk, e.g., surface testing, air sampling and/or product testing;
e) Precautionary or warning labels shall only be used where the outcome of the risk assessment identifies allergen cross-contamination as a risk to the consumer, even though all the necessary control measures have been effectively implemented. Applying warning labels does not exempt the organization from implementing the necessary allergen control measures or undertaking verification testing;
f) All personnel shall receive training in allergen awareness and specific training on allergen control measures associated with their area of work;
g) The allergen management plan shall be reviewed at least annually, and following any significant change that impacts food safety, a public recall or a product withdrawal by the organization as a result of an allergen/s, or when trends in industry show contamination of similar products relating to allergens. The review shall include an evaluation of the effectiveness of existing control measures and the need for additional measures. Verification data shall be trended and used as input for the review.
h) For Food Chain Category D: Where there is no allergen-related legislation for the country of sale pertaining to animal feed, this section of the Scheme requirements may be indicated as 'Not Applicable,' unless a claim relating to an allergen status has been made on the animal feed.

2.5.7 ENVIRONMENTAL MONITORING (FOOD CHAIN CATEGORIES BIII, C, I & K)

The organization shall have in place:

a) A risk-based environmental monitoring program for the relevant pathogens, spoilage, and indicator organisms;
b) A documented procedure for the evaluation of the effectiveness of all controls on preventing contamination from the manufacturing environment and this shall include, at a minimum, the evaluation of microbiological controls present; and shall comply with legal and customer requirements.
c) Data of the environmental monitoring activities, including regular trend analysis; and
d) The environmental monitoring program shall be reviewed for continued effectiveness and suitability, at least annually, and more often if required, including when the following triggers occur:

   i. Significant changes related to products, processes, or legislation;
   ii. When no positive testing results have been obtained over an extended period of time;
   iii. Trend in out of specification microbiological results, related to both intermediate and finished products, linked to environmental monitoring;
   iv. A repeat detection of pathogens during routine environmental monitoring; and
   v. When there are alerts, recalls or withdrawals relating to product/s produced by the organization.

2.5.8 FOOD SAFETY AND QUALITY CULTURE (ALL FOOD CHAIN CATEGORIES)

a) In accordance with and in addition to clause 5.1 of ISO 22000:2018, as part of the organizations' commitment to cultivating a positive food safety and quality culture, senior management shall establish, implement, and maintain a food safety and quality culture objective(s) as part of the management system. The following elements shall be addressed as a minimum:

   - Communication,
   - Training,
   - Employee feedback and engagement, and
   - Performance measurement of defined activities covering all sections of the organization impacting on food safety and quality.

b) The objective(s) shall be supported by a documented food safety and quality culture plan, with targets and timelines and included in the management review and continuous improvement processes of the management system.

2.5.9 QUALITY CONTROL (ALL FOOD CHAIN CATEGORIES)

a) The organization shall:
   i. In addition to, and aligned with, clauses 5.2 and 6.2 of ISO 22000:2018, establish, implement, and maintain a quality policy and quality objectives.
   ii. Establish, implement and maintain quality parameters in line with finished product specifications, for all products and/or product groups within the scope of certification, including product release that addresses quality control and testing.
   iii. In addition to, and aligned with, clauses 9.1 and 9.3 of ISO 22000:2018, undertake analysis and evaluation of the results of the quality control parameters, as defined under 2.5.9 (a)(ii) above, and include it as an input for the management review; and
   iv. In addition to, and aligned with, clause 9.2 of ISO 22000:2018, include quality elements as defined in this clause, within the scope of the internal audit.

b) Quantity control procedures, including for unit, weight, and volume, shall be established, and implemented, to ensure products meet the applicable customer and legal requirements. This shall include a program for calibration and verification of equipment used for quality and quantity control.

c) Line start-up and change-over procedures shall be established and implemented to ensure products, including packaging and labelling, meet applicable customer and legal requirements. This shall include having controls in place to ensure labelling and packaging from the previous run have been removed from the line.

2.5.10 TRANSPORT, STORAGE AND WAREHOUSING (ALL FOOD CHAIN CATEGORIES)

a) The organization shall establish, implement, and maintain a procedure and specified stock rotation system that includes FEFO principles in conjunction with the FIFO requirements.

b) For food chain category C0, in addition to ISO/TS 22002-1:2009 clause 16.2, the organization shall have specified requirements in place that define post-slaughter time and temperature in relation to chilling or freezing of the products.

c) For food chain category FI, in addition to BSI/PAS 221:2013 clause 9.3, the organization shall ensure that product is transported and delivered under conditions which minimize the potential for contamination.

d) Where transport tankers are used, the following shall apply in addition to clause 8.2.4 of ISO 22000:2018:
   i. Organizations that use tankers for transportation of their final product shall have a documented risk-based plan to address transport tank cleaning. It shall consider potential sources of cross-contamination, and appropriate control measures, including cleaning validation. Measures shall be in place to assess cleanliness of the tanker at the point of reception of the empty tanker, prior to loading.
   ii. For organizations receiving raw material in tankers, the following shall be included in the supplier agreement as a minimum to ensure product safety and prevent cross-contamination: tanker cleaning validation, restrictions linked to prior use and applicable control measures relevant to the product being transported.

2.5.11 HAZARD CONTROL AND MEASURES FOR PREVENTING CROSS-CONTAMINATION (ALL FOOD CHAIN CATEGORIES, EXCLUDING FII)

a) For food chain categories BIII, C and I, the following additional requirement applies to ISO 22000:2018 clause 8.5.1.3: The organization shall have specific requirements in place

where packaging is used to impart or provide a functional effect on food (e.g., shelf-life extension).

b) For food chain category C0, the following requirement applies in addition to ISO/TS 22002-1:2009 clause 10.1: The organization shall have specified requirements for an inspection process at lairage and/or at evisceration to ensure animals are fit for human consumption;
c) For food chain category D, the following requirement applies in addition to ISO/TS 22002-6:2016 clause 4.7: The organization shall have in place procedures to manage the use of ingredients/additives that contain components that can have an adverse animal health impact.
d) For all food chain categories, excluding FII, the following requirements relating to foreign matter management apply, in addition to clause 8.2.4 (h) of ISO 22000:2018:
    i. The organization shall have a risk assessment in place to determine the need and type of foreign body detection equipment required. Where the organization deems no foreign body detection equipment is necessary, justification shall be maintained as documented information. Foreign body detection equipment includes equipment such as magnets, metal detectors, X-ray equipment, filters, and sieves.
    ii. A documented procedure shall be in place for the management and use of the equipment selected.
    iii. The organization shall have controls in place for foreign matter management including procedures for the management of all breakages linked to potential physical contamination (e.g., metal, ceramic, hard plastic).

2.5.12 PRP VERFITICATION (FOOD CHAIN CATEGORIES BIII, C, D, G, I & K)

The following additional requirement applies to ISO 22000:2018 clause 8.8.1:

- The organization shall establish, implement, and maintain routine (e.g., monthly) site inspections/PRP checks to verify that the site (internal and external), production environment and processing equipment are maintained in a suitable condition to ensure food safety. The frequency and content of the site inspections/PRP checks shall be based on risk with defined sampling criteria and linked to the relevant technical specification.

2.5.13 PRODUCT DESIGN AND DEVELOPMENT (FOOD CHAIN CATEGORIES BIII, C, D, E, F, I & K)

A product design and development procedure shall be established, implemented, and maintained for new products and changes to product or manufacturing processes to ensure safe and legal products are produced. This shall include the following:

a) Evaluation of the impact of the change on the FSMS taking into account any new food safety hazards (incl. allergens) introduced and updating the hazard analysis accordingly,
b) Consideration of the impact on the process flow for the new product and existing products and processes,
c) Resource and training needs,
d) Equipment and maintenance requirements,
e) The need to conduct production and shelf-life trials to validate product formulation and processes are capable of producing a safe product and meet customer requirements. A process for on-going shelf-life verification shall be in place, at a frequency based on risk.
f) Where a ready-to-cook product is produced, the cooking instructions provided on the product label or packaging shall be validated to ensure food safety is maintained.

2.5.14 HEALTH STATUS (FOOD CHAIN CATEGORY D)

In addition to ISO/TS 22002-6 clause 4.10.1, the organization shall have a procedure to ensure that the health of personnel does not have an adverse effect on the feed production operations. Subject to legal restrictions in the country of operation, employees shall undergo a medical screening prior to employment in feed contact operations, unless documented hazards or medical assessment indicates otherwise. Additional medical examinations, where permitted, shall be carried out as required and at intervals defined by the organization.

2.5.15 EQUIPMENT MANAGEMENT (ALL FOOD CHAIN CATEGORIES, EXCLUDING FII)

In addition to clause 8.2.4 of ISO 22000:2018, the organization shall:

a) Have a documented purchase specification in place, which addresses hygienic design, applicable legal and customer requirements, and the intended use of the equipment, including product handled. The supplier shall provide evidence of meeting the purchase specification prior to installation.
b) Establish and implement a risk-based change management process for new equipment and/or any changes to existing equipment, which shall be adequately documented including evidence of successful commissioning. Possible effects on existing systems shall be assessed and adequate control measures determined and implemented.

2.5.16 FOOD LOSS AND WASTE (ALL FOOD CHAIN CATEGORIES, EXCLUDING I)

In addition to clause 8 of ISO 22000:2018, the organization shall:

a) Have a documented policy and objectives detailing the organization's strategy to reduce food loss and waste within their organization and the related supply chain.
b) Have controls in place to manage products donated to not-for-profit organizations, employees, and other organizations; and ensure that these products are safe to consume.
c) Manage surplus products or by-products intended as animal feed/food to prevent contamination of these products.
d) These processes shall comply with the applicable legislation, be kept up to date, and not have a negative impact on food safety.

2.5.17 COMMUNICATION REQUIREMENTS (ALL FOOD CHAIN CATEGORIES)

In addition to clause 8.4.2 of ISO 22000:2018, the organization shall inform the certification body within 3 working days of the commencement of the events or situations below and implement suitable measures as part of their emergency preparedness and response process:

a) Serious events that impact the FSMS, legality and/or the integrity of the certification including situations that pose a threat to food safety, or certification integrity as a result of a Force majeure, natural or man-made disasters (e.g., war, strike, terrorism, crime, flood, earthquake, malicious computer hacking, etc.);
b) Serious situations where the integrity of the certification is at risk and/or where the Foundation can be brought into disrepute. These include, but are not limited to:
    - Public food safety events (e.g., public recalls, withdrawals, calamities, food safety outbreaks, etc.);
    - Actions imposed by regulatory authorities as a result of a food safety issue(s), where additional monitoring or forced shutdown of production is required;
    - Legal proceedings, prosecutions, malpractice, and negligence; and

- Fraudulent activities and corruption.

2.5.18 REQUIREMENTS FOR ORGANIZATION WITH MULTI-SITE CERTIFICATION (FOOD CHAIN CATEGORIES E, F & G)

2.5.18.1 CENTRAL FUNCTION

a) The management of the central function shall ensure that sufficient resources are available, and that roles, responsibilities and requirements are clearly defined for management, internal auditors, technical personnel reviewing internal audits and other key personnel involved in the FSMS.

2.5.18.2 INTERNAL AUDIT REQUIREMENTS

In addition to clause 9.2 of ISO 22000:2018, the organization shall adhere to the following requirements relating to internal audits:

a) An internal audit procedure and program shall be established by the central function covering the management system, central function, and all sites. Internal auditors shall be independent from the areas they audit and be assigned by the central function to ensure impartiality at site level.
b) The management system, centralized function and all sites shall be audited at least annually or more frequently based on a risk assessment; and the effectiveness of corrective action shall be demonstrated.
c) Internal auditors shall meet at least the following requirements, and this shall be assessed by the CB annually as part of the audit:

   Work experience: 2 years' full-time work experience in the food industry including at least 1 year in the organization.
   Education: completion of a higher education course or in the absence of a formal course, have at least 5 years work experience in the food production or manufacturing, transport, and storage, retailing, inspection, or enforcement areas.
   Training:

   i. For FSSC 22000 internal audits, the lead auditor shall have successfully completed a FSMS, QMS or FSSC 22000 Lead Auditor Course of 40 hours.
   ii. Other auditors in the internal audit team shall have successfully completed an internal auditor course of 16 hours covering audit principles, practices, and techniques. The training may be provided by the qualified internal Lead Auditor or through an external training provider.
   iii. FSSC Scheme training covering at least ISO 22000, the relevant prerequisite programs based on the technical specification for the sector (e.g., ISO/TS 22002-x; PAS-xyz) and the FSSC additional requirements – minimum 8 hours.

d) Internal audit reports shall be subject to a technical review by the central function, including addressing the non-conformities resulting from the internal audit. Technical reviewers shall be impartial, have the ability to interpret and apply the FSSC normative documents (at least ISO 22000, the relevant ISO/TS 22002-x; PAS-xyz and the FSSC additional requirements) and have knowledge of the organizations processes and systems.
e) Internal auditors and technical reviewers shall be subject to annual performance monitoring and calibration. Any follow-up actions identified shall be suitably actioned in a timely and appropriate manner by the Central function.

PART 3 REQUIREMENTS FOR THE CERTIFICATION PROCESS

CONTENTS PART 3 REQUIREMENTS FOR THE CERTIFICATION PROCESS

1 PURPOSE

This Part states the requirements for the execution of the certification process to be conducted by licensed Certification Bodies (CBs).

