



FOOD SAFETY SYSTEM CERTIFICATION 22000

ANNEX 1: CB CERTIFICATE SCOPE STATEMENTS



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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 or FSSC 22000-Quality 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:

- 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 that shall have been audited by the CB. The audit report shall contain sufficient objective evidence to support the full scope of certification of all activities in the scope statement;
- 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 mentioned (e.g. sterilization, pasteurization, fermentation, drying) but not all it is strongly advised not to put all individual process steps in the scope statement (e.g. receiving raw materials, storing raw materials, mixing, proofing, baking, packaging in plastic, storage is not preferred).
- 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 food 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 mention-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 clause 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 in the scope of certification (ISO/TS 22003:2013 9.1.1)(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 or FSSC 22000-Quality certification are defined in Part 1H of the scheme documents.

4.1 FOOD CHAIN CATEGORY A - FARMING OF ANIMALS

The scope statement shall contain the type of animal concerned.

EXAMPLES

Certificate scope statement	Acceptable	Comments and recommendations
Receiving of day-old chickens, growing (production) and loading to abattoir for slaughter.	¥ es	

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		Comments and recommendations
Sorting, packing and chilled storage of grapes.	Yes	

4.2 FOOD CHAIN CATEGORY C - FOOD MANUFACTURING

- 1) Packaging activities limited to (inline) unfolding of packaging, blowing of bottle preforms, printing etc. are not considered as food packaging production and are included in the food scope of certification where linked with food manufacturing at the site.
- 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.



Certificate scope statement	Acceptable	Comments and recommendations
Production of eggs	Yes 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.	Yes/No 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

All requirements as described under 4.2 (Food Manufacturing) apply with the following additional requirements:

• The target animal group shall be mentioned (e.g., cattle, chicken, dogs, cats, pet birds...)

EXAMPLES

Certificate scope statement	Acceptable	Comments and recommendations
Production of pet food.	No	Missing is the type of food and target animal group(s).
Production and transport of dry feed mixtures for cattle.	Yes	Allowed if the transport process is owned by the company.
Manufacturing of dry pet food for small pets (rodents).	¥es	

4.4 FOOD CHAIN CATEGORY E - CATERING

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 is delivered to consumers. In this case the airline is the caterer.
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. in a central kitchen and serving from food trucks at festivals.	Yes	



Certificate scope statement	Acceptable	Comments and recommendations
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. Central preparation and service at
Production of food for events such as weddings and conferences. Prepared off-site and delivered to the event location.	No	satellite locations is allowed.

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

Food chain category FI:

- 1) Category FI is a Distribution category 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. grilling of meat, reheating of ready to eat foods bake-off of bread, cutting of meat or fish) and shall be mentioned in the scope statement.
- 3) Please note that ISO/TS 22003:2013 describes category F as Distribution. In many languages this means the same as transportation but that is not the case here.
- 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 Fl includes physical storage of products.

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 selling 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	



Certificate scope statement	Acceptable	Comments and recommendations
Selling 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	
Distribution of powder and sauces.	No	It is not clear what the distribution activities are. A clear reference to specific wholesale or retail activities shall be made.
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	
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 No	Trading is not allowed. 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".

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	



Certificate scope statement	Acceptable	Comments and recommendations
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).

Certificate scope statement	Acceptable	Comments and recommendations
Production of food-grade gas mixtures in cylinders CO ₂ , N ₂ , O ₂ , are used as food ingredient. Production of food-grade solid CO ₂ (Dry Ice).	Yes	
The manufacturing of liquid flavors and dry "mineral and salt blend" concentrate ingredients for use in the beverage use 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.



Certificate scope statement	Acceptable	Comments and recommendations
Production of food gases (Nitrogen, Oxygen, Argon, Nitrogen Dioxide, Carbon Dioxide, Hydrogen) and gas mixtures for use as food ingredient or processing aid in the food industry.	Yes	
Production of preservatives, antioxidants, and anti-caking agents intended for use in the feed industry.	Yes	





FOOD SAFETY SYSTEM CERTIFICATION 22000

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 ensure that their templates meet the requirements listed in this Annex with regard to content (the lay-out and order of the content is at the CB's discretion). The completed audit report It 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 whether or not CB are complying conformance with FSSC 22000 audit reporting requirements;
- 2. Be used by all CBs to train their auditors and personnel involved in the review and to ensure an informed certification decision process on the content requirements of the audit report, is made to ensure in support of a robust certification process.
- 3.—Be used by all Training Organizations in their training programs for internal auditor and lead auditor courses;

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 the audit reports. for:

Stage 1 audit report

Stage 2 audit report (see note 1)

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 complying 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.

