



FSSC 22000 SCHEME VERSION 5.1

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TRANSLATIONS

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

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INTRODUCTION

With a growing world population, there is an increasing need for affordable, safe, and good quality food products. To fulfill this need, FSSC 22000 provides a trusted brand assurance platform to the food industry. Key in this mission is the availability of the FSSC 22000 certification Scheme for food safety management systems. This document contains the new Version 5.1 of the FSSC 22000 Scheme published in November 2020. The main factors that initiated the development of this version have been:

- Incorporating the GFSI benchmarking requirements version 2020.1
- Strengthening the licensing process and the Integrity Program
- Minor editorial changes or amendments to the V5 Scheme requirements

ABOUT THE SCHEME

The Scheme consists of six Parts and two Appendices which are bundled in this document. Furthermore, there are nine Annexes. All these documents also contain mandatory Scheme requirements. Lastly, there are guidance documents on several topics to provide additional support. All documents can be downloaded for free from the FSSC 22000 website.

HOW THE SCHEME IS ORGANIZED

PART 1 SCHEME OVERVIEW

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

PART 2 REQUIREMENTS FOR ORGANIZATIONS TO BE AUDITED

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

PART 3 REQUIREMENTS FOR THE CERTIFICATION PROCESS

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

PART 4 REQUIREMENTS FOR CERTIFICATION BODIES

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

PART 5 REQUIREMENTS FOR ACCREDITATION BODIES

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

PART 6 REQUIREMENTS FOR TRAINING ORGANIZATIONS

This part describes the requirements for licensed Training Organizations (TOs) who wish to provide approved Scheme training courses.

APPENDIX 1 DEFINITIONS

This part contains all definitions that have been used throughout all Scheme documents.

APPENDIX 2 NORMATIVE REFERENCES

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

ANNEXES

There are nine Annexes which are mandatory and necessary for proper implementation of the Scheme:

- Annex 1 CB Certificate scope statements
- Annex 2 CB Audit report template (FSSC 22000)
- Annex 3 CB Audit report template (FSSC 22000-Quality)
- Annex 4 CB Certificate templates
- Annex 5 AB Accreditation certificate scope
- Annex 6 TO Course specifications
- Annex 7 TO Training certificate templates
- Annex 8 E-learning requirements for training organizations
- Annex 9 CB Requirements for the use of information and communication technology (ICT)

PART 1 **SCHEME OVERVIEW**

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1 INTRODUCTION

1.1 THE SCHEME

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

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

- ISO 22000 requirements for any organization in the food chain;
- ISO 9001 requirements (where FSSC 22000-Quality is required);
- Relevant prerequisite programs (PRPs) based on technical specifications for the sector (e.g., ISO/TS 22002-x; PAS xyz); and
- FSSC 22000 Additional Requirements as determined by our stakeholders.

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

The Scheme provides a voluntary certification model that can be applied across the entire food supply chain. It can cover supply chain sectors where specific prerequisite programs (PRPs) have been developed and accepted. The food chain category description used by this Scheme is defined according to ISO/TS 22003:2013 (see Chapter 3).

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

1.2 OWNERSHIP AND GOVERNANCE

The Foundation FSSC 22000 (hereafter the Foundation) retains the ownership and the copyright of all Scheme related documentation and also holds the agreements for all involved Certification Bodies, Accreditation Bodies and Training Organizations.

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

1.3 LANGUAGE

English is the official and valid version of the Scheme.

2 FEATURES

2.1 AIM AND OBJECTIVES

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

The specific Scheme objectives are to:

- a) Establish and maintain an accurate and reliable Register of certified organizations that have demonstrated to comply with the Scheme requirements;
- b) Promote the accurate application of food safety and quality management systems;
- c) Promote national and international recognition and general acceptance of food safety and food safety quality management systems;
- d) Provide information and campaigns on food safety and quality management systems;
- e) Provide support for the certification of food safety management systems in the field of food safety and quality.

The Foundation endeavors to achieve these objectives by:

- a) Entering into agreements with Certification Bodies, Accreditation Bodies and Training Organizations;
- b) Taking appropriate measures in the event of abuse or improper use of the certificates issued by licensed Certification Bodies or Training Organizations;
- c) Taking appropriate measures in the event of abuse or improper use of the Foundation's FSSC 22000 logo;
- d) Supporting, supervising, and financing of other foundations and organizations which strive to achieve similar or partially similar objectives as mentioned above.