2 GENERAL

The CB shall manage its certification management system according to the requirements of ISO/IEC 17021-1:2015, ISO 22003-1:2022, and the FSSC 22000 requirements including any FSSC Board of Stakeholder decisions and other mandatory documents published by the Foundation.

The CB shall control all Scheme related documentation and records according to its own procedures.

The CB shall have procedures of certification that confirm the compliance of the certified organizations to that of the Scheme and the accreditation requirements.

3 RESOURCES

The CB shall provide sufficient resources to enable the reliable supply of its FSSC 22000 certification service.

4 CONTRACT PROCESS

4.1 APPLICATION

The CB shall collect and document the information from the applicant organization in an application form which details the minimum information as required in the ISO/IEC 17021-1 and ISO 22003-1:2022, and additional Scheme requirements.

4.2 SCOPE

The CB shall assess the scope proposed by the organization on the application form and review it against the requirements of ISO 22003-1:2022 and the requirements of the Scheme.

4.3 AUDIT TIME INCLUDING AUDIT DURATION

The CB shall calculate the audit time including the audit duration based on the information gathered from the organization's application and follow the requirements of ISO/IEC 17021-1 and ISO 22003-1, with the below specific/additional FSSC 22000 requirements:

a) The duration of an audit day normally is eight (8) hours and only includes effective auditing time. In exceptional circumstances an audit day may be longer than 8 hours but shall never exceed ten (10) hours and then only in accordance with the relevant International Labor Organization (ILO) and national legislative requirements;

b) The audit duration calculation for FSSC 22000 shall be documented by the CB, including justifications for reduction or addition of time based on the minimum audit duration;
c) The audit duration shall be stated in auditor working hours indicating the effective audit duration based on the audit plan. Deviations to the audit durations and audit plan shall be recorded in the audit report (including motivations);
d) The audit duration shall only apply to FSSC 22000 qualified auditors and not to other team members(s) not assigned as an auditor (e.g., technical experts, interpreters, observers, witnessors and trainee auditors);
e) Where the FSSC 22000 audit is undertaken in combination or integrated with other food safety audits as a combined audit, the audit duration stated in the report shall be of the total combined audit and be aligned with the audit plan. Total audit duration is then longer than for FSSC 22000 alone and shall be sufficient to ensure that all the FSSC 22000 requirements are being covered. This is considered as an increase in audit duration and the reason for this shall be justified in the audit report.
f) A minimum of 50% of the total audit duration shall be spent on auditing the operational food safety planning and the implementation of PRPs and control measures. This includes time spent auditing the facilities, conducting the traceability exercise(s) and reviewing the relevant records. Operational food safety planning does not include activities related to FSMS development, training, internal audit, management review and improvement.
g) The CB shall provide the audit duration and audit time determination to the organization and make it available to its AB and The Foundation.

4.3.1 BASIC AUDIT DURATION CALCULATION (SINGLE SITE)

The total audit duration/site audit time (for a single site) is defined as $D_s + T_{FSSC}$ where:

a) $D_s = (T_D + T_H + T_{FTE})$ which is the total audit duration calculated according to ISO 22003-1:2022; and
b) T_{FSSC} shall be calculated as follows:

    i. 1.0 auditor day (8 working hours) when the company has less than 250 FTE and 1 or 2 HACCP studies.
    ii. 1.5 auditor day (12 working hours) when the organization has 250 FTE or more; or 3 HACCP studies or more.

When properly documented and justified, a reduction of the D_s audit duration can be made in accordance with ISO 22003-1:2022, Annex B. The reduction in D_s audit duration can never be more than 0.25 auditor day (2 working hours) and the D_s cannot be reduced below 1 day. The reduction cannot be applied to the T_{FSSC}.

Preparation and reporting time shall be in addition to the audit duration – the below refers to the minimum time to be allocated:

a) At least 0.25 auditor day (2 working hours) for audit preparation.
b) At least 1.0 auditor day (8 working hours) for audit reporting.

Where more than one food chain category is included in the scope of certification, additional reporting time may be required, based on the audit complexity.

If after the calculation the result is a decimal number, the exact hours may be used or where rounding is applied to the number of days, this shall be rounded upwards to the nearest half day (e.g., 5.3 audit days becomes 5.5 audit days).

An interpreter may be added to the audit team to support members of the audit team. The interpreter shall be assigned by the CB and be independent of the organization audited. Where an interpreter is required to support the audit team, the audit duration of the relevant audit or audit part (in cases where the interpreter is not present for the full audit duration), shall be increased with at least 20% to allow for the translation process.

4.3.2 SURVEILLANCE AND RECERTIFICATION AUDITS

For surveillance and recertification audits, the basic audit duration shall be calculated as follows:

a) Surveillance audits: (one-third of D_s) + T_{FSSC}, plus any other additional audit time (as per §5.2 below).
b) Recertification audits: (two-thirds of D_s) + T_{FSSC}, plus any other additional audit time (as per §5.2 below).

Additional or special audits may be performed in addition to the regular surveillance or recertification audits – but never as a replacement. These additional (special) audits shall be documented and uploaded to the Assurance Platform as special audits.

4.3.3 MINIMUM AUDIT DURATION

For all audit types (initial, surveillance, recertification), the following minimum audit duration principles apply:

a) The minimum D_s is 1 day (8 working hours).
b) The minimum basic FSSC 22000 audit duration is then 2 days (refer 4.3.1 b) for all food chain categories;
c) The minimum audit duration shall always be respected, except where the exemption below applies.
d) Basic audit duration is the minimum duration for a single site and does not include additional time i.e., for off-site activities.

The following exemption applies to the minimum audit durations:

i. For organizations that have simple processes, less than 20 FTE and maximum 1 HACCP study, further reductions are allowed to a minimum audit duration of 1.5 days for all audit types.
ii. For subcategory FII, a minimum audit duration of 1.5 days may be applied for all audit types.

Where the exemption above is applied, the CB shall ensure that the audit duration allows for an effective audit based on audit objectives, scope and specific audit needs and covering the full FSSC 22000 requirements.

4.4 CONTRACT

A certification contract shall be in place between the CB and the organization applying for certification, detailing the scope of the certification, and referring to all relevant Scheme requirements.

This contract shall detail or have reference to the legally enforceable certification agreement between the CB and the organization which shall include, but are not limited to:

1) Ownership of the certificate and the audit report content shall be held by the CB;
2) Conditions under which the certification contract can be terminated;
3) Conditions under which the certificate can be used by the certified organization;
4) Terms of confidentiality in relation to information gathered by the CB during the certification process;
5) The certified organization allows the CB to share information relating to the certification and auditing process with the Foundation, their Accreditation Body, the IAF, GFSI and governmental authorities when required;
6) The certified organization allows the CB and Foundation FSSC to share information regarding their certification status with external parties;
7) Procedures for nonconformity management;
8) Procedures for complaints and appeals;
9) Inclusion of information on the certified status of the organization on the FSSC 22000 website and in the Assurance Platform;
10) Cooperation in, and acceptance of witness assessments by the CB, AB and/or the Foundation when requested;
11) Communication obligations of certified organizations to the CB within 3 working days related to the following:

    a. Any significant changes that affect the compliance with the Scheme requirements and obtain advice of the CB in cases where there is doubt over the significance of a change;
    b. Serious events that impact the FSMS, legality and/or the integrity of the certification, including situations that pose a threat to food safety or certification integrity as a result of Force majeure, natural or man-made disasters (e.g., war, strike, terrorism, crime, flood, earthquake, malicious computer hacking, etc.);
    c. Serious situations where the integrity of the certification is at risk and/or where the Foundation can be brought into disrepute. These include, but are not limited to:
        - Public food safety events (e.g., public recalls, withdrawals, calamities, food safety outbreaks, etc.);
        - Actions imposed by regulatory authorities as a result of a food safety issue(s), where additional monitoring or forced shutdown of production is required;
        - Legal proceedings, prosecutions, malpractice, and negligence; and
        - Fraudulent activities and corruption.
    d. Changes to organization name, contact address and site details;
    e. Changes to organization (e.g., legal, commercial, organizational status or ownership) and management (e.g., key managerial, decision-making, or technical staff);
    f. Major changes to the food safety management system, scope of operations and product categories covered by the certified management system (e.g. new products, new processing lines, etc.);
    g. Any other change that renders the information on the certificate inaccurate.

5 PLANNING AND MANAGING AUDITS

5.1 GENERAL

1) The 3-year certification cycle (ISO/IEC 17021-1 §9.1.3) shall be respected.

2) The CB shall perform the stage 1 and stage 2 audits for initial certification according to the requirements of ISO/IEC 17021-1 and ISO 22003-1. The interval between stage 1 and stage 2 audits shall not be longer than 6 months. The Stage 1 shall be repeated if a longer interval is needed.
3) Any part of the FSMS that is audited during the Stage 1 audit, and determined to be fully implemented, effective and in conformity with requirements, does not necessarily need to be re-audited during Stage 2. In this case, the audit report includes these findings and clearly states that conformity has been established during the Stage 1 of the audit.
4) Surveillance audits shall be conducted within the calendar year as per the requirements of ISO/IEC 17021-1, to ensure that the organization's management system continues to fulfil the Scheme requirements and that certification integrity is maintained. The date of the first surveillance audit, after the initial certification, shall not exceed 12 months from the initial certification decision date, otherwise the certification shall be suspended.
5) Each surveillance audit is a full system audit and shall cover all the Scheme requirements.
6) Recertification audits shall take place in a timely manner, preferably at least three (3) months prior to the expiry date of the certificate, allowing enough time for the certification process to be completed prior to the expiry of the certificate. Where the certificate expires prior to the recertification activities being undertaken, the CB can restore certification within 6 months, provided that the outstanding recertification activities are completed, otherwise a full initial certification audit (Stage 1 and Stage 2) shall be conducted. Recertification audits are full system audits against the Scheme requirements.
7) Where a certified organization moves to another location, at least a Stage 2 audit shall be conducted, resulting in the start of a new 3-year certification cycle.
8) General:
    a. Audits shall be carried out at the premises of the organization in accordance with the audit duration calculated, and shall be conducted over a continuous number of days (excluding weekends when it is not a working day and public holidays). Where the ICT Audit Approach is utilized, the requirements of Annex 5 apply.
    b. It is the organization's responsibility to communicate any local holidays or shutdowns in a timely manner to facilitate audit scheduling.
    c. The CB shall have a process for determining the audit timing, including seasonal activities where relevant, to allow for auditing the organization operating on a representative number of product lines and/or activities covered by the scope of certification.
    d. The audit shall be carried out in a mutually agreed language. An interpreter may be added to the team by the CB to support members of the audit team.
    e. The CB is expected to operate with discretion in case of emergencies (e.g., fire, major catastrophic event, another audit on-going).

5.2 MULTIPLE FUNCTIONS ACROSS MORE THAN ONE SITE

5.2.1 HEAD OFFICE FUNCTIONS

1) In all cases where functions pertinent to the certification of the site (such as procurement, product development, supplier approval, quality assurance etc.) are controlled by a Head Office (part of the same legal entity or part of the same larger organization), the Scheme requires that these functions be audited and included in the certification of the site, including interviewing the personnel described in the FSMS as having the (delegated) authority and responsibility for these functions. This Head Office audit shall be documented.

2) Where it is not possible to audit these functions and access information during the site audit, a separate head office audit shall be conducted prior to the site audit. The subsequent audit at the site(s) shall include confirmation that the requirements set out by the Head Office are appropriately incorporated into site-specific documents and implemented in practice. It might be necessary to follow up on certain topics with the Head office during the site audit, in which case the Head office shall make the information available.
3) The site audit report shall include which FSMS functions and/or processes have been audited at the Head Office, including the information, and supporting objective evidence gathered relating to the Head office functions.
4) Where the same Head office is linked to more than one site, the following applies:
    a. The Head office audit is conducted before the site audits within a time frame of 12 months from the site audits, but typically as close to the site audits as possible.
    b. A separate audit report is generated for the Head office that shall be uploaded to the FSSC Assurance Platform together with each site audit report;
5) Every site linked to the head office shall have a separate audit, audit report and certificate.
6) The Head office functions shall be audited at every audit type (initial, surveillance, recertification). The audit may be conducted onsite, or remotely based on a feasibility assessment and in accordance with the requirements of Annex 5.
7) Nonconformities identified at the Head office shall be dealt with as set out in section 6.2 of this Part.
8) The Head Office cannot receive a separate certificate as the functions/process audited are part of the site's audit. The Head Office is referenced on the site certificate, regardless of whether assessed as part of the site audit or as a separate audit, and shall indicate which FSMS functions and/or processes have been managed at the Head office. Wording such as: "*This audit included the following central FSMS processes managed by (name and location of Head Office): (describe FSMS processes managed at the Head Office)*", may be used.

5.2.1.1 HEAD OFFICE AUDIT DURATION

a) For organizations where some functions pertinent to the certification are controlled by a Head Office separate to the site(s), and where these functions are audited separate to the site (prior to the site audit), the minimum audit duration of the Head office shall be 0.5 auditor day (4 working hours). Depending on the nature, complexity (including the number of sites linked to the Head office) and extent of these functions, more time shall be added. In all instances the audit duration shall be appropriate to allow for the relevant functions to be fully assessed.
b) Where the Head Office functions are assessed as part of and at the same time as the audit at the site, no additional audit time is required.
c) A maximum of 20% audit duration reduction can be allowed for each of the single sites linked to the off-site Head Office. The 20% reduction is only applied to the minimum audit duration (D_s) of the site as per ISO 22003-1:2022, Annex B.
d) Additional time is required for the planning and report writing of the head office audits and is not included in the basic site audit duration.