Note 1: A stage 2 audit report shall be used for all audits that are not stage 1 audits, head office audits or special audits. The audit criteria shall be adjusted relevant to the type of audit conducted (for example surveillance, recertification, transition etc.).

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 are not to 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 NC 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 (and where it is not a FSSC 22000-Quality 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 95.



- 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 client-organization shall include the nonconformity report, audit plan, and the audit program, and the attendance register.
- 10. The complete audit pack All information in the audit report template shall be uploaded into the Portal Assurance Platform along with attachments in PDF including the final audit report, checklists, audit plan, audit program, integrity declaration, attendance register and nonconformity reports. Where nonconformity reports are separate to the audit report these Supporting audit documentation shall be uploaded as a zipped file with the audit report to facilitate uploading into the Portal Assurance Platform. It is not required to upload supporting evidence for closure of nonconformity details for upload in the Assurance Platform portal are required to-shall always be completed uploaded-in English.

Notes:

- This Annex is designed for food manufacturing audits, and the ISO/TS 22002-1:2009 PRP checklist is used here-in this example. It applies to Food Chain Categories BIII, C and K and DII.
- 2) For Food Chain Categories A, DI, E, FI, G or I, the CB shall substitute the relevant PRP checklist. 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 postal address is not available)
Contact person	Name & function
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 when various seasonal activities are conducted per scope. (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 postal address is not available)
Date and duration 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 the head office representative is present at 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 <mark>(s)</mark> /Address	Full physical address (or other unique identification of site location (i.e., GPS, GLN etc. where a physical postal address is not available)
Date and duration of off- site activity audit/s	
Duration of off-site activity audit/s (in hours)	
Activities at location/s	Describe the any 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 postal address is not available)
Date and duration 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 2.5.14 for report content requirements
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)	Can be an addendum to the report

1. 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 ISO/TS 22003:2013 9.2.3.1.2
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. *ICT Audit Approach / On-site *Note: include the extent of the remote audit i.e. full remote audit or partly remote audit
Audit dates and locations (where applicable)	Start and end date DD/MM/YYYY Add dates per off-site activity/separate locations audited where relevant
Audit Duration Stage 1	In hours, for example 8 hours (1 MD = 8 hours) In days for example 1.5 days

1.1 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) ISO/TS 22003, Table A.1)
Scope statement	Scope statement as per Annex 1 requirements. Where exclusions are applicable, the exclusion shall has to 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 (exclusions may not have an (negative) influence on the certified end products 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

1.2 AUDIT PLAN

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

1.3 AUDIT TEAM

Name	Function	Audit delivery method	Date(s)	Time (<mark>in hours)</mark>
Auditor name	Includes lead auditor, auditor, translators, technical expert, witnessor, trainees, observers	i.e., remote/onsite	DD/MM/YYYY	08h00-17h00 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



2. AUDIT RESULTS

2.1 OVERVIEW OF CLIENTS' PREPAREDNESS FOR STAGE 2

Management system documentation including the ability to meet statutory, regulatory and customer requirements Client's site-specific conditions (environment; equipment and processes)	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. Summary description of site environment and any external risks. Short list of principle processes/activities 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 control limits, monitoring systems, and corrective actions for breach of action criteria/critical limits, Validation process implementation and results, 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 afternoons/evening).

2.2 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.

2.3 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	
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 postal address is not available).
Contact person	Name and function.
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	 Indicate whether the site has Describe what seasonal activities are conducted. Included in the scope, what they are and relevant production timings or (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 postal address is not available).
Date and duration 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 postal address is not available).
Date and duration of off- site <mark>activity</mark> 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 <mark>physical</mark> address (or other unique identification of site location (i.e. GPS, GLN etc. where a physical postal address is not available)
Date and duration of Central Functions audit	
Duration of Central Functions audit (in hours)	
Overview of Central Functions	Also, refer to FSSC 22000 Additional Requirement 2.5.18-2.5.14 for report content requirements
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)	Can be an addendum to the report

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 – <mark>9.3.1.3</mark>		
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 <mark>used during the audit</mark> as applicable		
Audit dates	Audit start date Audit end date		

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Audit Duration	In hours, for example 8 hours (1 MD = 8 hours) i.e., 1.5 days
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 <mark>(sub)</mark> -category	Food chain (sub)-categories supporting the scope statement (multiple food chain categories may be applicable, see Scheme Part 1, Table 1 ISO/TS 22003, Table A.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 (exclusions may not have an (negative) influence on the certified end products) 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 and indicate any changes since the previous audit

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 TE, witnessor, trainees, observers	i.e., remote/onsite	DD/MM/YYYY	08h00-17h00 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

Audit type Stage 1, Stage 2, Surveillance, Recertification, Transition Announced / Unannounced Audit date/s DD/MM/YYYY **CB** conducting previous In case of a transfer, indicate the name of the previous CB audit if different to current CB **Actions taken on NCs** Provide comments on the organization's ability to determine the raised at previous audit 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.