2.2 NATURE OF THE SCHEME

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

The Scheme:

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

3 SCOPE

The Scheme is intended for the audit, certification, and registration of organizations for the following food chain (sub)categories (in line with ISO/TS 22003:2013; see also Table 1):

Table 1. Overview of (Sub)Categories

Category	Subcategory	Description	Example of included activities and products	Normative Documents
A	AI	Farming of animals for meat/milk/eggs/honey	Raising animals used for meat production, egg production, milk production or honey production (associated farm packing and storage).	ISO 22000: 2018 ISO/TS 22002-3, FSSC 22000 Additional requirements
	AII	Farming of Fish and seafood	Raising fish and seafood used for meat production (associated farm packing and storage).	ISO 22000: 2018 ISO/TS 22002-3, FSSC 22000 Additional requirements
C	CI	Processing of perishable animal products	Slaughtering, deboning, evisceration, gutting, cutting, sorting, washing, pasteurizing, trimming, curing, fermentation, smoking, freezing, chilling, cooling, scalding. Final product examples: fish, meat, poultry, eggs, frozen and/or chilled dairy products and fish/seafood products.	ISO 22000:2018, ISO/TS 22002-1:2009, FSSC 22000 Additional requirements
C	CII	Processing of perishable plant products	De-shelling, drying, packing, sorting, washing, rinsing, fluming, trimming, slicing, pasteurizing, roasting, scalding, peeling, de-husking, cooling, chilling, freezing and final product. Final product examples: chilled or frozen e.g., fresh fruits, fresh juices, vegetables, grains, nuts and pulses, meat replacers based on plant materials (e.g., soy), frozen water-based products	ISO 22000:2018, ISO/TS 22002-1:2009, FSSC 22000 Additional requirements
	CIII	Processing of perishable animal and plant products (mixed products)	Mixing, cooking, packing, ensemble cooling, chilling, freezing Final products e.g., mixed products, pizza, lasagna, sandwich, dumplings, ready-to-eat meals.	ISO 22000:2018, ISO/TS 22002-1:2009, FSSC 22000 Additional requirements

Category	Subcategory	Description	Example of included activities and products	Normative Documents
	CIV	Processing of ambient stable products	Mixing, cooking, packing, bottling, brewing, drying, pressing, milling, blending, roasting, refining, ensemble, distilling, drying, canning, pasteurizing, sterilization. Final product examples: canned products, biscuits, bread, snacks, oil, drinking water, beverages alcoholic and nonalcoholic, pasta, flour, sugar, food-grade salt, dairy products with long shelf life, margarines.	ISO 22000:2018, ISO/TS 22002-1:2009, FSSC 22000 Additional requirements
D	DI	Production of feed	Production of single or multiple products, whether processed, semi-processed or raw, which are intended to be fed to food producing animals	ISO 22000:2018, ISO/TS 22002-6:2016, FSSC 22000 Additional requirements
	DIIa	Production of pet food (only for dogs and cats).	Production of single or multiple products, whether processed, semi-processed or raw, which are intended to be fed to non-food producing animals being dogs and cats. Examples: Dry and wet pet food, treats, cooled, chilled, frozen, and ambient stable.	ISO 22000:2018, ISO/TS 22002-1:2009, FSSC 22000 Additional requirements
	DIIb	Production of pet food (for other pets).	Production of single or multiple products, whether processed, semi-processed or raw, which are intended to be fed to non-food producing animals other than dogs and cats. Examples: Dry and wet pet food, treats, cooled, chilled, frozen, and ambient stable.	ISO 22000:2018, ISO/TS 22002-6:2016, FSSC 22000 Additional requirements
E	EI	Catering	Activities in restaurants, hotels, workplace cafeterias, handling foods at remote sites, transport, and delivery directly to consumers. Activities for coffee shops, food trucks and event catering.	ISO 22000:2018, ISO/TS 22002-2:2013, FSSC 22000 Additional requirements

Category	Subcategory	Description	Example of included activities and products	Normative Documents
F	FI	Retail /Wholesale	<p>Activities: receipt, picking, storage, display of food products, dispatch, transport, and delivery</p> <p>Examples: supermarkets; hypermarkets; convenience stores; cash and carry; mass/club stores, wholesalers selling to restaurants</p>	ISO 22000:2018, BSI/PAS 221:2013, FSSC 22000 Additional requirements
G	GI	Provision of transport and storage services for perishable food and feed.	Transport and storage with cooling, chilling, or frozen temperatures. Additional activities such as re-packing of packed product, freezing and thawing.	ISO 22000:2018, ISO/TS 22002-5:2019, FSSC 22000 Additional requirements
	GII	Provision of transport and storage services for ambient stable food, feed, and packaging materials.	Transport and storage. Additional activities such as re-packing of packed product.	ISO 22000:2018, ISO/TS 22002-5:2019, FSSC 22000 Additional requirements
I	I	Production of food packaging and packaging materials.	<p>All manufacturing activities for plastic, carton, paper, metal, glass, wood, and other materials to be used as packaging materials in the food/feed industry.</p> <p>Examples: bottles, boxes, jars, barrels, cork, cans; devices for closing packaging materials such as tape, plastic strips, or other when the manufacturer can prove that they belong to a food/feed packaging material; Production of labels with direct food contact.</p>	ISO 22000:2018, ISO/TS 22002-4:2013, FSSC 22000 Additional requirements
K	K	Production of Bio-chemicals	<p>Mixing, cooking, packing, distilling, drying, canning, sterilization for all products at ambient, chilled, and frozen temperatures.</p> <p>Final products: e.g., food and feed additives, vitamins, minerals, bio-cultures, flavorings, enzymes and processing aids, gases as ingredients and/or packaging gas.</p>	ISO 22000:2018, ISO/TS 22002-1:2009, FSSC 22000 Additional requirements

3.1 FARMING OF ANIMALS (CATEGORY A)

Food chain subcategory AI refers to farming of livestock animals on land for human consumption. Activities such as hunting, or trapping are not included.