5.2.2 OFF-SITE ACTIVITIES

1) Where one manufacturing, processing or service process is split across more than one physical address, these locations may be covered in one audit provided that the different addresses are part of the same legal entity and under the same FSMS. This is limited to two sites (main site and satellite site) or to organizations with a campus style set-up

(multiple facilities at one location that is part of the same organization). These sites are required to be in the same country and the audit must be delivered in a continuous manner that is in accordance with the audit duration calculated.

2) Storage facilities at another location shall also be included in the same audit provided they are part of the same legal entity and under the same FSMS. Storage facilities are limited to those only used for, and directly linked to the storage of the site's products. Where activities or services are provided for other customers (including sister companies), separate certification will be required for these off-site storage facilities.
3) The certificate shall include the audited locations with activities per location (on the certificate or as an Annex to the certificate) – refer Annex 3.
4) The audit report shall clearly reflect what was audited at each location included in the certification, include a sufficient level of detail (objective evidence) in the summary sections, and allow audit findings to be identified as site specific.

5.2.2.1 OFF-SITE ACTIVITY AUDIT DURATION

a) Off-site manufacturing activities: Where off-site manufacturing, processing or service activities take place, a 50% audit time reduction of D_S may be applied for the satellite site OR the parameters (e.g., FTE, HACCP studies) of the satellite site shall be included in the main site audit duration calculation as specified in §4.3. Additional time shall be added for travelling between sites and is therefore not included in the audit duration.
b) Off-site storage and cross docking**:** At least 0.25 auditor day (2 working hours) additional audit time shall be added to the FSSC 22000 audit duration for each off-site storage or cross docking facility. Transshipment is not covered in this requirement.

5.3 MULTI-SITE CERTIFICATION

5.3.1 GENERAL

a) A multi-site organization is an organization having an identified central function at which certain FSMS activities are planned, controlled or managed, and a network of sites at which such activities are fully or partially carried out, as per ISO 22003-1:2022 clause 9.1.5.2.
b) A multi-site organization does not need to be a unique legal entity, in which case all sites shall have a legal or contractual link with the central function of the organization and be subject to a single management system, which is laid down, established and subject to continuous oversight, surveillance and internal audits by the central function.
c) Multi-site certification (including sampling) is only allowed for the following food chain (sub)categories:

- E – Catering
- FI – Retail/wholesale
- FII - Brokering/Trading/E-commerce
- G – Storage and distribution

d) When applying multi-site certification all requirements of IAF MD 1 shall be met, except:

i. Paragraph 6.1.3 (size of sample). This IAF MD 1 paragraph shall be replaced by the ISO 22003-1:2022 sampling regime paragraph 9.1.5.4; except that the following calculation shall be utilized for Food Chain Categories E, F and G:

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, rounded up to the next whole number: $y = 20 + \sqrt{(x - 20)}$.

ii. Paragraph 7.3: Calculating audit duration:

Central Function: The central function audit duration shall be calculated based on Ds, using the Table in Annex B of ISO 22003-1:2022. The calculation of the Ds is based on:

- FTE: the number of FTE of the central function that is responsible for, and involved in, the central function activities.
- Food Chain category: if there are multiple categories or subcategories, use the category or subcategory with the highest TD value to determine the DS.
- Number of HACCP studies: use the number of different HACCP studies within the multisite organization.

The central function audit duration shall always be calculated separately from the site audits, regardless of whether the central function is based at a site or not. The audit duration of the central function shall be equal to or greater than Ds for all audit types (initial, surveillance and recertification) and cannot be less than 1.0 auditor day in all instances. T_{FSSC} is not required to be added to the central function audit duration.

Sites: Audit duration for sites are calculated individually, based on the specific parameters linked to that site. A maximum of 50% audit duration reduction can be allowed for each of the sites belonging to the multi-site organization. The 50% reduction is only applied to the minimum audit duration (Ds) as per ISO 22003-1:2022, Annex B, Table B.1;

Site audit duration:

- Initial audit = (50% of Ds) + T_{FSSC}
- Surveillance audits = [1/3rd of (50% of Ds)] + T_{FSSC}
- Recertification audits = [2/3rd of (50% of Ds)] + T_{FSSC}

The audit duration for a site cannot be below 1.5 auditor day for all audit types (initial, surveillance and recertification) and all applicable Food Chain Categories.

e) Audit duration excludes preparation and report writing time. It is required that additional time is added for the central function and each of the sites for audit preparation and report writing.
f) During the Stage 1 audit, the Central Function shall be audited as a minimum - it is not required to include sites in the Stage 1 audit. Although not required, it is recommended to include some of the sites to determine readiness for the Stage 2 audit. If a site is not audited during the Stage 1 audit, then the full initial audit duration shall be applied at the Stage 2 duration for that site.
g) For subsequent audits, the central function shall be audited at least annually and before the CB audits of the (sampled) sites. In exceptional cases, a small number of the (sample) sites may be audited prior to the audit of the central function. The site audits shall be conducted as close to the central function audit as possible, but always within 12 months of the central function audit.

h) Separate reports may be produced for the Central function and each of the sites respectively. Alternatively, one audit report may be produced for the multi-site organization, including the central function information, containing specific information about each site audited and complying with the content of Annex 2. The summary sections of the audit report shall clearly reflect what was audited at each site with supporting objective evidence.
i) The certificate shall be a group certificate issued to the multi-site organization. It is not allowed to issue certificates to individual sites in the case of multi-site certification.

5.3.2 SAMPLING METHODOLOGY

a) For organizations with 20 sites or fewer, all sites shall be audited.
b) For organizations with more than 20 sites and that meets the sampling criteria, the sampling requirements as set out in ISO 22003-1:2022, paragraph 9.1.5 apply, except for the sampling methodology (calculation), where the Scheme requirement in 5.3.1 (d) in this document apply.
c) In addition to (b): where sampling is allowed, the CB shall ensure that all sites are audited over the course of the initial certification cycle (Initial, surveillance, surveillance) and subsequent certification cycle respectively (recertification, surveillance, surveillance). Therefore, the sample size might need to be increased to meet this requirement, but can never be lower than what is defined in (b).
d) The methodology sets the minimum sample sizes, and therefore based on the risk categories, complexity and performance of the sites, an increase in the sample size might be required.
e) Where sites are added to the group, an audit is required before adding them to the certificate, either as a special audit (scope extension) or as part of the regular audit.
f) Once every 3 years, the regular audit shall be conducted fully unannounced as set out in Part 3, section 5.4.1, including the central function and the (sampled) site audits.

5.3.3 REQUIREMENTS FOR THE CENTRAL FUNCTION

a) The central function shall hold the contract with the CB and request to include multi-site sampling as part of the application process should they wish to include it.
b) It is the responsibility of the central function to ensure management commitment to the FSMS and have sufficient resources and technical capacity in place to support the system and the internal audit program. The central function shall be impartial from the sites (e.g., have different/ dedicated employees, governance, management etc.).
c) It might be necessary to follow up on certain topics with the Central function during or after a site audit, in which case the responsible individual/s at the Central function shall make the information available.
d) The central function shall take responsibility for coordinating, addressing, and closing out of nonconformities raised at site level in conjunction with the relevant sites. Failure of the central function or any of the sites to meet the Scheme requirements shall result in the whole organization, including the central function and all sites, not gaining certification. Where certification has previously been in place, this shall initiate the CB process to suspend or withdraw the certification.

5.3.4 NONCONFORMITY MANAGEMENT

Nonconformities raised at multi-site organizations shall follow the requirements of the Scheme (refer Part 3, section 6.2) as well as those in IAF MD1, section 7.7 and ISO 22003-1:2022, section 9.1.5, with the following specific requirements in addition:

a) Where a critical nonconformity is identified, the certificate of the multi-site organization shall be suspended within 3 working days of issuing the critical nonconformity, regardless of whether the central function audit or site audits have been completed.
b) Where a major nonconformity is identified and the audit takes more than 28 calendar days to complete (central function and site audits), the organization shall provide a corrective action plan including any temporary measures or controls necessary to mitigate the risk until the nonconformity can be closed. If no corrective action plan is provided within 28 days, the certificate shall be suspended.
c) The timeline for closure of nonconformities starts at the end of the audit – after completion of the central function audit and all the site audits.

5.4 UNANNOUNCED AUDITS

5.4.1 FREQUENCY

1) The CB shall ensure that for each certified organization at least one surveillance audit is undertaken unannounced after the initial certification audit and within each three (3) year period thereafter.
2) The initial certification audit (stage 1 and stage 2) cannot be performed unannounced.
3) The organization, once certified, can voluntarily choose to conduct all audits (surveillance and recertification) as unannounced audits.

5.4.2 EXECUTION

1) The CB determines the date of the unannounced audit as part of the audit program.
2) The site shall not be notified in advance of the date of the unannounced audit and the audit plan shall not be shared until the opening meeting. In exceptional cases where specific visa or security restrictions apply, contact with the certified organization may be needed as part of the visa application process. However, in these exceptional cases, the exact dates of the unannounced audit shall not be confirmed, only a time window, which is typically 30 days.
3) The unannounced audit takes place during normal operational working hours with consideration of all shifts, where applicable.
4) Blackout days may be agreed in advance between the CB and the certified organization.
5) The audit will start with an inspection of the production facilities and premises commencing within 1 hour after the auditor has arrived on site. In case of multiple buildings at the site the auditor shall, based on the risk, decide which buildings/facilities shall be inspected in which order.
6) All Scheme requirements shall be assessed including production or service processes in operation. Where parts of the audit plan cannot be audited, an (announced) follow-up audit shall be scheduled within 28 calendar days, whilst still meeting the calendar year requirement.
7) The CB decides which of the surveillance audits shall be chosen for the unannounced audit taking into consideration the requirement that unannounced audits shall be conducted at least once every 3 years and adhering to the calendar year requirement.
8) If the certified organization refuses to participate in the unannounced audit, the certificate shall be suspended within 3 working days of the date of refusal. The CB shall withdraw the certificate if the unannounced audit is not conducted within a six-month timeframe from the date of suspension.

9) The audit of separate Head offices controlling certain FSMS processes pertinent to certification separate to the site(s) (see 5.2.1) shall be announced. Where Head Office activities are part of a site audit, it shall be unannounced.
10) Secondary sites (off-site activities) and off-site storage, warehouses and distribution facilities shall also be audited during the unannounced audit.

5.5 USE OF INFORMATION AND COMMUNICATION TECHNOLOGY

Information and Communication Technology (ICT) may be used as a remote auditing tool during regular FSSC 22000 audits with the following applications and meeting the applicable requirements of IAF MD4:

1) For conducting interviews and reviewing policies, procedures, or records as part of the on-site audit; as well as head office functions where appropriate.
2) When utilizing the ICT Audit Approach as set out in Annex 5.
3) For full remote audits, in the case of a serious event, where the requirements in the Full Remote Audit Addendum are met.
4) For category FII, the regular surveillance audits may be conducted as full remote audits. The requirements in the Full Remote Audit Addendum shall be met, with the exception that it is not limited to circumstances linked to a serious event.

5.6 TRANSFER OF CERTIFICATION

The transfer of certification is defined as the recognition of an existing and valid management system certification, granted by one accredited certification body, (the "issuing certification body"), by another accredited certification body, (the "accepting certification body") for the purpose of issuing its own certification. The requirements for the transfer of accredited certification as per IAF MD2 shall be followed.

The accepting/new CB needs to determine the eligibility of certification for transfer. Only existing, valid, and accredited FSSC 22000 certificates may be transferred. It is not possible to transfer expired or suspended certificates. The accepting CB shall conduct a pre-transfer review to determine if the certificate may be transferred. This review shall be conducted by means of a documentation review, and where identified as needed, a pre-transfer visit may be conducted to confirm the validity of the certification. The pre-transfer visit is not an audit. The pre-transfer review shall be uploaded to the Assurance Platform as part of the transfer. The transfer process, including the issuance of the certificate, shall be completed before the expiry of the current certificate.

5.7 UPGRADE AUDITS

The Foundation will issue instructions when upgrade audits are required. This typically occurs when there is a significant change to the Scheme requirements e.g., a Version change.

The CB shall:

1) Follow the upgrade requirements as issued by the Foundation;
2) Ensure all staff and auditors are familiar with the upgrade process;
3) Additional audit duration shall be recalculated and advised to the clients where applicable;
4) Following the successful upgrade audit (including closure of nonconformities) the certificate will be re-issued when required as part of the upgrade requirements.

5.8 TRANSITION AUDITS

1) Transition audits to FSSC 22000 certification are where an organization holding existing accredited certification to ISO 22000 or a GFSI recognized certification program wants to transition (move) to FSSC 22000 certification. In order to qualify for a transition audit, the existing certification shall still be valid at the time of the transition audit and have an equivalent scope of certification.
2) The valid ISO 22000 or equivalent GFSI recognized certificate does not have to be issued by the CB undertaking the transition audit.
3) Transition audits are the start of a new certification cycle and shall therefore be a Stage 2 audit.
4) The minimum audit duration of the transition audit shall be (two-thirds of D_s) + T_{FSSC} and shall meet the minimum audit duration requirements in §4.3. A Stage 1 audit may be performed at the discretion of the CB.
5) A successful transition audit shall result in an FSSC 22000 certificate with a validity of three (3) years.