2.4.1 AUDIT DETAILS PREVIOUS AUDIT



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
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

	Reference (std., clause)	(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 2 Date	For example: ISO 22000:2018 §7.1 of suspension:	Provide a clear statement of the deviation to the requirement. Provide detailed objective evidence. Indicate potential or actual impact on food safety. DD/MM/YYYY	Completed by client	Completed by client	Completed by client	Auditor name and date of acceptance of Root cause analysis, CAP and correction	
			Follow-up A	ludit			
Date	of follow-up au	dit: 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							

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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							
Or	site 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							

Note: Corrective action reports for minor, major and/or critical nonconformities may be included in the audit report, or as a separate document. 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
Continued certification	
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 ISO/TS22003: 2013 and V5 V6 Part 3, clause 4.3, 5.2 and 5.3

Ð	Ħ	MS	FTE	FSSC additional	
1.5	0.5	0.25	1.0	0.5	
Audit duration calcu	llation	Example:			
(man days)		Initial audit Ts + T	fssc = 3.75 man da	/S	
		Surveillance audi	t = 1.5 man days		
		Recertification au	idit = 3 days		
Audit time reductio	h	Justify any reduct	ions given to Ts		
Existing Managemer certification in place	•	Yes/No – if yes specify			
Number of HACCP st to product groups)	umber of HACCP studies (linkedIndicate the number of HACCP studies – linked to the product groups)product groups)product group				
Number of employe (Used for audit duratio determine T _{FTE})		FTE = total number of employees including seasonal workers + non-production staff having an impact on food safety office workers; however, where shifts with similar activities apply, then FTE = number of employees on main shift including seasonal workers and office workers non- production staff having an impact on food safety			
Number of shifts					
Description of activi different from main	f activities per shift if n main shiftWhere activities are different across shifts, provide sho overview of activities per shift			s shifts, provide short	
Employees per main	shift (FTE)				
Audit preparation ti	ation time (in hours)E.g., 2 hours				
Audit reporting time	e (in hours)	E.g., 8 hours			
NAMES OF A DESCRIPTION OF A				1 1 2 1 1	

Note: In addition to completing the above mandatory fields, the audit duration calculation shall may be uploaded in the FSSC Assurance Platform portal as a separate document for each audit as long as all information required is captured. 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.

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4. CHECKLISTS

Note: It is not required to reflect the sub-sub clauses (e.g., 7.5.3.1; 8.5.1.5.1) in the ISO 22000 checklist section of the audit report, but should a nonconformance be identified, this needs to be reflected to this level and included in the report. 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. The portal checklist contains all the clauses to the lowest level.

4.1 ISO 22000:2018

ISO 22000:2018		Conform		Grade	lf No – detail NC	NC#
Clause	Requirement	Yes	No	Minor/Maj or/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) (risks and opportunities) 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	lf No – detail NC	NC#
Clause	Requirement	Yes	No	Minor/Maj or/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) Demonstrate the 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 Overview of 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) and that the food safety team is multidisciplinary and has the right persons/expertise with brief overview of disciplines/areas covered;

c) Detail what mechanisms are in place to ensure communication within the organization and to interested parties is effective. 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 relevant available to each individual worker – linked to food safety culture;

d) Food safety culture: provide an overview of how food safety culture is 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

e) How continual improvement is promoted within the organization

The summary shall include confirmation that an overview of what was covered during the interview was held with top management, including who was interviewed.