3.2 FOOD MANUFACTURING (CATEGORY C)

Food chain category C involves the following food processing activities:

- a) Processing of perishable animal products. Production of animal products including fish and seafood, meat, eggs, dairy and fish products.
- b) Processing of perishable plant products. Production of plant products including fresh fruits and fresh juices, vegetables, grains, nuts, and pulses, frozen water-based products (e.g., ice).
- c) Processing of perishable animal and plant products. Production of mixed animal and plant products including pizza, lasagna, sandwich, dumpling, ready-to-eat meals.
- d) Processing of ambient stable products. Production of food products from any source that are stored and sold at ambient temperature, including canned foods, biscuits, bread, snacks, oil, drinking water, beverages, pasta, flour, sugar, food-grade salt.

3.3 ANIMAL FEED PRODUCTION (CATEGORY D)

Food chain category D covers the production of animal feed and pet food:

- a) Production of feed from a single or mixed food source, intended for food-producing animals.
- b) Production of pet food (only for dogs and cats). Production of feed from a single or mixed food source, intended for non-food producing animals.
- c) Production of pet food (for other pets).

3.4 CATERING (CATEGORY E)

Food chain category E applies when the catering service is delivered to consumers. The food is prepared at the place of consumption or at a satellite unit.

Examples include:

- Production units/kitchens that serve food directly to the consumer or offer food for immediate consumption, e.g., restaurants, hotels, cafeterias;
- Catering handling foods at remote site with direct serving to consumers, e.g., canteens, coffee shops, food trucks and event catering.

3.5 RETAIL AND WHOLESALE (CATEGORY F)

Food chain category FI applies to retail and wholesale activities.

Retail is defined as selling goods to the final customer (i.e., consumer), in small quantities for consumption and not for the purpose of resale. Retailers shall have physical building and facilities (i.e., shops). The retailer may offer internet sales or home deliveries that may be included in the scope only when linked to the physical retail location but not as a stand-alone activity.

Wholesale is defined as the buying of goods from manufacturers or other sellers and selling of goods to other businesses like retailers, industries, and occasionally end consumers. The wholesaler may offer internet sales or deliveries that may be included in the scope only when linked to the physical wholesale location but not as a stand-alone activity.

Wholesalers always take ownership of the products and activities may include food, feed and/or packaging products for food and feed.

For both retail and wholesale, in-shop activities that only serve to give pre-prepared food a final process step may be included (e.g., grilling of meat, bake-off of bread, cutting meat or fish).

3.6 TRANSPORT AND STORAGE (CATEGORY G)

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

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

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

Food chain category I covers packaging that includes the production of food/feed packaging, food/feed packaging materials and intermediate products for:

- a) Direct food contact surfaces or materials (i.e., physically touching the food or in contact with headspace) that will be in contact with the food during normal use of the food packaging and/or;
- b) Indirect food contact surfaces or materials that are not in direct contact with the food during normal use of the food packaging, but there is the possibility for substances to be transferred into the food.

Packaging material used for personal care, pharmacy or other uses are outside the scope of the standard. Disposable tableware can only be certified when it is sold together (and as part of) the food product. Examples are spoons that are packed with yoghurt, forks or chopsticks packed with ready-to-eat food. The intended use, including that it is sold together (and as part of) the food product, shall be clearly specified in the scope statement.

3.8 PRODUCTION OF BIOCHEMICALS (CATEGORY K)

Food chain category K involves the production of Bio-Chemicals and applies to the production of food and feed additives, vitamins, minerals, bio-cultures, flavorings, enzymes, and processing aids but excludes pesticides, drugs, fertilizers, and cleaning agents.

3.9 FSSC 22000 - QUALITY

FSSC 22000-Quality certification is a voluntary addition to the FSSC 22000 certification requirements and supplements these requirements with all those of ISO 9001:2015 for Quality Management Systems resulting in a FSSC 22000 certificate for the category FSSC 22000-Quality.

The requirements for the development, implementation and maintenance of a quality management system are laid down in the standard ISO 9001:2015 "Quality Management Systems - Requirements".