5.9 ALLOCATION OF AUDIT TEAM

1) All audit team members shall meet the competence requirements set out by the Foundation in Part 4 of the Scheme.
2) The audit team shall have the combined competence for the food chain sub-categories supporting the scope of the audit and following the requirements of ISO/IEC 17021-1 and ISO 22003-1.
3) An auditor is not allowed to perform more than two 3-year certification cycles at the same certified organization either as lead auditor or co-auditor. If an auditor starts auditing within a certification cycle, he/she will be rotated out after six (6) years. The auditor shall be rotated out for a minimum of one (1) regular FSSC 22000 audit (excluding Stage 1, follow-up and special audits) before being allowed to conduct FSSC 22000 audits at the applicable organization again.

5.10 MANAGEMENT OF SERIOUS EVENTS

1) The CB shall have a process to review planned audits when a serious event affects a certified organization, and the audit cannot be performed as planned.
2) The CB shall assess the risks of continuing certification and establish a documented policy and process, outlining the steps it will take in the event a certified organization is affected by a serious event to ensure the integrity of certification is maintained. The minimum content of the risk assessment shall cover the aspects listed in IAF ID3, section 3.
3) The outcome of the Risk Assessment and planned actions shall be recorded. Deviations from the audit program and their justification for changes shall be recorded. CBs shall establish in consultation with certified organizations a reasonable planned course of action.
4) In cases where the regular surveillance audit cannot take place within the calendar year as a result of a serious event, an exemption shall be requested from the Foundation for approval, or the certificate shall be suspended.
5) In the case of a serious event, a full remote audit may be conducted if the conditions as set out in the Full Remote Audit Addendum are met. Where a full remote audit has been conducted, the audit delivery method shall be referenced on the certificate, as per the requirements of Annex 3.

6 AUDIT DOCUMENTATION

6.1 WRITTEN AUDIT REPORT

The CB shall provide a written report for each audit.

a) The audit report is to be treated confidentially by the CB but shall be made available to the relevant Authorities when requested and after approval of the organization.
b) The audit report shall confirm that all Scheme requirements are assessed, reported on and a statement of (non) conformity given. Furthermore, it shall conform to all relevant requirements of ISO/IEC 17021-1.
c) The mandatory audit reports issued by the Foundation shall be used. The minimum content and reporting requirements as set out in Annex 2 of the Scheme shall be met when completing the audit report.
d) Both the procedural and operational conditions of the FSMS shall be verified to assess the effectiveness of the FSMS meeting the Scheme requirements and reported.
e) In exceptional cases, certain requirements can be deemed not applicable (N/A). Where a requirement is deemed to be N/A then suitable justification shall be recorded in the relevant section of the audit report. Note: this applies only to those clauses in the audit report that have the option to select N/A; all other clauses shall be assessed in full.
f) Exclusions from scope shall be assessed and justified in the audit report, in accordance with the requirements as per Annex 1.
g) Deviations from the audit plan shall be justified and documented accordingly in the audit report.
h) The audit duration calculation shall be uploaded in the FSSC Assurance Platform as a separate document for each audit, including the formula and the calculation details for all audits (initial certification, surveillance and recertification). Where off-site activities are applicable, this shall be specifically indicated and included in the audit duration calculation. Multisite certification shall include the calculation for the Central Function and each of the sites.
i) Auditors shall report all nonconformities (NCs) at all audits. For each nonconformity (NC), a clear concise statement of the requirement, the NC statement, grade of the NC and the objective evidence shall be recorded in the audit report.
j) The CB's nonconformity report shall meet the content requirements in Annex 2. A copy of the nonconformity report shall be provided to the organization at the closing meeting; and shall be uploaded to the Assurance Platform as a separate document for each audit.
k) A Head Office report shall contain as a minimum a summary of the functions performed, objective evidence of documents reviewed, interviews conducted, and the NCs found at the Head Office. This report shall be uploaded to each site on the Assurance Platform that this Head Office is linked to. At each site audit the implementation of the corrective actions shall be verified and reported.
l) The full FSSC 22000 audit report shall be sent to the (certified) organization within 2 weeks of the certification decision for all audits conducted.
m) It is the Foundation's requirement that audit reports are written in English. Where an organization requests the report to be written in the language the audit was conducted in (if other than English), this is allowed based on mutual agreement between the CB and the organization. However, the mandatory fields for upload in the Assurance Platform shall always be completed in English. In all instances where CBs are translating audit reports, the CB shall have verification procedures in place to ensure the translations are accurate.

6.2 NONCONFORMITIES

In accordance with the definitions in the Scheme and as defined below, the CB is required to apply these criteria as a reference against which to determine the level of nonconformities for findings. There are three nonconformity grading levels:

a) Minor nonconformity;
b) Major nonconformity;
c) Critical nonconformity.

Nonconformities shall always be written to the most relevant Scheme requirement linked to the specific audit criteria in ISO 22000:2018; the specified PRP standard or the FSSC 22000 Additional Requirement.

Nonconformities raised at a Head Office audit are assumed to have an impact on the equivalent procedures applicable to all sites. Corrective actions shall therefore address issues of communication across the certified sites and appropriate actions for impacted sites. Such nonconformities and corrective actions shall be clearly identified in the relevant section of the site audit report and shall be cleared in accordance with the CB procedures before issuing the site certificate or completing the certification decision.

The Scheme does not allow "Opportunities for Improvement".

6.2.1 MINOR NONCONFORMITY

A minor nonconformity shall be issued when the finding does not affect the capability of the management system to achieve the intended results:

1) The organization shall provide the CB with objective evidence of the correction, evidence of an investigation into causative factors, exposed risks, and the proposed corrective action plan (CAP);
2) The CB shall review the corrective action plan and the evidence of correction and approve it when acceptable. The CB approval shall be completed within 28 calendar days after the last day of the audit. Exceeding this timeframe shall result in a suspension of the certificate, or in the case of an initial audit, the Stage 2 audit shall be repeated within maximum 6 months of the last day of the previous Stage 2 audit;
3) Corrective action(s) (CA) shall be implemented by the organization within the timeframe agreed with the CB;
4) The effectiveness of implementation of the corrective action plan shall be reviewed, at the latest, at the next scheduled audit. Failure to address a minor nonconformity from the previous audit could lead to a major nonconformity being raised at the next scheduled audit.

6.2.2 MAJOR NONCONFORMITY

A major nonconformity shall be issued when the finding affects the capability of the management system to achieve the intended results, or a legislative noncompliance linked to quality:

1) The organization shall provide the CB with objective evidence of an investigation into causative factors, exposed risks, and evidence of effective implementation;
2) The CB shall review the corrective action plan and conduct an on-site follow-up audit to verify the implementation of the CA to close the major nonconformity. In cases where documentary evidence is sufficient to close out the major nonconformity, the CB may

decide to perform a desk review. This follow-up shall be done within 28 calendar days from the last day of the audit;
3) The major nonconformity shall be closed by the CB within 28 calendar days from the last day of the audit. When the major cannot be closed in this timeframe, the certificate shall be suspended;
4) Where completion of corrective actions might take more time in specific instances, the CAP shall include any temporary measures or controls necessary to mitigate the risk until the permanent corrective action is implemented. Supporting evidence of the temporary measures or controls shall be submitted to the CB for review and acceptance within 28 calendar days from the last day of the audit.
5) If a major non-conformity is raised at the Stage 2 audit, the nonconformity shall be closed by the CB within 28 calendar days from the last day of the audit. Where completion of corrective actions might take more time, the Corrective Action Plan (CAP) shall include the temporary measures or controls necessary to mitigate the risk until the permanent corrective action is implemented. Evidence of these temporary measures shall be submitted and accepted by the CB within 28 calendar days from the last day of the audit. Based on this information, a certification decision shall be taken. In addition, where temporary measures are accepted, the CB shall agree a suitable timeframe with the organization, to verify the effective implementation of the permanent corrective action, but not later than 6 months after the last day of the audit. In any event, where the 28 calendar days after the last day of the audit is exceeded e.g., not closing the major nonconformity or non-acceptance of the evidence of the temporary measures, the full Stage 2 audit shall be repeated.

6.2.3 CRITICAL NONCONFORMITY

A critical nonconformity is issued when there is a significant failure in the management system, a situation with direct adverse food safety impact and no appropriate action is being observed or when food safety legality and/or certification integrity is at stake:

1) When a critical nonconformity is raised at a certified organization the certificate shall be suspended within 3 working days of being issued, for a maximum period of six (6) months;
2) When a critical nonconformity is issued during an audit, the organization shall provide the CB with objective evidence of an investigation into causative factors, exposed risks, and the proposed CAP. This shall be provided to the CB within 14 calendar days after the audit;
3) A separate audit shall be conducted by the CB between six (6) weeks to six (6) months after the regular audit to verify the effective implementation of the corrective actions. This audit shall be a full on-site audit (with a minimum on-site duration of one day). After a successful follow-up audit, the certificate and the current audit cycle will be restored, and the next audit shall take place as originally planned (the follow-up audit is additional and does not replace an annual audit). This follow-up audit shall be documented, and the report uploaded as part of the audit documentation linked to the audit where the critical NC was raised;
4) The certificate shall be withdrawn when the critical nonconformity is not effectively resolved within the six (6) month timeframe;
5) When a critical NC is raised at an initial certification audit, the audit is failed, and the full certification audit shall be repeated.

6.3 ADDITIONAL AUDIT DOCUMENTATION

In addition to the written audit report and the regular audit documentation, the following mandatory documentation is required:

1) An attendance register (or similar document) that confirms the actual presence of the auditor(s) and organization representatives during the audit. This document shall:

   - Be signed by a representative of the organization being audited and the lead auditor;
   - Indicate the start time, lunch break duration and end time of each day and
   - Be uploaded as part of the mandatory audit documentation in the FSSC Assurance Platform for each audit.

2) A signed integrity declaration by the senior representative of the organization and the auditor(s) confirming that all of the below has been met:

   a. No actual or perceived conflict of interest exists, to ensure the impartiality of the audit;
   b. The integrity of the audit or the audit process has not been compromised in any way and
   c. The audit was conducted in an ethical manner.

7 CERTIFICATION DECISION PROCESS

7.1 GENERAL

1) CBs shall conduct a technical review for all audits in line with the requirements of ISO/IEC 17021:2015 and to:

   a. Confirm the audit team held the relevant competency;
   b. Verify the correct audit duration was delivered;
   c. Agree with the audit report content and outcome, including meeting the minimum level of documented evidence as required by Annex 2; and
   d. Agree with the NC's (objective evidence and grading) and effectiveness of corrections and corrective actions and/or plans.

2) Any actions required as a result of the technical review shall be addressed, followed by the CB making a decision on the certification status of the organization (e.g., grant certification, maintain certification, suspend, or withdraw).
3) The CB shall keep documented information of technical reviews, any review queries and resulting certification decisions relating to the audit. The names of those conducting the review and certification decision and corresponding dates of review/decisions made, shall be recorded.
   Note: not all decisions may lead to issuing a new certificate.
4) The maximum certificate validity period is 3 years from the date of initial certification decision, with subsequent 3-year cycles.
5) The certificate in the FSSC Assurance Platform shall be an accurate reflection of the current certification status and scope of the organization.

7.2 CERTIFICATE DESIGN AND CONTENT

1) The CB shall issue FSSC 22000 certificates in accordance with the requirements of ISO/IEC 17021-1, ISO 22003-1:2022, the scope of certification and certificate templates set out by the Foundation (see Annex 1 and Annex 3).

2) The certificate shall be in English and match with the certificate in the Assurance Platform and the details on the public register. It is possible to include a translation of the scope statement following the English statement on the certificate. Refer to the requirements set out in Annex 3 where copies of certificates are being issued in other languages.
3) The FSSC 22000 logo shall be used by the CB on its certificates.
4) Head Office details shall be included, where applicable.
5) Where applicable Off site and Multi-site locations shall be listed, (including name, address, and activities); details may be provided in an Annex to the certificate.
6) The Certified Organizations Identification Code (COID) and the QR code supplied through the FSSC Assurance Platform shall be included.
7) Dates on the certificates shall be as follows:
    a. Certificate decision date: date at which a new decision is made after a certification or recertification audit (excluding regular surveillance audits).
    New certificate decision dates are also required in situations such as version changes of the Scheme and/or scope extensions/reductions. In these cases, the valid until date remains unchanged;
    b. Initial certification date (i.e., the certification decision date linked to the initial audit). This is a fixed date that is maintained as long as the organization is linked to the CB and holds a valid FSSC 22000 certificate. In the case of a transfer (see Part 3, §5.3), the initial certification date is the certification decision date of the transfer linked to the new CB. In addition, the accepting CB may quote the organization's initial certification date on the certification documents with the indication that the organization was certified by a different certification body before a certain date.
    c. Issue date: date certificate is issued to the client; or re-issue date when a new certificate is issued (e.g., because of version change, scope extension etc.);
    d. Valid until date: certificate expiry date (e.g., original certification decision date plus 3 years minus 1 day for the initial cycle).

7.3 CERTIFICATE SUSPENSION OR WITHDRAWAL OR SCOPE REDUCTION

1) *Suspension*: the CB shall suspend certification when a critical nonconformity is issued and/or there is evidence that the certified organization is either unable or unwilling to establish and maintain conformity with Scheme requirements.
2) *Withdrawal*: the CB shall withdraw a certificate when:
    a. The status of suspension cannot be lifted within six (6) months;
    b. The organization ceases its FSSC 22000 certification activities;
    c. Any other situation where the integrity of the certificate or audit process is severely compromised.
3) *Scope reduction*: When the CB has evidence that the certified organization holds a certificate where the scope is not an accurate reflection of the management system for example due to changes at locations or the control of the organization, the CB shall reduce the certification scope accordingly. The CB 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.
4) Certificates may be suspended or withdrawn by The Foundation or by the CB upon instruction by the Foundation, as a result of CB noncompliance to Scheme requirements or termination of a CB license with the Foundation.