ISO 22000:2018		Conform		Grade	lf No – detail NC	NC #	
Clause	Requirement	Yes	No	Minor/Maj or/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 with including PDCA principles. Provide examples of significant changes that have taken place since the



previous audit, how they were managed Describe findings related to changes (e.g. compared to previous audit, to FSMS, etc.) and the effect on the operational FSMS, *if applicable.*

ISO 22000:2018		Conform		Grade	lf No – detail NC	NC #
Clause	Requirement	Yes	No	Minor/Maj or/Critical		
7	Support	I	1	•		
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)					



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. *levels of the organization.* For external experts, details of requirements, competency, and scope of work (may be identified in contract). Training requirements for these individuals are identified and records of completion available including communication of the requirements in 7.3. Provide an overview on the food safety team (multidisciplinary, disciplines/areas covered). Detail 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? Provide evidence that the organization has a procedure for procurement in emergency situations to ensure that products still conform to specified requirements and the supplier has been evaluated. Detail if any instance of emergency use of non approved suppliers has occurred (date, supplier, material) and confirm if procedure was followed effectively.

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	lf No – detail NC	NC #
Clause	Requirement	Yes	No	Minor/Maj or/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			

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

<u>Prerequisite Programs (PRPs)</u>: Do not list all the out individual PRP documents here. -make-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.

<u>Traceability System:</u> 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 Conduct a traceability exercise conducted by the auditor during this audit and report results (detail product tested, whether speed of completion was in accordance with the by organizations procedures, and the outcome of test/mass balance). Where the organization undertakes rework, define how traceability is maintained.

<u>Emergency preparedness and response:</u> Detail the document that addresses the management of potential emergency situations. *including the requirement to report situations where there is an impact* on food safety and/or the FSSC 22000 certificate. 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. Where applicable, indicate if the CB was informed of the emergency situation. Document the frequency (e.g. annually), date, nature and outcome of the periodic test (*minimum once per annum test*) and any changes to the procedures following the occurrence of any incident, emergency situations or tests. Is there a procedure for contingency Detail whether the procedure addresses planning in place the management of interruptions of essential services including for example the for-disruption of water, electricity or of refrigeration supply.?

<u>Hazard control:</u> Brief overview of preliminary information collected, how it is maintained and updated, 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 describe-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. Document OPRPs & CCP's: what are they, control limits, monitoring and corrective actions in case of breach. Complete the below table, and add additional rows if needed.

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

*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.

Provide supporting information on 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.?

<u>Control of monitoring and measuring</u>: Detail the processes in place for control of monitoring and measuring equipment.

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

<u>Control of product and process nonconformities:</u> 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. Indicate samples 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	lf No – detail NC	NC #
Clause	Requirement	Yes	No	Minor/Maj or/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					

<u>Monitoring, measuring, analysis and evaluation:</u> 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 are used as an input for management review and updating the FSMS.

<u>Internal audit:</u> 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 report shall confirm that the frequency of internal audits is based on risk, in accordance with 9.2.1 (a). (importance of the processes concerned, changes in the FSMS, and the results of monitoring, measurement) and the results of previous audit findings. Indicate whether the audit program schedule-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 audit program and the internal audit reports. Detail records of internal audit clink to improvement), follow-up actions/verification and escalation mechanisms should NCs not be addressed, or audit program falls behind.

<u>Management review:</u> 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) of this clause 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 and the FSSC 22000 Scheme, as a result of the output of the management review. Detail the date of the last Management Review and if minutes are available that address the requirements of 9.3.2 and 9.3.3

ISO 22000:2018		Conform		Grade	lf No – detail NC	NC #
Clause	Requirement	Yes	No	Minor/Maj or/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.

reviewed for effective implementation including identification of trends, root cause analysis and elimination of the cause of the NC to prevent reoccurrence.

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	lf No – detail NC	NC #			
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	lf N/A – provide justification				
4	Construction and layout of buildings									
4.1	General requirements									
4.2	Environment									
4.3	Locations of establishments									

Summary:

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

<u>Environment</u>: 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.

<u>Location of establishment</u>: 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 2	ISO/TS 22002-1:2009		onforr	n	Grade	lf No – detail NC	NC #				
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	lf N/A – provide justification					
5	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.

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Overview of air filtration system, Comment on the maintenance of floors, walls, ceilings, overhead structures, drains, and other internal structures and fittings.etc. 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), food, 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. If wooden pallets are used how are they treated to prevent insect infestation and/or chemical leaching.

ISO/TS 2	ISO/TS 22002-1:2009		onforr	n	Grade	lf No – detail NC	NC#			
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	lf N/A – provide justification				
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:

Detail how the organization monitors the quality of utilities to minimize product contamination risk.

<u>Water supply</u>: Detail the water type (potable, non-potable) water types, 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 <u>Boiler chemicals</u> are used, provide information on approval for use, storage, security measures and any areas of concern where steam comes in direct contact with product. Identify who is responsible for the addition of these chemicals.