PART 2
REQUIREMENTS
FOR
ORGANIZATIONS
TO BE AUDITED

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1 PURPOSE

This part describes the Scheme requirements against which licensed Certification Bodies shall audit the Food Safety Management System (FSMS) or FSMS and Quality Management System (QMS) of the organization in order to achieve or maintain certification for FSSC 22000 or FSSC 22000-Quality, respectively.

2 REQUIREMENTS

2.1 GENERAL

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

The audit requirements for FSSC 22000 certification consist of:

- 1) ISO 22000:2018 food safety management system requirements;
- 2) Sector specific prerequisite program (PRPs) requirements (ISO/TS 22002-x series or other specified PRP standard) and;
- 3) FSSC 22000 Additional requirements.

The audit requirements for FSSC 22000-Quality certification consist of:

- 1) ISO 22000:2018 food safety management system requirements;
- 2) ISO 9001:2015 quality management system requirements;
- 3) Sector specific prerequisite program (PRPs) requirements (ISO/TS 22002-x series or other specified PRP standard) and;
- 4) FSSC 22000 Additional requirements.

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

2.2 ISO 22000

For both FSSC 22000 and FSSC 22000-Quality certification, the requirements for the development, implementation, and maintenance of the Food Safety Management System (FSMS) are laid down in the standard ISO 22000:2018 "Food safety management systems - Requirements for any organization in the food chain".

2.3 ISO 9001

For FSSC 22000-Quality certification, the requirements for the development, implementation, and maintenance of the Quality Management System (QMS) are laid down in the standard ISO 9001:2015 "Quality management system - Requirements".

2.4 PREREQUISITE PROGRAMS

The Scheme specifies mandatory application of technical specifications detailing the pre-requisite programs (PRPs) as referenced in clause 8.2 of ISO 22000:2018. These PRP requirements are specified in the ISO/TS 22002-x series and/or the BSI/PAS 221 standards.

2.5 FSSC 22000 ADDITIONAL REQUIREMENTS

2.5.1 MANAGEMENT OF SERVICES AND PURCHASED MATERIALS

- a) In addition to clause 7.1.6 of ISO 22000:2018, the organization shall ensure that where laboratory analysis services are used for the verification and/or validation of food safety, these shall be conducted by a competent laboratory (including both internal and external laboratories as applicable) that has the capability to produce precise and repeatable test results using validated test methods and best practices (e.g. successful participation in proficiency testing programs, regulatory approved programs or accreditation to international standards such as ISO 17025).
- b) For food chain categories C, D, I, G and K, the following additional requirement applies to ISO 22000:2018 clause 7.1.6:
The organization shall have a documented procedure for procurement in emergency situations to ensure that products still conform to specified requirements and the supplier has been evaluated.
- c) In addition to ISO/TS 22002-1:2009 clause 9.2, the organization shall have a policy for the procurement of animals, fish and seafood that are subject to control of prohibited substances (e.g., pharmaceuticals, veterinary medicines, heavy metals, and pesticides);
- d) For food chain categories C, D, I, G and K, the following additional requirement applies to ISO/TS 22002-1 clause 9.2; ISO/TS 22002-4 clause 4.6 and ISO/TS 22002-5 clause 4:
The organization shall establish, implement, and maintain a review process for product specifications to ensure continued compliance with food safety, legal and customer requirements.

2.5.2 PRODUCT LABELLING

In addition to clause 8.5.1.3 of ISO 22000:2018, the organization shall ensure that finished products are labelled according to all applicable statutory and regulatory requirements in the country of intended sale, including allergen and customer specific requirements.

Where product is unlabeled, all relevant product information shall be made available to ensure the safe use of the food by the customer or consumer.

2.5.3 FOOD DEFENSE

2.5.3.1 THREAT ASSESSMENT

The organization shall have a documented procedure in place to:

- a) Conduct a threat assessment to identify and assess potential threats;
- b) Develop and implement mitigation measures for significant threats.

2.5.3.2 PLAN

- a) The organization shall have a documented food defense plan specifying the mitigation measures covering the processes and products within the FSMS scope of the organization.
- b) The food defense plan shall be supported by the organization's FSMS.
- c) The plan shall comply with applicable legislation and be kept up to date.

2.5.4 FOOD FRAUD MITIGATION

2.5.4.1 VULNERABILITY ASSESSMENT

The organization shall have a documented procedure in place to:

- a) Conduct a food fraud vulnerability assessment to identify and assess potential vulnerabilities;
- b) Develop and implement mitigation measures for significant vulnerabilities.

2.5.4.2 PLAN

- a) The organization shall have a documented food fraud mitigation plan specifying the mitigation measures covering the processes and products within the FSMS scope of the organization.
- b) The food fraud mitigation plan shall be supported by the organization's FSMS.
- c) The plan shall comply with the applicable legislation and be kept up to date.