7.3.1 ACTION UPON SUSPENSION OR WITHDRAWAL AND SCOPE REDUCTION

1) In case of suspension or withdrawal, the organizations' management system certification is invalid. The CB shall complete the following actions within 3 working days after the certification decision for suspension or withdrawal has been made:
    a. Change the status of the certified organization in the Assurance Platform and its own system and shall take any other measures it deems appropriate;
    b. Inform the organization in writing of the suspension or withdrawal decision, including the reason for the suspension or withdrawal and resulting actions required from the organization;
    c. Instruct the organization to take appropriate steps in order to inform its interested parties.
2) In case of scope reduction, the organizations' management system certification is invalid beyond the revised certification scope statement. The CB shall complete the following actions within 3 working days after the certification decision has been made:
    a. Change the scope of the certified organization in the FSSC 22000 database and its own system and shall take any other measures it deems appropriate;
    b. Inform the organization in writing of the scope change;
    c. Instruct the organization to take appropriate steps in order to inform its interested parties.

8 ASSURANCE PLATFORM DATA AND DOCUMENTATION

8.1 DATA OWNERSHIP

a) A (certified) organization is the owner of an audit report, whilst the CB is responsible for the report content and related data.
b) A (certified) organization is the certificate holder, not the owner. The CB is the owner of the certificate and responsible for the certificate content and related data.

8.2 DATA UPLOAD REQUIREMENTS

For all audit types, the required data and documentation shall be entered in the Assurance Platform at the latest 28 calendar days after the certification decision with a maximum of 2 months after the last day of the audit. The mandatory data in the Assurance Platform shall be entered in English.

8.3 DATA QUALITY CONTROL

The CB shall have a data quality control process in place that provides assurance for CB Assurance Platform Data Quality. The quality parameters include the following as a minimum:

a) Completeness: All the mandatory data has been registered in the Assurance Platform;
b) Timeliness: All the data has been registered in the Assurance Platform within the required timelines;
c) Validity: The registered data values meet the Scheme requirements;
d) Accuracy: The data is a true representation of the actual facts relating to the complete audit and the certification process;

e) Consistency: The registered data in the Assurance Platform is a true representation of the data stored in the CBs internal system(s).

8.4 ASSURANCE PLATFORM

a) Each (certified) organization is allocated a unique code in the Assurance Platform that is linked to the organization, namely the Certified Organization Identification Code (COID). The COID stays with the organization to ensure traceability, also in the event of a transfer. The CB shall communicate the COID to the organization once generated in the Assurance Platform, and to the accepting CB when requested in the case of a transfer.
b) When requested by the certified organization, CBs shall provide the Certified Organization access to the associated Organization Profile, Audit and Certification data registered in the FSSC Assurance Platform in a timely manner, using the available functionality.
c) CBs shall ensure that Certified Organization access is only granted to authorized individual(s).

PART 4 REQUIREMENTS FOR CERTIFICATION BODIES

CONTENTS PART 4 REQUIREMENTS FOR CERTIFICATION BODIES

1 PURPOSE

This Part contains the requirements for certification bodies (CBs) who wish to provide Scheme certification services to organizations.

Where the term "Scheme Requirements" is used, this refers to the FSSC 22000 Scheme requirements, ISO/IEC 17021-1, ISO 22003-1:2022, and Board of Stakeholders (BoS) decision list.

2 RELATION WITH THE FOUNDATION

2.1 LICENSING

1) As a prerequisite for the license application, the CB shall hold a valid ISO/IEC 17021-1:2015 and ISO 22003-1:2022 accreditation for ISO 22000.
2) For the Scheme Requirements, the FSSC 22000 accreditation shall cover the applicable food chain categories and sub-categories in which it supplies its FSSC 22000 certification services.
3) The CB shall provide the Foundation with information and documentation related to its accreditation to the Scheme when requested.
4) The Foundation is entitled to request information from the Accreditation Body related to the CB accreditation.
5) The CB may hold more than one accreditation for FSSC 22000 for the main location which shall be covered by a single FSSC license.
6) In case the CB has multiple locations holding their own FSSC 22000 accreditation, the Foundation shall be informed about the additional accreditations as part of the initial application and subsequently when changes occur. These locations with their own accreditations will form part of the main license and will be included in the IP Assessment Program of the licensed CB. Any costs associated with related additional IP activities will be for the CBs account.
7) Alternatively, the CB may opt to have a separate FSSC license with the Foundation for each accredited location, which will be subject to its own IP activities and costs.

2.1.1 LICENSE APPLICATION PROCESS

1) CBs shall apply to obtain a license with the Foundation to be eligible to perform valid and recognized FSSC 22000 Scheme certification activities. Licenses are issued to specified CB office location(s) as requested in the license application form. In the case of outsourcing of any certification related activities this shall also be described in the application.
2) A license may cover multiple Food Chain Categories for FSSC 22000, and related Addendums where applicable.
3) By signing the License Agreement, the CB commits to the implementation of all Scheme requirements and any other obligations outlined in the license agreement.

2.1.2 LICENSES

2.1.2.1 LICENSE AGREEMENT (PROVISIONAL STATUS)

1) The CB shall submit an application to the Foundation specifying the food chain categories and sub-categories, as per Part 1, Table 1 of the Scheme, which they wish to provide

certification services in. As part of the application, the CB shall submit the relevant documentation required by the Integrity Program as part of the on-boarding process.

2) Upon review of the information and successful completion of the applicable stages of the Foundation's Integrity Program, the CB shall be granted a license with provisional status and be listed as provisionally approved in the FSSC 22000 CB list on the FSSC website.
3) The CB shall then proceed with the extension of their ISO/IEC 17021-1 accreditation to include FSSC 22000 with an AB accepted by the Foundation, and submit the written confirmation of acceptance of the application to the Foundation in a timely manner.
4) The provisional status allows a CB to use the Scheme for unaccredited certification once authorization has been received from the Foundation as per the Integrity Program on-boarding process requirements. Unaccredited certificates shall be registered on the Assurance Platform. After accreditation has been obtained, these unaccredited certificates may be replaced with an accredited certificate either immediately or following the next certification audit and in accordance with the specific AB requirements.
5) The provisional status of the license is valid for twelve (12) months from the date of signature by the Foundation and within this period of time the CB shall:
    a. Achieve accreditation from an AB accepted by the Foundation for FSSC 22000 for the categories and sub-categories covered in the license agreement. If accreditation is not achieved within the required timeline, the provisional license will be terminated and already issued certificates shall be withdrawn. Refer to Part 5 of the Scheme for more detail on the FSSC 22000 requirements relating to the accreditation process;
    b. Have at least five (5) certified or audited organizations registered on the Assurance Platform.
    c. Successfully complete the applicable stages of the Integrity Program on-boarding process.

2.1.2.2 LICENSE AGREEMENT (FULL STATUS)

After the criteria under 2.1.2.1 have been met, the CB shall submit to the Foundation:

a) A copy of its accreditation certificate to ISO/IEC 17021-1 and ISO 22003-1 for FSSC 22000, covering the categories and sub-categories in the license agreement;
b) A copy of its AB assessment reports (office and witness assessments).

Upon successful completion of the applicable Integrity Program stages, the Foundation shall issue a new license agreement and/or update the status of the license agreement of the CB listed on the FSSC website and in the Assurance Platform.

2.1.3 LICENSE MAINTENANCE

In order to maintain its license, the CB shall:

a) Have at least fifty (50) certificates registered in the Assurance Platform with a minimum of one for each licensed food chain category. For new CBs, this shall be achieved within 36 months of receiving the full license.
b) Comply with all the requirements of the FSSC 22000 certification Scheme for CBs;
c) Meet the financial obligations to the Foundation.

2.1.4 LICENSE EXTENSION

1) The CB shall submit an application to the Foundation specifying the food chain sub-categories (or category if no subcategory) for which it requests an extension of the existing license.

2) The CB shall be granted a provisional status for the new sub-category (or category if no subcategory) following a successful review, registered in the Assurance Platform and displayed in the approved FSSC 22000 CB list on the FSSC website.
3) The CB may only apply to the AB for accreditation after the provisional license has been granted by the Foundation for the extension to scope. The CB shall share with the Foundation the written AB confirmation of acceptance to start the accreditation process.
4) The provisional status allows a CB to issue unaccredited certification for the new sub-category (or category if no subcategory). Unaccredited certificates shall be registered on the Assurance Platform. After accreditation, these certificates may be replaced with an accredited certificate if in compliance with the specific AB requirements.
5) The provisional status of the license is valid for 12 months from the date of signature by the Foundation and within this period of time the CB must achieve accreditation from an AB accepted by the Foundation for the (sub)-categories linked to the scope extension.
6) At least one certificate shall be listed in the Assurance Platform for the new category within the timelines defined.

2.1.5 SUSPENSION, TERMINATION AND REDUCTION

The Foundation has the right to suspend, terminate or limit the scope of a CB's license agreement. Reasons include, but are not limited to:

1) Accreditation not achieved within 12 months from the date of the provisional license being granted;
2) Termination of the accreditation;
3) Not meeting the minimum number of certificates specified by the Foundation;
4) Sanction committee decision;
5) Non-payment of the fee to the Foundation;
6) Repetitive noncompliance with the Scheme requirements;
7) Noncompliance with the Integrity Program or components there-of;
8) Situations where the Foundation might be brought into disrepute and/or the integrity of the certification might be at risk;
9) Contractual breaches.

2.1.5.1 SUSPENSION

1) The conditions applicable to suspensions are defined in the Foundation's Integrity Program Sanction Policy.
2) When a CB's license is suspended by the Foundation, the Foundation will determine the extent to which the CB will be allowed to maintain its auditing and certification activities for a defined period of time. The Foundation will publish suspensions on the FSSC website, and the Accreditation Body will be notified.
3) The Foundation will restore the suspended license when the CB has demonstrated that the issue which resulted in the suspension has been resolved and the conditions for lifting the suspension have been met.
4) Failure to resolve the issues that resulted in the suspension in a time established by the Foundation shall result in termination or reduction of the scope of the license as per the Integrity Program Sanction Policy.

2.1.5.2 TERMINATION

1) When a CB's license is terminated by the Foundation, the CB cannot apply for a new license within the time frame as defined by the Foundation in the termination documentation.

2) The CB shall agree with the Foundation the transfer of its certified organizations following the requirements outlined in the license agreement.

2.2 ENGAGEMENT

2.2.1 COMMUNICATION

1) The CB shall appoint a FSSC 22000 contact person who is competent in the Scheme requirements and maintains contact with the Foundation. The official language for contact with the Foundation is English, therefore, the CB shall appoint the necessary resources (e.g., translator or interpreter), as needed.
2) This person shall be accountable for all aspects of the FSSC 22000 Scheme implementation and ensure that the following responsibilities are defined and implemented within the CB:
    a. Appoint a contact person for the FSSC 22000 IT systems;
    b. Appoint a responsible person for managing the Integrity Program;
    c. Appoint a representative to attend mandatory FSSC related event/s;
    d. Keep up to date with the Scheme developments including IT developments;
    e. Managing of other additional information required by the Foundation;
    f. Communicate new information, requirements, interpretations, or changes to the Scheme to the relevant parties involved within one month, unless specified otherwise by the Foundation.
3) The CB shall assign responsibility for the development, implementation and maintenance of the CBs quality system relating to the FSSC 22000 Scheme. This designated employee shall also have the responsibility for reporting on the performance of the quality system for the purposes of management review and continuous improvement.

The CB shall communicate the following to the Foundation within 3 working days:

1) Changes on the FSSC 22000 accreditation status: e.g., scope extension or scope reduction, suspension, or withdrawal, and extension of validity of accreditation certificate, together with a written communication to the Foundation about the circumstances leading to this, and any delays in obtaining accreditation that could impact the license;
2) Any significant changes in its ownership, legal status, management personnel, structure, or constitution that (potentially) impact the CB management of the Scheme in a timely manner;
3) Any situation, possible conflict or problem that could result in bringing the Foundation or GFSI into disrepute;
4) After notification by a certified organization of any public recall resulting in death and/or hospitalization or generating significant media coverage;
5) After notification by the certified organization of serious situations and/or serious events where the integrity of the FSSC 22000 certification is compromised as described in Part 3. Note: whilst all serious events need to be reported to the CB by the certified organization, only those serious events where certification integrity is compromised shall be reported to the Foundation. The CB shall manage all serious events in accordance with Part 3, Section 5.10.

2.2.2 RESPONSIBILITIES

1) The CB shall cooperate with all requests from the Foundation to report information regarding all aspects of the performance and integrity of the Scheme.