<u>Air quality and ventilation</u>: 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 <u>compressed air and other gases</u> 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 <u>lighting</u> 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		С	onforr	n	Grade	lf No – detail NC	NC #
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	lf N/A – provide justification	
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						

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 are suitable and appropriate for the size of the premises, including reference to cleaning and maintenance.

ISO/TS 2	22002-1:2009	C	onforr	n	Grade	lf No – detail NC	NC #			
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	lf N/A – provide justification				
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 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 2	ISO/TS 22002-1:2009		Conform			lf No – detail	NC #	
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	NC lf N/A – provide justification		
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. Describe mechanisms for dealing with emergency use of non-approved suppliers, how this is evaluated and controlled including responsibilities. Detail if any instance of emergency use of non-approved suppliers has occurred (date, supplier, material) and confirm if procedure was followed effectively.

Food chain category CI only: verify procedure for suppliers of animals, fish and seafood which are subject to control of prohibited substances (e.g. pharmaceuticals, veterinary medicines, heavy metals and pesticides).

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 2	ISO/TS 22002-1:2009		nform		Grade	lf No – detail	NC #	
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	NC lf N/A – provide justification		
10	Measures for prevention of	cross con	tamin	ation				
10.1	General requirements							
10.2	Microbiological cross contamination							
10.3	Allergen management							
10.4	Physical contamination							
Summa	Summary:							

Provide an overview of the programs in place to prevent, control and detect contamination, including measures to prevent physical, allergen and microbiological contamination.



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

Food chain category CI only: detail if specified requirements are in place for an inspection process at lairage and/or at evisceration to ensure animals are fit for human consumption.

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.

<u>Physical contamination:</u> 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 2	ISO/TS 22002-1:2009		nform		Grade	lf No – detail	NC #
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	NC If N/A – provide justification	
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	lf No – detail	NC #
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	NC If N/A – provide justification	
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			

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 2	22002-1:2009	Cor	nform		Grade	lf No – detail	NC #
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	NC If N/A – provide justification	
13	Personnel hygiene and emp	oloyee fac	ilities				
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 is-are staff canteen-catering facilities on site, detail how hygienic conditions are maintained, and controls in place for storage, cooking and holding incl. temperature. where cooking/holding temperatures/time limitations etc. are specified and storage facilities for food brought on site.

<u>Workwear and protective clothing</u> - 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.



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

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

Summary:

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

ISO/TS 22002-1:2009		Conform			Grade	lf No – detail	NC #
Clause Requirement		Yes	No	N/A	Minor/major/ critical	NC lf N/A – provide justification	
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. Detail when the last mock recall was completed, the outcome and if any improvements were required. Where an actual recall occurred, provide details, and 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	lf No – detail	NC#
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	NC lf N/A – provide justification	
16	Warehousing	-					
16.1	General requirements						



16.2	Warehousing requirements			
16.3	Vehicles, conveyances, and containers			

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 and 14.2 of ISO/TS 22002-1.

Food chain category CI only: detail if specified requirements are in place that define post slaughter time and temperature in relation with chilling or freezing of the products.

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 2	22002-1:2009	Cor	nform		Grade	lf No – detail	NC#			
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	NC lf N/A – provide justification				
17	Product information/consu	mer awar	eness							
17.1	Product information and consumer awareness									
	Summary: Detail process of label approval that covers required information (customer and legislative requirements).									
conform	nt the sample(s) reviewed (labo ance to requirements whether a hem to make informed choices.		0							
ISO/TS 2	22002-1:2009	Cor	nform		Grade	lf No – detail	NC#			
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	NC lf N/A – provide justification				

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	lf No – detail NC lf N/A – provide	NC#
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	justification	
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. Provide details where emergency suppliers were used 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	lf No – detail NC lf N/A – provide	NC#
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	justification	
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. H**alal**, 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	lf No – detail NC lf N/A – provide	NC#
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	justification	
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 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.-(can refer to PRP clause 18 to avoid duplication), for the supply chain and if company complies with applicable legislation (to be kept up to date)
- 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	lf No – detail NC lf N/A – provide	NC#		
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	justification			
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 threat assessment has been conducted using a defined methodology, breadth of assessment (supply chain and not only at site level) and relevant vulnerabilities threats 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) Detail training and communication strategy for employees*
- *e)* 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	lf No – detail NC lf N/A – provide	NC#
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	justification	
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	lf No – detail NC lf N/A – provide	NC#
Clause	Requirement	Yes	No	N/A	Minor/major/	justification	
					critical		
2.5.6	Management of allergens (All Food Chain Categories)						
	(Food Chain Categories C, E, Fl, G, I & K)						