2.5.5 LOGO USE

- a) Certified organizations, Certification Bodies and Training Organizations shall use the FSSC 22000 logo only for marketing activities such as organization's printed matter, website, and another promotional material.
- b) In case of using the logo, the organization shall comply with the following specifications:

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

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

- c) The certified organization is not allowed to use the FSSC 22000 logo, any statement or make reference to its certified status on:
 - i. a product;
 - ii. its labelling;
 - iii. its packaging (primary, secondary or any other form);
 - iv. in any other manner that implies FSSC 22000 approves a product, process, or service.

2.5.6 MANAGEMENT OF ALLERGENS (FOOD CHAIN CATEGORIES C, E, FI, G, I & K)

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

- a) Risk assessment covering all potential sources of allergen cross-contamination and;

- b) Control measures to reduce or eliminate the risk of cross-contamination.

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

The organization shall have in place:

- a) Risk-based environmental monitoring program;
- b) Documented procedure for the evaluation of the effectiveness of all controls on preventing contamination from the manufacturing environment and this shall include, at a minimum, the evaluation of microbiological and allergen controls present;
- c) Data of the monitoring activities including regular trend analysis.

2.5.8 FORMULATION OF PRODUCTS (FOOD CHAIN CATEGORY D)

The organization shall have in place procedures to manage the use of ingredients that contain nutrients that can have adverse animal health impact.

2.5.9 TRANSPORT AND DELIVERY (FOOD CHAIN CATEGORY FI)

The organization shall ensure that product is transported and delivered under conditions which minimize the potential for contamination.

2.5.10 STORAGE AND WAREHOUSING (ALL FOOD CHAIN CATEGORIES)

- a) The organization shall establish, implement, and maintain a procedure and specified stock rotation system that includes FEFO principles in conjunction with the FIFO requirements.
- b) In addition to ISO/TS 22002-1:2009 clause 16.2, the organization shall have specified requirements in place that define post-slaughter time and temperature in relation with chilling or freezing of the products.

2.5.11 HAZARD CONTROL AND MEASURES FOR PREVENTING CROSS-CONTAMINATION (FOOD CHAIN CATEGORIES C & I)

- a) For food chain category I, the following additional requirement applies to ISO 22000:2018 clause 8.5.1.3:
 - The organization shall have specified requirements in place in case packaging is used to impart or provide a functional effect on food (e.g., shelf-life extension).
- b) For food chain category CI, the following requirement apply in addition to ISO/TS 22002-1:2009 clause 10.1:
 - The organization shall have specified requirements for an inspection process at lairage and/or at evisceration to ensure animals are fit for human consumption;

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

For food chain categories C, D, G, I and K, the following additional requirement applies to ISO22000: 2018 clause 8.8.1:

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

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

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

- a) Evaluation of the impact of the change on the FSMS taking into account any new food safety hazards (incl. allergens) introduced and updating the hazard analysis accordingly,
- b) Consideration of the impact on the process flow for the new product and existing products and processes,
- c) Resource and training needs,
- d) Equipment and maintenance requirements,
- e) The need to conduct production and shelf-life trials to validate product formulation and processes are capable of producing a safe product and meet customer requirements.

2.5.14 HEALTH STATUS (FOOD CHAIN CATEGORY D)

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

2.5.15 REQUIREMENTS FOR ORGANIZATIONS WITH MULTI-SITE CERTIFICATION (FOOD CHAIN CATEGORY A, E, FI & G)

2.5.15.1 – Central function

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

2.5.15.2 - Internal Audit Requirements

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

Work experience: 2 years' full time work experience in the food industry including at least 1 year in the organization.

Education: completion of a higher education course or in the absence of a formal course, have at least 5 years work experience in the food production or manufacturing, transport, and storage, retailing, inspection or enforcement areas.

Training:

- i. For FSSC 22000 internal audits, the lead auditor shall have successfully completed a FSMS, QMS or FSSC 22000 Lead Auditor Course of 40 hours.

- ii. Other auditors in the internal audit team shall have successfully completed an internal auditor course of 16 hours covering audit principles, practices, and techniques. The training may be provided by the qualified internal Lead Auditor or through an external training provider.
 - iii. FSSC scheme training covering at least ISO 22000, the relevant prerequisite programs based on the technical specification for the sector (e.g., ISO/TS 22002-x; PAS-xyz) and the FSSC additional requirements – minimum 8 hours.
- d) Internal audit reports shall be subject to a technical review by the central function, including addressing the non-conformities resulting from the internal audit. Technical reviewers shall be impartial, have the ability to interpret and apply the FSSC normative documents (at least ISO 22000, the relevant ISO/TS 22002-x; PAS-xyz and the FSSC additional requirements) and have knowledge of the organizations processes and systems.
- e) Internal auditors and technical reviewers shall be subject to annual performance monitoring and calibration. Any follow-up actions identified shall be suitably actioned in a timely and appropriate manner by the Central function.

PART 3
REQUIREMENTS
FOR THE
CERTIFICATION
PROCESS

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1 PURPOSE

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

Where reference to FSSC 22000 requirements is made, this is also applicable for FSSC 22000-Quality unless stated otherwise.