2) In case the range of CB certification services offered is wider than those accredited, the CB shall ensure that the limits and scope of the accreditation shall be made clear and publicly available. Any ambiguity in relation to the scope of services offered by the CB for the Scheme shall be resolved with the Foundation, and certification services that are outside the scope of the accreditation, shall be distinguished from those that are accredited.
3) The CB is responsible for the full application of these Scheme requirements and shall be prepared to demonstrate compliance at any time with all these requirements.
4) The CB shall adhere to the requirements for the use of the FSSC 22000 logo, as detailed under Part 2, Section 2.5.5 of the Scheme. The FSSC 22000 logo may only be used by FSSC 22000 licensed CBs.
5) The CB commits to operating in accordance with the FSSC Code of Ethics, which is publicly available on the FSSC website.
6) The CB shall participate in mandatory FSSC, harmonization and calibration events as defined by The Foundation, and shall share the applicable information to all relevant staff.
7) The CB shall participate in the Integrity Program.
8) The CB shall inform its AB(s) on any changes in the license status (e.g., reduced, extended, suspended, etc.) made by the Foundation.
9) The CB shall share information concerning the certified organization with the Foundation, GFSI and governmental authorities when required by law.
10) The CB shall take appropriate steps to assess the situation and have procedures in place to ensure the integrity of certification is maintained after a serious event, serious situation, and/or food safety incident notification and maintain records to support the decision made.
11) The CB shall ensure that all Scheme-related data in the Assurance Platform is complete, up to date, accurate and meets the Scheme requirements.
12) An annual performance report shall be submitted by the CB to the Foundation with the minimum content as specified and communicated by the Foundation.

2.3 INTEGRITY PROGRAM

1) The CB shall participate in the Integrity Program which is the Foundation's system of ongoing monitoring. This program covers all activities of its licensed CBs to ensure compliance with all Scheme requirements. The CB shall provide any documentation requested by the Foundation for the Integrity Program within the required timelines.
2) The monitoring activities include but are not limited to:
    a. Desk reviews of audit documentation, certificates, auditor competence and Assurance Platform data quality and registration;
    b. Auditor assessment and registration in the Assurance Platform;
    c. Office assessments on the CBs management system, their operations and documentation to demonstrate compliance to the Scheme requirements;
    d. Witnessed audits;
    e. Performance measured through agreed key performance indicators and components of the Integrity program;
    f. Compliance breaches and their effective resolution;
    g. Complaints and serious events.
3) The frequency, duration and scope of the Integrity Program monitoring activities can be increased based on risk and performance trends.

Further information on sanctions, the escalation protocol, as well as conditions for suspensions and terminations can be found in the Integrity Program Sanction Policy.

2.3.1 NONCONFORMITY

1) The Foundation's Integrity Program defines a "nonconformity" as any breach of Scheme, Integrity Program and/or The Foundation's requirements.
2) Nonconformities ("NCs") requiring a response from the CB shall be raised by the Foundation in response to:
    a. Any discrepancy raised by the Integrity Program;
    b. Feedback from users of the Scheme;
    c. Feedback from Certified organizations;
    d. Feedback from Accreditation Bodies;
    e. Feedback from Governmental authorities;
    f. Feedback from the media; and
    g. Any other feedback deemed credible.

2.3.2 FOLLOW-UP

1) When a nonconformity is received, the CB shall:
    a. Record and manage the nonconformity in its internal system,
    b. Respond in the set timeframe and act to:
        i. Restore conformity (i.e., implement corrections and provide evidence of implementation);
        ii. Investigate to identify the causal factors (root cause);
        iii. Perform an impact analysis;
        iv. Provide a documented Corrective Action Plan (CAP) detailing the nonconformity, grading, root cause analysis, correction, results of the impact analysis, planned corrective action, responsible person(s), due dates, measures of effectiveness and date closed.
2) Then:
    a. Take corrective actions to manage the identified causal factors so that the risks exposed by recurrence are reduced to an acceptable level, provide objective evidence of implementation;
    b. Use the opportunity to investigate how else and where else a similar nonconformity could occur;
    c. Take preventive action to manage these causal factors so that the risks exposed by occurrence are similarly reduced to an acceptable level.

3) Failure to meet the deadlines for nonconformities will result in the Integrity Program Sanction Policy being initiated.

2.3.3 SANCTIONS

1) CBs that persistently fail to conform to the requirements of the Scheme, put the integrity of the Scheme at risk, or bring the Foundation into disrepute, shall be investigated by the Foundation as per the Integrity Program Sanction Policy.
2) Sanctions against non-compliant CBs could include, but are not limited to:
    a. Suspension of the license to issue certifications under the Scheme until discrepancies have been satisfactorily corrected;
    b. Termination of the license to issue certifications under the Scheme.

The CB shall respond to the sanctions as indicated in the sanction notification. Details are provided in the Integrity Program Sanction Policy.

3 COMPETENCE

3.1 GENERAL

1) The CB shall follow the requirements described in Annex C of ISO 22003-1:2022 for defining the competences required to conduct the activities of application review and audit duration calculation, audit team selection, audit planning activities, technical review, and certification decision.
2) There shall be a documented process for initial and ongoing competency review of all these functions. Records of training and competency reviews shall be maintained.

3.2 TECHNICAL REVIEWER AND CERTIFICATION DECISION MAKER

3.2.1 TECHNICAL REVIEWER

The technical reviewer shall meet the same requirements as set out below for the certification decision maker but is not required to have food safety management system auditing experience. The technical review and certification decision functions may be separate, or the technical review and certification decision may be made by the same individual where the competency requirements are being met.

3.2.2 CERTIFICATION DECISION MAKER

1) Those making the decision to issue, maintain, extend, or reduce scope, suspend, or withdraw a certificate for registration in the FSSC 22000 Register of certified organizations shall have the following demonstrable competencies;
    a. Meet the requirements of Annex C of ISO 22003-1:2022;
    b. Knowledge of the FSSC 22000 Scheme requirements;
    c. Knowledge of food safety management systems and the ability to assess them.

3.3 TECHNICAL EXPERT

1) When deemed necessary a technical expert can be assigned to the audit team to cover competency at (sub)category level.
2) The CB shall have in place a procedure for approval of technical experts who shall have demonstrable experience in the (sub)category supporting the scope of the audit. The technical expert shall always operate under the direction of a qualified FSSC 22000 auditor and their time does not count towards audit duration.
3) Where a technical expert is used, the CB shall ensure that the technical expert is registered on the Assurance Platform as part of the audit team, with the role of technical expert. The technical expert shall meet the requirements for subcategory approval, as defined under section 3.5.3 below as a minimum.
4) Where a technical expert is used, the CB shall ensure that at least one auditor in the team has a qualification in the category.
5) For the (sub)categories BIII, D, E, F, G and K, where the requirements of 3.3 (4) above cannot be met, at least one auditor in the audit team shall have a qualification in category C.
6) In all instances, the CB shall ensure that the audit team meets the qualification requirements linked to the scope of the (certified) organization.

3.4 WITNESSOR

1) The witnessed audit shall be conducted by an FSSC 22000 qualified auditor, an auditor qualified for a GFSI recognized certification program that can demonstrate competence in the FSSC 22000 Scheme requirements, or by a CB FSSC 22000 technical certification person of equivalent competence and experience (e.g., FSSC 22000 Technical reviewer, FSSC 22000 Scheme Manager, etc.).
2) Witnessors shall be assessed and qualified by the CB as suitable to undertake witness audits.
3) The witnessor shall have received training in witness audit techniques.
4) The witnessor shall play no active part in the audit.
5) Witnessors shall have, as a minimum, the equivalent competency of the function being evaluated (see ISO 22003-1:2022 Annex C). A witnessor may be supported by a technical expert where needed, in which case the technical expert may not participate in the audit.
6) A witness audit performed by the CB can only be substituted by an Accreditation Body (AB) witnessed audit if it is the first witness audit under a provisional license. This includes provisional licenses where the CB applies for an extension to scope for FSSC 22000.

3.5 AUDITOR QUALIFICATION PROCESS

The CB shall have a system and documented procedures for selecting, training, evaluating, (re) qualification and maintenance of qualification of the auditor, taking into account the requirements of ISO/IEC 17021-1:2015, ISO 22003-1:2022 Annex C, and the additional FSSC 22000 requirements as detailed below.

3.5.1 INITIAL TRAINING AND EXPERIENCE

The CB shall ensure that auditors, including auditors transferring from other CBs, meet the following initial training and experience requirements:

1) Work Experience

    a. Experience in the food or associated industry including at least 2 years' full-time work, taking an active role in quality assurance or food safety functions in production or manufacturing and retailing, food safety auditing and/or food safety inspection or enforcement that is covered within the scope of the Scheme. Food safety or quality consultancy experience in a food or associated industry can be used to meet a maximum of six (6) months of the work experience requirement. The number of man-days of consultancy provided shall be equivalent to the duration allocated towards work experience.

2) Education

    a. Education: A degree in a food related or bioscience discipline or has successfully completed a food related or bioscience higher education course.

3) Training

    Successful completion of each of the following courses, including an exam:

    a. Lead Auditor Course for FSMS or QMS – minimum 40 hours;
    b. HACCP training – minimum 16 hours;

c. ISO 22000 Standard (current version) – minimum 8 hours (if not included as part of Lead Auditor Training Course);
d. Food defense training – minimum 2 hours, covering food defense threat assessment methodology and possible mitigation measures;
e. Food fraud training – minimum 2 hours, covering food fraud vulnerability assessment methodology and possible mitigation measures;
f. FSSC 22000 Scheme requirements (including Parts 1 - 4 and Annexes 1, 2 and 5);
g. Training in accreditation requirements (ISO 22003-1:2022 and ISO/IEC 17021-1) as applicable to the auditing processes of the CB. If included as part of the Lead Auditor Training Course, this shall be clearly specified in the course curriculum or syllabus;
h. Training in the relevant PRP standard/s – minimum 3 hours per PRP standard.

4) Other

a. Audits: a minimum of ten (10) audit days consisting of at least five (5) third-party food safety certification audits that cover elements of FSMS, HACCP and PRP requirements in the relevant industry sector. The five (5) audits shall include at least two (2) FSSC 22000 audits under supervision of a FSSC 22000 qualified auditor and one (1) FSSC 22000 witness audit. Where an already qualified FSSC 22000 auditor moves from another CB, the two (2) audits under supervision are not required, only the FSSC 22000 witness audit.
b. For Category I: a primary qualification, a degree or higher certificate in packaging technology and a relevant certificate in food technology, food hygiene or related science subject OR a primary qualification in food technology, food safety/ hygiene or related science subject and successful completion of a training course (minimum 30 hours plus certificate) in packaging technology that meets the requirements defined by WPO Packaging. This training shall include the following topics as a minimum and documented evidence thereof shall be available:
    i. Basics of packaging principles and concepts;
    ii. Packaging legislation, standards, and regulations;
    iii. Packaging materials manufacturing;
    iv. Specifics to packaging of food/feed products;
    v. Quality/food safety control and testing;
    vi. Printing processes and printing inks;
    vii. Packaging recycling and
    viii. Design of packaging materials.

3.5.2 INITIAL ASSESSMENT AND APPROVAL

1) The CB shall complete the following prior to the initial qualification/approval of the auditor:
    a. provide supervised training in relevant food safety audits;
    b. conduct an FSSC 22000 witnessed audit of the auditor to confirm competence is attained; and
    c. document the sign-off of the satisfactory completion of the training program and witnessed audit.
2) Supervised training in food safety audits are audits whereby the trainee auditor conducts part or the entire audit under the supervision of an FSSC 22000 qualified auditor in the sub-category. The FSSC 22000 qualified auditor may not audit other sections whilst supervising the trainee auditor.

3) The witnessed audit shall be at FSSC 22000 Stage 2, surveillance, or recertification audit. Stand-alone Stage 1, Follow-Up and Special Audits cannot be used as witness audits.
4) The initial witness audit shall be a solo witness audit, where the auditor being witnessed conducts the full FSSC 22000 audit. Where a solo witness audit is not possible, an audit team audit may be utilized, if all of the following conditions are being met:
    a. The auditor being witnessed shall have the role of lead auditor;
    b. The auditor being witnessed shall hold at least one of the (sub)category code(s) for the audit and shall audit the relevant HACCP study, product specific aspects, as well as auditing the relevant production processes;
    c. A restriction is applied to the number of audit team members: the audit team shall only be made up of the auditor being witnessed and one (1) co-auditor.
5) A witness audit assessment report shall be completed by the witnessor to confirm performance, including but not limited to:
    a. The knowledge and skills as set out in Annex C of ISO 22003-1:2022 Table C.1, for auditing and leading the audit team;
    b. An assessment of knowledge of the application of the FSSC 22000 Scheme requirements; and
    c. An assessment of knowledge of the applicable laws and regulations.
6) Already qualified FSSC 22000 auditors moving from another CB shall always be subject to a witness audit by the new CB as part of the approval process. Where the new CB deems remote witnessing to be sufficiently robust, the new CB may use ICT to conduct the witness audit remotely to approve the FSSC 22000 auditor, subject to a feasibility assessment and only if the objectives of the witness audit can be met. Refer to Annex 5 for more information.
7) All FSSC 22000 auditors (including auditors in training) shall be registered in the FSSC Assurance Platform in accordance with the instructions of the Foundation.