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 HACCP study incorporates these 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	lf No – detail NC lf N/A – provide	NC#
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	justification	
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	

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 and allergen-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 and allergen), frequency, general overview of results of testing (trend analysis etc.) and corrective actions or adjustments to the program as needed. Detail if the monitoring is conducted in-house or externally. 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 this* is already covered in PRP clause 11

FSSC 22000 Additional Requirement		Conform			Grade	lf No – detail NC lf N/A – provide	NC#
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	justification	
2.5.8	Food safety and quality culture (All Food Chain Categories) Formulation of products (Food Chain Category D)						

Summary:

Reference the procedure that addresses this requirement. Provide an overview of the formulated products and the relevant customer and legislative requirements. Detail which ingredients are used that can have adverse animal health impacts, and how these are controlled.

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	lf No – detail NC lf N/A – provide	NC#
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	justification	
2.5.9	Quality control (All Food Chain Categories) Transport and delivery (Food Chain						
	delivery (Food Chain Category Fl)						

Provide an overview of the transport and delivery services involved. Detail conditions/systems that are aimed at minimizing potential contamination during transport and delivery.

- 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	lf No – detail NC lf N/A – provide	NC#
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	justification	
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	lf No – detail NC lf N/A – provide	NC#
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	justification	
2.5.11	Hazard control and measures for preventing cross- contamination (All Food Chain Categories)-(Food Chain Category C & I)						

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	lf No – detail NC lf N/A – provide	NC#
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	justification	
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		C	onfor	m	Grade	lf No – detail NC lf N/A – provide	NC#
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	justification	
2.5.13	Product <mark>Design and</mark> Development (Food Chain Categories <mark>BIII</mark> , C, D, E, F, I & K)					This clause may only be indicated as N/A for FCC A, and G	
Summary: Where product development is applicable, 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	lf No – detail NC lf N/A – provide	NC#	
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	justification	
2.5.14	Health Status (Food Chain Category D)					This clause may not be indicated as N/A for FCC D	

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 220 Require	000 Additional ment	Conform		Grade	lf No – detail NC lf N/A – provide	NC#	
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	justification	
2.5.15	Equipment Management (All Food Chain Categories, excluding Fll)					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 220 Require	00 Additional ment	l Conform		Grade	lf No – detail NC lf N/A – provide	NC#	
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	justification	
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 products or by-products intended for animal feed/food.

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

FSSC 22000 Additional Requirement		Conform		Grade	lf No – detail NC lf N/A – provide	NC#	
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	justification	
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	lf No – detail NC lf N/A – provide	NC#	
Clause	Requirement	Yes	No	N/A	Minor/major/	justification	
					critical		
2.5.1 <mark>8</mark>	Requirements for Organizations with Multi-site Certification (Food Chain Category A, E, FI & G)					This clause may not be indicated as N/A for multi-site groups	
2.5.1 <mark>8</mark> .1	Central Function s						
2.5.1 <mark>8</mark> .2	Internal Audit Requirements						

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?





FOOD SAFETY SYSTEM CERTIFICATION 22000

ANNEX 3: CB CERTIFICATE TEMPLATES



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 Portal 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 system-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 with multi-site activities certification (refer Part 3, section 5.3)
- 5. FSSC 22000-Quality for single sites
- 6. FSSC 22000-Quality with head office
- 7.—FSSC 22000-Quality with off-site activities
- 8.—FSSC 22000-Quality with multi-site activities

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

Food Safety System Certification 22000 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 of registration number:			
Certification decision date:			
Initial certification date:	Authorized by:		
Issue date:	Position of signatory	AB <mark>Symbol Mark</mark>	
Valid until:			
Issued by:		QR Code	
Name and address of certification body	CB Mark logo		
The authenticity of this certificate can be verified in the FSSC 22000 database of Certified Organizations available on www.fssc 22000 .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

Food Safety System Certification 22000 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 audited-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 of registration number: Certification decision date: Initial certification date: Issue date: Valid until:

Authorized by: Position of signatory AB

AB Symbol Mark

Issued by: Name and address of certification body

CB Mark logo

QR Code

The authenticity of this certificate can be verified in the FSSC 22000 database of Certified Organizations available on www.fssc22000.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

Food Safety System Certification 22000 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 describe FSMS processes audited at each the 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 of registration number: Certification decision date: Initial certification date: Issue date: Valid until: Issued by: Name and address of certification body

CB Mark logo

Authorized by:

Position of signatory

QR Code

AB Symbol Mark

The authenticity of this certificate can be verified in the FSSC 22000 database of Certified Organizations available on www.fssc22000.com.