2 GENERAL

The CB shall manage its certification management system according to the requirements of ISO/IEC 17021-1:2015, ISO/TS 22003:2013, and the FSSC 22000 requirements including any FSSC Board of Stakeholder decisions.

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

The CB shall have procedures of certification that confirm the compliance of the certified organizations.

3 RESOURCES

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

4 CONTRACT PROCESS

4.1 APPLICATION

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

4.2 SCOPE

The CB shall assess the scope proposed by the organization on the application form and review it against the requirements in Annex 1.

4.3 AUDIT DURATION

The CB shall calculate the audit duration based on the information gathered from the organization's application and following the requirements of ISO/IEC 17021-1, ISO/TS 22003 and FSSC 22000 as follows:

- a) The duration of an audit day normally is eight (8) hours; the effective audit duration does not include a lunch break (unless in contradiction with local legislation);

- b) The audit duration calculation for FSSC 22000 shall be documented by the CB, including justifications for reduction or addition of time based on the minimum audit duration;
- c) The audit duration shall be stated in auditor working hours indicating the effective audit time based on the audit plan. Deviations to the audit durations and audit plan shall be recorded (including motivations);
- d) The audit duration does not include planning, reporting or travel activities, only actual auditing time;
- e) The audit time shall only apply to auditors that are fully qualified, registered FSSC 22000 auditors;
- f) Where the FSSC 22000 audit is undertaken in combination or integration with other food safety audits as a combined audit, the audit duration stated in the report shall be of the total combined audit and be aligned with the audit plan. Total audit duration is then longer than for FSSC 22000 alone. This is considered as an increase in audit duration and the reason for this shall be justified.

4.3.1 BASIC AUDIT TIME CALCULATION (SINGLE SITE)

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

- a) $T_s = (T_D + T_H + T_{MS} + T_{FTE})$ calculated according to ISO/TS 22003:2013; and
- b) T_{FSSC} shall be calculated as follows:
 - i) 0.5 auditor day (4 working hours) when the company has less than 250 FTE and 1 or 2 HACCP studies.
 - ii) 1.0 auditor day (8 working hours) when the organization has 250 FTE or more; or 3 HACCP studies or more.

When properly documented and justified, a reduction of the T_s audit time can be made in accordance with ISO/TS 22003:2013, Annex B. The reduction in T_s audit time can never be more than 0.25 auditor day (2 working hours) and the T_s cannot be reduced below 1 day. The reduction cannot be applied on T_{FSSC} .

Preparation and reporting time shall be in addition to the audit time:

- a) At least 0.25 auditor day (2 working hours) shall be added to the FSSC 22000 site audit time for audit preparation.
- b) At least 0.5 auditor day (4 working hours) additional shall be added to the FSSC 22000 site audit time for audit reporting.

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

4.3.2 SURVEILLANCE AND RECERTIFICATION AUDITS

- a) Surveillance audits: audit duration shall be (one-third of T_s) + (T_{FSSC}), plus any other additional audit time (as per §4.3.4 below).
- b) Recertification audits: audit duration shall be (two-thirds of T_s) + (T_{FSSC}), plus any other additional audit time (as per §4.3.4 below).

Additional (special) audits may be performed on top – but never as a replacement of the annual surveillance/recertification audits. These special audits shall be documented and uploaded in the Portal.

4.3.3 MINIMUM AUDIT DURATION

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

- a) The minimum T_s is 1 day as per ISO/TS 22003, Annex B.
- b) The minimum basic FSSC 22000 audit duration is then 1.5 - 2 days depending on the FSSC additional time (refer 4.3.1 b); however, for categories C, D, I and K the minimum audit duration shall always be 2 days;
- c) The minimum audit duration for the annual audits shall always be respected.

The following exemptions apply to the minimum audit durations:

- a) For organizations with simple processes, having 5 FTE or less and maximum 1 HACCP study, further reductions are allowed, but the total time $T_s + T_{FSSC}$ shall be minimum one day for all audit types.
- b) For organizations in category C, D, I or K that have simple processes, less than 20 FTE and maximum 1 HACCP study, further reductions are allowed to a minimum audit duration of 1.5 days for all audit types.
- c) For subcategory A, ISO/TS 22003:2013 states a minimum audit duration of 0.5 days, the minimum FSSC 22000 audit duration for this category shall be 1 day.

Where any of the exemptions above are applied, the CB shall ensure that the audit duration allows for an effective audit, covering the full FSSC 22000 requirements.

4.3.4 ADDITIONAL AUDIT TIME

Additional time shall be required for the following situations:

- a) Separate Head Office
 - i. For organizations where some functions pertinent to the certification are controlled by a Head Office separate to the manufacturing site(s), the minimum time shall be 0.5 auditor day (4 working hours) to audit the functions pertinent to the certification at the Head Office.
 - ii. When the responsible person from the Head Office attends the audit at manufacturing site, no extra audit time is calculated.
 - iii. A maximum of 20% audit time reduction can be allowed for each of the single manufacturing sites belonging to the group where the shared functions are controlled by the (off-site) Head Office. The 20% audit time reduction is applied to the minimum audit time (T_s) as per ISO/TS 22003:2013, Annex B.