3.5.3 ASSIGNMENT OF SUBCATEGORIES (INITIAL AND EXTENSION)

1) Auditors shall be approved/qualified for at least one (sub)category (see Part 1 table 1) prior to, or at the same time the initial auditor approval is granted.
2) Auditors shall be approved/qualified per subcategory or category where no subcategory exists (see Part 1 table 1), where the CB shall demonstrate that the auditor complies with the following requirements:
    a. Experience:
        i. Six (6) months' work experience in the subcategory. Where food safety or quality consultancy work is used to demonstrate work experience, the number of man-days shall add up to six months, OR
        ii. Five (5) audits against a GFSI approved or recognized standard, Dutch HACCP or ISO 22000 in the subcategory as a qualified auditor OR
        iii. Five (5) audits against a GFSI approved or recognized standard, Dutch HACCP or ISO 22000 in the subcategory as a trainee under the supervision of a qualified auditor for the subcategory, OR
        iv. A combination of the above.
    b. demonstrated specific competence in the subcategory.
    c. meeting the CB's own competency criteria for the subcategory.
3) The CB shall have defined competency criteria for each subcategory to ensure knowledge of products, processes, practices and applicable laws and regulations of the relevant

subcategory. Competence across the whole subcategory, or category where no subcategory exists, shall be demonstrated. Where (sub)categories have a broad range of products with different technologies, e.g., CIV or I, the CB shall further split these up in their system based on defined criteria. It shall be clear for which parts of the (sub)category the auditor is qualified for, and this evidence shall be uploaded to the auditor register on the Assurance Platform.

4) For already approved FSSC 22000 auditors, the following may be used to extend an auditor's (sub)categories, as an alternative to 3.5.3 (2) above:

    a. Auditors qualified for category C may be approved for Category G; and auditors qualified for sub-category CIII may be approved for Category E. This is subject to the following:
        i. Successful completion of the related PRP training (refer Part 3, Section 3.5.1(3)(g)), and
        ii. The CB undertaking an evaluation of the auditor's competency for the (sub)category in line with the competency requirements detailed within Table C.1 of ISO 22003-1:2022 and using an evaluation method or combination of evaluation methods as detailed under Annex B of ISO/IEC 17021-1:2015.
    b. Existing FSSC 22000 Auditors qualified for at least one (sub)-category, may extend their approval to Category FII, following the CB's evaluation of the auditor's competency for the sub-category in line with the competency requirements detailed within Table C.1 of ISO 22003-1:2022, and using an evaluation method or combination of evaluation methods as detailed under Annex B of ISO/IEC 17021-1:2015.

5) It remains the responsibility of the CB to demonstrate competence in a subcategory, or category where no subcategories exist.

3.5.4 MAINTENANCE OF AUDITOR QUALIFICATION

3.5.4.1 AUDITS

1) Each auditor shall perform at least five (5) FSSC 22000 audits at different organizations each calendar year, either as a lead or co-auditor. In this context, stand-alone stage 1 audits and special audits do not count. In the first year of approval, the minimum number of FSSC 22000 audits required shall be determined on a pro-rata basis, and the number shall always be rounded upwards to the next whole number.
2) In the event when the requirement in (1) cannot be met, the CB shall ensure that the auditor has performed at least five (5) audits against an approved GFSI scheme (post-farm gate only) of which at least one (1) FSSC 22000 audit either as a lead or co-auditor. The CB shall mark this auditor in the Assurance Platform as working under a temporary exemption arrangement with an appropriate justification. The exemption shall be allowed for a maximum of 12 months. An exemption can be applied in the following cases:

    a. long term sickness of the auditor
    b. extended leave (e.g., maternity, paternity, sabbatical)
    c. lack of clients in the region/country*
    d. due to a serious event

    * For lack of clients, the temporary exemption cannot be applied for more than one year for the same auditor.

3) In case an auditor has demonstrated he/she performed FSSC 22000 audits for another licensed CB, these are also allowed to be included. The CB shall register these audits onto the Assurance Platform.

3.5.4.2 ONGOING TRAINING

1) Auditors shall attend any relevant annual training, including those specified by the Foundation (e.g., harmonization or calibration events), conferences, seminars and/or network meetings in order to keep up to date with Scheme requirements, normative documents, industry sector best practices, food safety and technological developments.
2) Auditors shall have access to and be able to apply relevant laws and regulations. The CB shall maintain written records of all relevant training undertaken.

3.5.4.3 WITNESSED AUDIT

1) At least one (1) FSSC 22000 witnessed audit shall be conducted every three (3) years by the CB to confirm acceptable auditor performance prior to the requalification of the auditor. The witness audit shall be conducted at an FSSC 22000 audit (Stage 2, Surveillance or Recertification). Stand-alone Stage 1, Follow-Up and Special Audits cannot be used as witness audits.
2) The same requirements apply for the 3-yearly witness audit as set out in Part 4, Section 3.5.2.4 and 3.5.2.5 above.
3) The 3-yearly witness audit shall:
    a. Be conducted during the course of each 3-year requalification cycle and prior to the requalification anniversary date; and
    b. Never be more than 3 years from the last witness audit date.

3.5.4.4 AUDITOR REQUALIFICATION

1) The overall auditor's performance shall be evaluated every three (3) years in order to confirm the continued competence of the auditor. The following aspects shall be evaluated by the appointed supervisor of the CB as part of the requalification process:
    a. The auditor's audit log;
    b. The auditor's training log; and
    c. The result of the 3-yearly witness audit.
2) The first requalification is due 3 years (36 months) from the date of the initial auditor qualification. This date is referred to as the requalification anniversary date and is a fixed date that sets the cycle for all future requalification cycles. For subsequent requalification, the requalification anniversary date is based on the below:
    - Initial qualification date + 3 years + 3 years etc.
    - The actual requalification shall be conducted within a 3-month window before the 3-year anniversary date but does not change the subsequent requalification anniversary date.
3) The evaluation shall consider the auditor's overall performance, including complaints from clients or other external or internal parties.
4) Documented sign-off of the satisfactory completion of the entire requalification process shall be uploaded in the Assurance Platform.

Note: Only one witnessed audit is required, irrespective of the number of categories/ subcategories that the auditor is qualified in.

3.5.4.5 RE-QUALIFICATION OF DISQUALIFIED AUDITORS

1) If an auditor is disqualified due to not meeting Scheme requirements, the CB can re-qualify the auditor by:
    a. Providing additional training or calibration, as a minimum on the latest updates and changes in the FSSC 22000 Scheme;
    b. The auditor undertaking a successful witness audit; and
    c. Providing any additional training or calibration needed, based on the outcome of the witness audit.
2) Following a successful witness audit, the CB shall produce a new sign-off document. The CB is responsible for ensuring that the auditor meets the competency criteria in ISO 22003-1:2022 and the current version of the Scheme.
3) The Re-qualification approval document must be uploaded to the auditor register on the Assurance Platform, including a comment that it is to reinstate a previously disqualified auditor.

PART 5 REQUIREMENTS FOR ACCREDITATION BODIES

CONTENTS PART 5 REQUIREMENTS FOR ACCREDITATION BODIES

1 PURPOSE

This Part specifies the requirements against which the Foundation will accept Accreditation Bodies (ABs) that provide accreditation services to licensed Certification Bodies.

1.1 IAF MEMBERSHIP

1) ABs providing accreditation to CBs for FSSC 22000 certification shall be a current member of the International Accreditation Forum (IAF) and:

    a. Be a signatory to the IAF Multilateral Recognition Arrangement (MLA) for Food Safety Management Systems (FSMS) to cover FSSC 22000 accreditation services; and
    b. Be a signatory to the IAF MLA for FSSC 22000 to cover FSSC 22000 accreditation services.

1.2 COMMUNICATION AND RESPONSIBILITIES

1) The AB shall sign the cooperation agreement with the Foundation, committing to information sharing and adherence to the Scheme requirements.
2) The AB shall appoint a primary and secondary contact person for communication with the Foundation.
3) The AB shall notify the Foundation in a timely manner of any changes in contact persons, its ownership, legal status, or any other issues that are relevant for accreditation. Changes in the IAF MLA status of the AB shall be communicated to the Foundation within 3 working days.
4) The AB shall participate in harmonization and calibration events as defined by The Foundation, including the annual FSSC event.
5) Communication on changes to the Scheme requirements and other related information shared with the ABs by The Foundation, shall be shared by the AB with all its assessors for the Scheme and records of such training shall be retained.
6) The AB shall inform the Foundation without undue delay in case the accreditation status of the CB changes (e.g., granted, extension, reduction, re-instate, suspension or withdrawal).
7) Upon request, the AB shall cooperate with the Foundation in relation to investigations into the performance of its accredited CBs, including but not limited to complaints and integrity issues.
8) Upon request, the AB shall share with the Foundation information on the performance of their CBs.
9) The AB commits to operate in accordance with the FSSC Code of Ethics, which is publicly available on the FSSC website.

2 ACCREDITATION

2.1 LICENSE AGREEMENT

1) The AB shall verify that the CB has a (provisional) license agreement with the Foundation to provide certification to FSSC 22000, for a predefined ISO 22003-1:2022 food chain sub-category (or category if no subcategory) as set out in Annex 4.

2) The AB shall not issue an accreditation certificate for a category or sub-category where no (provisional) license with the Foundation has been granted, this includes scope extensions to new sub-categories (or category if no subcategory).

2.2 ACCREDITATION PROCESS

2.2.1 GENERAL

1) The AB shall issue a confirmation of application for accreditation to FSSC 22000 Scheme including the detailed scope to the applicant CB.
2) The AB shall issue a confirmation of declining an application for accreditation including the detailed scope to the applicant CB and reason for denying the application.
3) The accreditation process shall cover all Scheme requirements applicable to the scope of accreditation.
4) Only after approval from the Foundation, the CB is allowed to provide FSSC 22000 audits under its provisional license with a qualified FSSC 22000 auditor. At least one of these audits shall be witnessed by the AB and at least one complete FSSC 22000 certification file shall be reviewed over the course of the initial accreditation process.
5) Office assessment reports of the CB shall be shared with the Foundation within 2 months from the last day of the office assessment.
6) Interim changes to Scheme requirements are communicated to the AB via the FSSC 22000 BoS Decision list (published on the FSSC website).

2.2.2 SCOPE OF ACCREDITATION

1) The scope of accreditation shall be clearly defined and be part of the accreditation certificate issued by the AB as defined below and summarized in Annex 4 to this part:

    a. FSSC 22000 (Food Safety Management System Certification) - Relevant applicable (sub)version.
    b. Normative documents (latest version linked to the Scheme) for providing certification:
        i. ISO 22000;
        ii. Sector specific PRPs;
        iii. Additional FSSC 22000 requirements.
    c. Food chain clusters, categories and sub-categories as indicated in Annex A of ISO 22003-1:2022; and
    d. Key activities and locations (owned and subcontracted) are covered under the accreditation, including critical locations where applicable.

2) Accreditation shall be granted to the requirements of ISO/IEC 17021-1:2015, ISO 22003-1:2022 and requirements for certification bodies of the FSSC 22000 Scheme.
3) The accreditation certificate shall include the initial accreditation date and valid until/expiry date.

2.2.3 WITNESSED AUDITS

1) The witnessed audits shall meet the requirements for witnessing activities for the Accreditation of Management Systems Certification Bodies as set out in section 7.5.6 of IAF MD 16:2015 with the below FSSC 22000 Scheme specific requirements:

a. Initial and scope extension assessments shall require at least one (1) FSSC 22000 witnessed audit of each category (as defined in ISO 22003-1:2022) detailed on the provisional or full CB license agreement;
b. The AB shall conduct FSSC 22000 witnessed audits covering all categories included in the CB accreditation scope during the AB accreditation cycle.
c. Witness audits shall always be for the full duration of the FSSC 22000 audit and covering all applicable Scheme requirements relevant to the audit.
d. For the CB to be awarded initial accreditation, the witness audit by the AB shall be conducted at a full system audit (e.g., initial audit (at least Stage 2) or at a transition audit). Subsequent witness audits may be conducted at a surveillance audit. In all instances, the full duration of the FSSC 22000 audit shall be witnessed by the AB.
e. The initial witnessed audit shall be conducted onsite; subsequent witnessing may be conducted onsite or remotely. Where subsequent witnessed audits are conducted remotely, this shall be based on a feasibility assessment, ensuring the ICT is appropriate to observe the complete audit and that the objectives of the witness audit can be met. The requirements of IAF MD4 shall be met where the AB utilizes ICT.
f. The AB assessor/assessment team shall have the appropriate competence and have detailed knowledge of the FSSC 22000 Scheme.
g. Witnessed audit reports shall be shared with the Foundation within 2 months from the last day of the witness audit.

2.3 INTEGRITY PROGRAM

1) The Foundation provides the AB access to all relevant CB outcomes of its Integrity Program and complaints management system related to ISO/IEC 17021-1:2015. The AB shall consider the content of this information during its annual CB assessments.
2) ABs are invited to attend, on a voluntary basis, and subject to the CBs agreement, the Integrity Program office assessments undertaken by the Foundation for its licensed CBs.
3) The Foundation shall inform the AB on suspensions or terminations of its licensed CBs and vice versa.

APPENDIX 1 DEFINITIONS

APPENDIX 1: DEFINITIONS

The following definitions apply to the terminology used in all Scheme documentation. Unless indicated in this Appendix, the terms, and definitions in the normative documents (ISO 22000:2018 and sector specific PRP standards) applies, supported by those in ISO/IEC 17021-1 and ISO 22003-1:2022.

ACCREDITATION

Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks (ISO/IEC 17011:2017).

ACCREDITATION BODY

Authoritative body that performs accreditation (ISO/IEC 17011:2017).

ACCREDITATION CERTIFICATE

Formal document or a set of documents, stating that accreditation has been granted for the defined scope (ISO/IEC 17011:2004).

ACCREDITATION SYMBOL

Symbol issued by an accreditation body to be used by accredited conformity assessment bodies to indicate they are accredited (ISO/IEC 17011:2017).

ACTIVE MATERIALS AND ARTICLES

Materials and articles that are intended to extend the shelf-life or to maintain or improve the condition of packaged food; they are designed to deliberately incorporate components that would release or absorb substances into or from the packaged food or the environment surrounding the food. Examples are oxygen absorbers and desiccants.