4. FSSC 22000 WITHMULTI-SITE ACTIVITIESCERTIFICATION



The Food Safety Management System of

Name of Organization

Location, Country

has been assessed and determined to comply with the requirements of

Food Safety System Certification 22000 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 at as detailed in Addendum 1 4 (when applicable for E and FI) Sampling was performed (not GFSI recognized) 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 of registration number:		
Certification decision date:		AB <mark>Symbol</mark> Mark
Initial certification date:	Authorized by:	
Issue date:	Position of signatory	
Valid until:		
Issued by:		QR Code
Name and address of certification body	CB Mark logo	-

The authenticity of this certificate can be verified in the FSSC 22000 database of Certified Organizations available on <u>www.fssc22000.com</u>.



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 of 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 logo

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FOOD SAFETY SYSTEM CERTIFICATION 22000

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 22002-3,	Food Safety System Certification 22000 (FSSC 22000) Version 5.1 for the following cluster and categories:				
Additional FSSC 22000	Cluster Farming				
requirements					
	Al: Farming of animals for meat, milk, eggs, and honey				
	All: Farming of fish and seafood				
	Accreditation granted in accordance with ISO/IEC 17021-1: 2015 and ISO/TS 22003:2013				
ISO 22000, ISO/TS 22002-1,	Food Safety System Certification 22000 (FSSC 22000) Version 6 for the following cluster and categories:				
Additional FSSC 22000	Cluster Primary Production				
requirements	- 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,	Food Safety System Certification 22000 (FSSC 22000) Version 6 for the following clusters and categories:				
Additional FSSC 22000 requirements	Cluster Food and feed processing Processing food for humans and animals				
	 Category C, Food, ingredient and pet food processing manufacturing 				
	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/TS 22003;2013 ISO 22003-1:2022.				
ISO 22000,	Food Safety System Certification 22000 (FSSC 22000) Version 5.1				
ISO/TS 22002-1,	for the following clusters and categories:				
Additional FSSC 22000	Cluster Food and feed processing				
requirements	 Category D, Animal feed production Dlla: Production of pet food (for dogs and cats only) 				
	Accreditation granted in accordance with ISO/IEC 17021-1: 2015 and ISO/TS 22003:2013.				

Normative documents	Certification scheme
ISO 22000, ISO/TS 22002-6,	Food Safety System Certification 22000 (FSSC 22000) Version 6 for the following cluster and categories:
Additional FSSC 22000 requirements	Cluster Food and feed processing Processing food for humans and animals
	 Category D, Animal feed production Feed and animal food processing DI: Production of feed
	DIIb: Production of pet food (other than cats and dogs)
	Accreditation granted in accordance with ISO/IEC 17021-1: 2015 and ISO/TS 22003:2013 ISO 22003-1:2022.
ISO 22000, ISO/TS 22002-2,	Food Safety System Certification 22000 (FSSC 22000) Version <mark>6</mark> for the following cluster and category:
Additional FSSC 22000	Cluster Catering/food service
requirements	 Category E, Catering/food service
	Accreditation granted in accordance with ISO/IEC 17021-1: 2015 and ISO/TS 22003:2013-ISO 22003-1:2022 .
ISO 22000, BSI/PAS 221,	Food Safety System Certification 22000 (FSSC 22000) Version <mark>6</mark> for the following cluster and category:
Additional FSSC 22000	Cluster Retail, transport, and storage:
requirements	 Category F, Distribution Trading, retail and e-commerce FI: Retail / Wholesale
	Accreditation granted in accordance with ISO/IEC 17021-1: 2015 and ISO/TS 22003:2013-ISO 22003-1:2022 .
ISO 22000,	Food Safety System Certification 22000 (FSSC 22000) Version 6 for the following cluster and category:
Additional FSSC 22000 requirements	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,	Food Safety System Certification 22000 (FSSC 22000) Version 6 for the following cluster and categories:
Additional FSSC 22000	Cluster Retail, transport, and storage
requirements	- Category G, Provision of Transport and storage services
	GI: Provision of transport and storage services for
	perishable food & feed Gll: Provision of transport and storage services for
	ambient stable food & feed