- b) Off-site activities

Where off-site manufacturing or service activities take place (see §5.2.2), a 50% audit time reduction of T_s may be applied for each additional site OR the parameters of the off-site activities shall be included in the audit calculation as under §4.3 and travel time between locations shall be included in the audit plan.

For off-site storage: At least 0.25 auditor day (2 working hours) additional audit time shall be added to the FSSC 22000 audit time for each off-site storage facility.

Cross docking is considered as an off-site activity which is covered by FSSC Part 3, section 5.2.2 with the exclusion of the last phrase of section 5.2.2, 1, which is the requirement with regard to the sole receiver/customer relationship. The requirements including audit duration calculations related to off-site activities may be applied for cross docking. Transshipment is not covered in this requirement.

- c) Additional time shall be considered in case an interpreter is required to support the audit team.

4.3.5 FSSC 22000-QUALITY

- a) The audit time for the ISO 9001 part of the audit shall be calculated using IAF MD 5.
- b) The audit duration for the integrated FSSC 22000 and ISO 9001 audit shall be based on IAF MD 11:2019, section 2.2, to which T_{FSSC} shall be added.

4.3.6 TRANSITION TO FSSC 22000

- 1) When transitioning from ISO 22000 or an equivalent GFSI recognized certification to FSSC 22000 certification, the minimum FSSC 22000 certification audit duration shall be two-thirds of the initial certification audit time, with a minimum of 1 auditor day (8 working hours plus T_{FSSC} as defined in §4.3.1.
The transition audit shall result in an FSSC 22000 certificate with a validity of three (3) years.
- 2) Transition to FSSC 22000-Quality is only possible when the organization has a valid ISO 22000 or FSSC 22000 certificate AND a valid ISO 9001 certificate. In this case, the audit duration is two-thirds of the initial combined audit time (see 4.3.5.) plus T_{FSSC} .

4.4 CONTRACT

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

This contract shall detail or have reference to the agreements between the CB and the organization which shall include but are not limited to:

- 1) Ownership of the certificate and the audit report content shall be held by the CB;
- 2) Conditions under which the certification contract can be terminated;
- 3) Conditions under which the certificate can be used by the certified organization;
- 4) Terms of confidentiality in relation to information gathered by the CB during the certification process;
- 5) The certified organization allows the CB to share information relating to the certification and auditing process with the Foundation, GFSI and governmental authorities when required;
- 6) Procedures for nonconformity management;
- 7) Procedures for complaints and appeals;
- 8) Inclusion of information on the certified status of the organization on the FSSC 22000 website and in the Portal;
- 9) Cooperation in allowing witness assessments by the AB and/or the Foundation when requested;

- 10) Communication obligations of certified organizations to the CB within 3 working days related to the following:
- a) Any significant changes that affect the compliance with the Scheme requirements and obtain advice of the CB in cases where there is doubt over the significance of a change;
 - b) Serious events that impact the FSMS or FSQMS, legality and/or the integrity of the certification which include legal proceedings, prosecutions, situations which pose major threats to food safety, quality, or certification integrity as a result of natural or man-made disasters (e.g., war, strike, terrorism, crime, flood, earthquake, malicious computer hacking, etc.);
 - c) Public food safety events (such as e.g., public recalls, calamities, food safety outbreaks, etc.);
 - d) Changes to organization name, contact address and site details;
 - e) Changes to organization (e.g., legal, commercial, organizational status or ownership) and management (e.g., key managerial, decision-making, or technical staff);
 - f) Changes to the management system, scope of operations and product categories covered by the certified management system;
 - g) Any other change that renders the information on the certificate inaccurate.

5 PLANNING AND MANAGING AUDITS

5.1 GENERAL

- 1) Annual audits shall take place to ensure certificate validity or that recertification is granted before the expiry date of the certificate.
- 2) The annual audit shall be carried out at the premises of the organization and is a full audit against all Scheme requirements. Surveillance audits shall be conducted within the calendar year as per the requirements of ISO/IEC 17021-1.
- 3) The audit shall be conducted over a continuous number of days in accordance with the audit duration calculated. Where the ICT Audit Approach is utilized, the requirements of Annex 9 apply.
- 4) The audit shall be carried out in a mutually agreed language. An interpreter may be added to the team by the CB to support members of the audit team.
- 5) The CB is expected to operate discretely in case of emergencies (e.g., fire, major catastrophic event, another audit on-going).
- 6) The CB shall perform the stage 1 and stage 2 audits for initial certification according to the requirements of ISO/IEC 17021-1.
- 7) The interval between stage 1 and stage 2 audits shall not be longer than 6 months. The Stage 1 shall be repeated if a longer interval is needed.
- 8) The 3-year certification cycle (ISO/IEC 17021-1 §9.1.3) shall be respected.