ADVISORY COMMITTEE

A representative group of stakeholders, appointed by the Foundation, who advise the Board of Stakeholders on the technical content of the Schemes.

AGENT/BROKER

An organization or individual that does not own but trades any type of food, feed and/or packaging. Such activities exclude production, storage, and any physical handling of the product; they can be performed under specific customer requirements or not (GFSI v2020.1).

AUDIT

Systematic, independent, documented process for obtaining evidence and assessing it objectively to determine the extent to which specified Scheme requirements are fulfilled.

APPEAL

Request for reconsideration of a decision made on a lodged complaint, as a result of a suspension or license termination.

ASSURANCE PLATFORM

Main digital platform provided by the Foundation, supporting key Scheme processes and data exchange needs.

ASSURANCE PLATFORM DATA

A piece of information that describes a Scheme related Fact that can be a collection of characters and numbers, representing human readable and understandable text, and/or files and attachments.

AUDITOR

Person who conducts an audit (ISO/IEC 17021-1:2015).

BLACK-OUT DAYS

Time periods shared by the certified organization with the certification body to avoid periods of extreme inconvenience during which the organization would find it difficult to participate fully in an unannounced audit and/or there is no production.

BOARD OF STAKEHOLDERS

Group of representatives appointed by the Scheme's stakeholders who are responsible for oversight including all certification and accreditation requirements.

CERTIFICATION

Process by which licensed certification bodies provide assurance that the food safety management system and its implementation by the audited organization comply with Scheme requirements.

CERTIFICATION BODY

Organization providing audit and certification services (ISO/IEC 17021-1:2015).

CERTIFICATION DECISION

Granting, continuing, expanding, or reducing the scope, suspending, re-instating, withdrawing, or refusing certification by a Certification Body (GFSI v7.2:2018).

CERTIFICATION DECISION DATE

Date on which the certification decision is taken.

CERTIFICATION SCHEME

Conformity assessment system related to management systems to which the same specified requirements, specific rules and procedures apply (ISO/IEC 17021-1:2015).

CERTIFICATE SUSPENSION

Declaration of certificate status as temporarily invalid.

CERTIFICATE WITHDRAWAL

Final inactivation of a certificate following a Certification decision.

CLEANING PROGRAM

The program established for the removal of soil, food, dirt, grease, or other extraneous matter to ensure that processing equipment and the environment are maintained in a hygienic condition. The methods applied include, but are not limited to, both sanitation and disinfection.

COMPETENCE

Ability to apply knowledge and skills to achieve intended results (ISO/IEC 17021-1:2015).

COMPLAINT

Expression of dissatisfaction made to an organization, related to its product or service, or the complaints-handling process itself, where a response or resolution is explicitly or implicitly expected (ISO 9000:2015).

CORRECTION

Action taken to eliminate the identified nonconformity.

CORRECTIVE ACTION

Action taken to eliminate the cause (s) of a nonconformity and to prevent recurrence.

CRITICAL NONCONFORMITY

Circumstance where there is a significant failure in the management system, a situation with direct adverse food safety impact and no appropriate action is being observed or when food safety legality and/or certification integrity is at stake.

CROSS DOCKING

Process by which goods (food, feed, animal food and packaging) are unloaded, sorted, consolidated, loaded, and shipped to the next destination (ISO/TS 22002-5:2019).

DATA OWNERSHIP

The act of having legal rights and complete control over a single piece or set of data elements. It defines and provides information about the rightful owner of data assets and the acquisition, use and distribution policy implemented by the data owner.

DISINFECTION

Reduction, by means of biological or chemical agents and/or physical methods in the number of viable microorganisms on surfaces, in water or air to a level that does not compromise food safety and/or suitability (CXC 1-1969).

ENVIRONMENTAL MONITORING

A program for the evaluation of the effectiveness of controls on preventing contamination from the site environment.

FEED

Single or multiple product(s), whether processed, semi-processed or raw, which is intended to be fed to food producing animals (GFSI v2020.1; ISO 22000:2018).

FOOD

Substance (ingredient), whether processed, semi-processed or raw, which is intended for consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of "food" but does not include cosmetics or tobacco or substances (ingredients) used only as drugs (GFSI v2020.1; ISO 22000:2018). Food is intended for consumption by humans and animals, and includes feed and animal food:
— feed is intended to be fed to food-producing animals;
— animal food is intended to be fed to non-food-producing animals, such as pets.

FOOD ADDITIVE

Any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result, (directly or indirectly) in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods. The term does not include contaminants, or substances added to food for maintaining or improving nutritional qualities (CODEX STAN 192-1995).

FOOD DEFENSE

The process to ensure the security of food, food ingredients, feed, or food packaging from all forms of intentional malicious attack including ideologically motivated attack leading to contamination or unsafe product (GFSI v2020.1).

FOOD FRAUD

A collective term encompassing the deliberate and intentional substitution, addition, tampering or misrepresentation of food, food ingredients, feed, food packaging or labelling, product information or false or misleading statements made about a product for economic gain that could impact consumer health (GFSI 2020.1).

FOOD LOSS AND WASTE

Food loss occurs before the food reaches the consumer as a result of issues in the supply chain (production, processing, storage, and distribution phases).
Food waste refers to food that is fit for consumption, but consciously discarded at the retail or consumption levels.
In the context of the FSSC 22000 Scheme, food loss and waste only relate to food – it does not include packaging material wastage.

FOOD SAFETY CULTURE

Shared values, beliefs and norms that affect mindset and behavior toward food safety in, across and throughout an organization (GFSI 2020.1).

FOOD SAFETY MANAGEMENT SYSTEM (FSMS)

Set of interrelated or interacting elements of an organization to establish policies and objectives and processes to achieve food safety management system objectives (ISO 22003-1:2022).

FOUNDATION FSSC

The legal owner of the FSSC Certification Schemes.

FOLLOW-UP AUDIT

An additional audit to a regular audit for which an extra visit is required when the audit could not be completed in the planned time and/or the audit plan could not be realized completely. As a follow-up is part of a regular audit, it shall be completed within a short timeframe from the main audit. A follow-up audit also includes the on-site close out of nonconformities.

FSSC LOGO

Logo issued by the Foundation which can be used by licensed CBs and certified organizations in accordance with FSSC 22000 Scheme requirements.

GFSI APPROVED STANDARDS

Standards deemed to be technically equivalent by GFSI. Technical Equivalence is a category of GFSI benchmarking process dedicated to government-owned standards. It acknowledges the equivalence of the standard's content to the relevant scope(s) of the GFSI Benchmarking Requirements Part III. The updated list of GFSI approved standards can be found on the GFSI website: https://mygfsi.com/how-to-implement/technical-equivalence/

GFSI RECOGNIZED STANDARDS

Standards that have been successfully benchmarked against the GFSI benchmarking requirements. The updated list of GFSI recognized standards can be found on the GFSI website: https://mygfsi.com/how-to-implement/recognition/

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) (ISO 22003-1:2022).

HYGIENIC DESIGN

Design and engineering (materials and fabrication) of equipment and premises that are easily cleanable assuring the food is safe and suitable for human consumption (EHEDG Glossary, Version 2020/08.G04).

MANUFACTURING/PROCESSING

Transformation of raw materials, by physical, microbiological, or chemical means, into a final product.

MAJOR NONCONFORMITY

Nonconformity that negatively affects the capability of the management system to achieve the intended results, or a legislative noncompliance linked to quality.

MINOR NONCONFORMITY

Nonconformity that does not affect the capability of the management system to achieve the intended results (ISO/IEC 17021-1:2015).

OUTSOURCE

Arrangement where an external organization performs part of an organization's function or process (ISO 22000:2018).

ORGANIZATION

Legal entity that has its own functions, with responsibilities, authorities, and relationships to comply with the Scheme requirements and that could cover multiple sites.

PERISHABLE PRODUCT

Products that lose their quality, or are likely to spoil over a specified time, even when handled correctly throughout the supply chain, therefore requiring temperature control during storage and/or transportation to prevent damage, spoilage, and contamination.

PRODUCT

Output that is a result of a process. A product can be a service (ISO 22000:2018).

PRODUCT RECALL

The removal by a supplier of a product from the supply chain that has been deemed to be unsafe and has been sold to the end consumer or is with retailers or caterers and is available for sale (GFSI 2020.1).

PRODUCT WITHDRAWAL

The removal of a product by a supplier from the supply chain that has been deemed to be unsafe, which has not been placed on the market for purchase by the end consumer (GFSI 2020.1).

PROCESS

Set of interrelated or interacting activities which transform inputs to outputs (ISO 22000:2018).

QUALITY MANAGEMENT SYSTEM

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 quality.

RAW MATERIAL

Commodities, parts, or substances that are assembled or processed to form a final product.

REWORK

The process of re-manufacturing semi-final and final products, to obtain a final product that complies with the customer requirements. It can also refer to material in a processed or semi-processed state that is intended to be re-used in subsequent manufacturing steps.

RISK

Effect of uncertainty (ISO 22000:2018).

SANCTION COMMITTEE

Committee that decides on possible sanctions based upon information provided by the Foundation in case of unacceptable CB performance.

SANITATION

All actions dealing with cleaning or maintaining hygienic conditions in an establishment, ranging from cleaning and/or sanitizing of specific equipment to periodic cleaning activities throughout the establishment (including building, structural, and grounds cleaning activities) (ISO/TS 22002-1:2009).

SCHEME

Set of rules and procedures that defines the objects of conformity assessment, identifies the specified requirements for the object of conformity assessment and provides the methodology for performing conformity assessment.

SCOPE

Extent and boundaries applicable of e.g., audit, certification, accreditation, or Scheme activity (ISO 9000:2015).

SERIOUS EVENT

A circumstance beyond the control of the organization, commonly referred to as “Force Majeure” or “act of God” (IAF ID3:2011) that prevents a planned audit from taking place. Examples include war, strike, riot, political instability, geopolitical tension, terrorism, crime, pandemic, flooding, earthquake, malicious computer hacking, other natural or man-made disasters.

SITE

A permanent location where a facility carries out work or activity. A site may have off-site activities in the context of the Scheme requirements that are included as part of the FSMS, e.g., head office, off-site manufacturing, and off-site storage.

SPECIAL AUDITS

Audits at certified organizations that are performed on top of, or in addition to, the annual surveillance/re-certification audits.

TABLEWARE

Disposable Consumer good products that come in contact with food and food packaging materials.

THREAT

Susceptibility or exposure to a food defense act (such as sabotage, malicious tampering, disgruntled employee, terrorist act, etc.) which is regarded as a gap or deficiency that could impact consumer health if not addressed.

UNANNOUNCED AUDIT

Audit that is conducted at the facility of the certified organization without prior notification of the audit date.

VULNERABILITY

Susceptibility or exposure to all types of food fraud, which is regarded as a gap or deficiency that could impact consumer health if not addressed.

WITNESSED AUDIT (AB)

An activity performed by a competent AB assessor, whereby the performance of the CAB is assessed through the observation of the CAB carrying out conformity assessment activities within its scope of accreditation (clause 3.25 of ISO/IEC 17011). The AB observes, without interfering or influencing, a complete FSSC 22000 audit performed by a CB auditor/audit team.

WITNESSED AUDIT (CB)

An activity performed by a competent CB witnessor, whereby the performance of the CB auditor is observed and evaluated, without interfering or influencing, at a complete FSSC 22000 audit performed by the CB auditor.

APPENDIX 2 REFERENCES

APPENDIX 2: NORMATIVE REFERENCES

- BSI/PAS 221:2013 Prerequisite programs for food safety in food retail - Specification
- GFSI Benchmarking Requirements (latest version)
- IAF MD 1 Audit and Certification of a Management System Operated by a Multi-Site Organization (latest version)
- IAF MD 2 Transfer of Accredited Certification of Management Systems (latest version)
- IAF ID 3 Management of Extraordinary Events or Circumstances Affecting ABs, CABs, and Certified Organizations
- IAF MD 4 The Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes (latest version)
- IAF MD 11 Application of ISO/IEC 17021-1 for Audits of Integrated Management Systems (latest version)
- IAF MD 16 Application of ISO/IEC 17011 for the Accreditation of Food Safety Management System (FSMS) Certification Bodies (latest version)
- IAF MD 20 Generic Competence for AB Assessors: Application to ISO/IEC 17011 (latest version)
- ISO 9001:2015 Quality management systems – Requirements
- ISO 22000:2018 Food safety management systems – Requirements for any organization in the food chain
- ISO/IEC 17021-1:2015 Conformity assessment – Requirements for bodies providing audit and certification of management systems.
- ISO 22003-1:2022 Food safety - Part 1: Requirements for bodies providing audit and certification of food safety management systems.
- ISO/IEC 17011:2017 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies.
- ISO 19011:2018 Guidelines for auditing management systems
- ISO/TS 22002-1:2009 Prerequisite programs on food safety – Part 1: Food manufacturing
- ISO/TS 22002-2:2013 Prerequisite programs on food safety – Part 2: Catering
- ISO/TS 22002-4:2013 Prerequisite programs on food safety – Part 4: Food packaging manufacturing
- ISO/TS 22002-5:2019 Prerequisite programs on food safety – Part 5: Transport and storage
- ISO/TS 22002-6:2016 Prerequisite programs on food safety – Part 6: Feed and animal food production
- FSSC 22000 Integrity Program documentation
- FSSC Code of Ethics
- FSSC Full Remote Audit Addendum