Normative documents	Certification scheme
	Accreditation granted in accordance with ISO/IEC 17021-1: 2015 and ISO/TS 22003:2013 ISO 22003-1:2022.
ISO 22000, ISO/TS 22002-4, Additional FSSC 22000	Food Safety System Certification 22000 (FSSC 22000) Version 6 for the following cluster and category:
requirements	Cluster Auxiliary services Packaging Material
	 Category I, Production of food and feed packaging and packaging material
	Accreditation granted in accordance with ISO/IEC 17021-1: 2015 and ISO/TS 22003:2013 ISO 22003-1:2022.
ISO 22000, ISO/TS 22002-1,	Food Safety System Certification 22000 (FSSC 22000) Version <mark>6</mark> for the following cluster and category:
Additional FSSC 22000 requirements	Cluster (Bio)chemical Bio/chemical
	- Category K, Production of Chemical and bio-chemical
	(excluding pesticides, drugs, fertilizers, and cleaning
	agents)
	Accreditation granted in accordance with ISO/IEC 17021-1: 2015 and ISO/TS 22003:2013 ISO 22003-1:2022.
ISO 22000, relevant PRP	Food Safety System Certification 22000 (FSSC 22000) Version 5.1 for the following category and scopes:
requirements , ISO 9001 ,	Category: FSSC 22000-Quality
Additional FSSC 22000 requirements	Scopes: Reference to IAF ID1 sector codes
	1. Agriculture and fishing (combined with ISO/TS 22002-3)
	 - 3. Food products and beverages (combined with ISO/TS
	22002-1 or ISO 22002-6)
	 — 29. Wholesale and retail trade (combined with BSI/PAS 221)
	∠∠+)
	 - 30. Hotels and restaurants (combined with ISO/TS 22002- 2)
	- 6. Wood and wood products (combined with ISO/TS 22002-4)

Normative documents	Certification scheme
	- 7. Pulp, paper, and paper products (combined with ISO/TS 22002-4)
	 — 14. Rubber and plastic products (combined with ISO/TS 22002-4)
	 — 17. Basic metals and fabricated metal products (combined with ISO/TS 22002-4)
	Accreditation granted for FSMS activities in accordance with ISO/IEC 17021-1: 2015 and ISO/TS 22003:2013.





FOOD SAFETY SYSTEM CERTIFICATION 22000

ANNEX 59: CB REQUIREMENTS FOR THE USE OF INFORMATION AND COMMUNICATION TECHNOLOGY (ICT)

Version 6 | April 2023



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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, analysing 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 to be mutually agreed upon between the CB and the certified organization prior to the audit.

The ICT audit approach consists of two (2) main steps 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.

In the first instance, tThe CB shall conduct an 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 the ability to provide 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) for the sub-category. 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 time 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-as towards audit duration time. Provisions for ensuring audit duration time 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.
- I) As an exception, and only in the case of serious events as defined by the Scheme (see Appendix 1), 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 portal 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.

It can also 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 part 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

The full Stage 1 audit may be conducted off-site (ISO/TS22003 clause 9.2.3.1.3) with the use of ICT. 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 timelines as referenced above are exceeded, the full surveillance audit shall be conducted on-site and in line with the audit programme or 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 and it is



preferred that the same auditor is used for both the remote and the on-site audit to ensure continuity. Where different auditors are used for the remote and on-site audit components, the competency requirements as defined in the Scheme shall be met and. 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 remote audit are examples of what may shall at least be included as part of the document a review undertaken during the remote audit component of the following key FSMS elements:

- Document/procedure reviews;
- HACCP plans and 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;
- Interviews with management and key personnel;

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 aligned to (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 on-site 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 remote audit 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 remote first audit component shall be recorded, and a copy of the nonconformity report left with the certified organization at the end of the remote first audit component. The timeline for closure of these nonconformities starts at the end of the remote first audit



component. The NC report produced following the on-site last audit component shall contain an overview of all the nonconformities raised, including the nonconformities raised at the remote first audit component, to provide a consolidated record. The timeline for the closure of NCs identified at the on-site last audit component starts at the end of the on-site last audit component.

iii. Where a critical nonconformity is identified at any time during the audit (remote or onsite), 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 needs to 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 parts. The requirements assessed during the remote audit shall be identified by placing a "R" at the beginning of the information.

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

The certification audit is only concluded once both the remote audit and the on-site audit components have been successfully completed. Following completion of the full audit (step 1 & 2 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 approved_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.