5.2 MULTIPLE FUNCTIONS ACROSS MORE THAN ONE SITE

5.2.1 HEAD OFFICE FUNCTIONS

- 1) In all cases where functions pertinent to the certification are controlled by a Head Office (such as procurement, supplier approval, quality assurance etc.), the Scheme requires that those functions be audited, interviewing the personnel described in the food safety management system as having the (delegated) authority and responsibility for these functions. This Head Office audit shall be documented.
- 2) The functions at the Head Office shall be audited separately where they are not part of a site being assessed.
- 3) Every site belonging to the group shall have a:
 - a. Separate audit,
 - b. Separate report and
 - c. Separate certificate
- 4) The Head Office audit shall be carried out prior to the site audit(s).
- 5) The subsequent audit at the site(s) shall include a confirmation that the requirements set out by Head Office are appropriately incorporated into site specific documents and implemented in practice.
- 6) The site audit reports and certificates shall show which FSMS functions and/or processes have been audited at the Head Office.
- 7) All individual sites shall be audited within a time frame of 12 months from the audit of the Head Office.
- 8) The Head Office cannot receive a separate certificate.
- 9) The Head Office is mentioned on the site certificate by use of wording such as

"This audit included the following central FSMS processes managed by (name and location of Head Office): (describe FSMS processes audited at the Head Office)"

5.2.2 OFF-SITE ACTIVITIES

- 1) Where one manufacturing or service process is split across more than one physical address, all locations may be covered in one audit provided that the different addresses are part of the same legal entity, under the same FSMS and that they are the sole receiver/customer of each other.
- 2) Storage facilities at another location shall also be included in the same audit provided they meet the requirements mentioned above.
- 3) The scope statement shall show the audited locations with activities per location (on the certificate or as an Annex to the certificate).
- 4) The audit report shall include all relevant requirements at all locations and allow audit findings to be identified as site specific.

5.3 MULTI-SITE CERTIFICATION

5.3.1 GENERAL

- a) Multi-site certification (including sampling) is only allowed for the following food chain (sub)categories:

- A – Animal Farming
 - E – Catering
 - FI – Retail/wholesale
 - G – Storage and distribution.
- b) When applying multi-site certification all requirements of IAF MD 1 shall be met, except:
- Paragraph 6.1.3 (size of sample). This IAF MD 1 paragraph shall be replaced by the ISO/TS 22003:2013 sampling regime paragraph 9.1.5.4.
 - Paragraph 7.3: For audit time calculation see 4.3.3 where the same principles for a Head Office can be used for the central function.
- c) A multi-site organization need not be a unique legal entity, but all sites shall have a legal or contractual link with the central function of the organization and be subject to a single management system, which is laid down, established and subject to continuous surveillance and internal audits by the central function.
- d) The central function shall be audited at least annually and before the CB audits of the (sampled) sites. If necessary, a small number of the sample sites may be audited prior to the audit of the central function.
- e) One audit report may be produced for the multi-site organization, including the central function information, specific information about each site audited and complying with the content of Annex 2 or Annex 3 (FSSC 22000-Quality). The summary sections of the audit report shall clearly reflect what was audited at each site with supporting objective evidence. Alternatively, separate reports may be produced for the Central function and each of the sites, respectively.
- f) The certificate shall be a group certificate.

5.3.2 SAMPLING METHODOLOGY

- a) The sampling requirements as set out in ISO/TS22003: 2013, paragraph 9.1.5.4 shall form the basis for determining the sample size. In addition, the risk categories and performance of the sites shall be considered and might result in an increase in the sample size.
- b) Where sites are added to the group, an audit is required before adding them to the certificate – either as a special audit or as part of the annual audit.
- c) Once every 3 years, the annual audit shall be conducted fully unannounced as set out in Part 3, section 5.4.1, including the central function and the site audits.

5.3.3 REQUIREMENTS FOR THE CENTRAL FUNCTION

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

5.3.4 NONCONFORMITY MANAGEMENT

Nonconformities raised at multi-site organizations (refer section 5.3) shall follow the requirements of the Scheme as well as those in IAF MD1, section 7.7 with the following specific requirements in addition:

- a) Where a critical nonconformity is identified, the certificate of the multi-site organization shall be suspended within 3 working days of issuing the critical nonconformity, regardless of whether or not all the site audits have been completed.
- b) Where a major nonconformity is identified and the audit takes more than 30 calendar days to complete (central function and site audits), the organization shall provide a corrective action plan including any temporary measures or controls necessary to mitigate the risk until the nonconformity can be closed.
- c) The timeline for closure of nonconformities starts at the end of the audit – after completion of the central function audit and all the site audits.

5.4 UNANNOUNCED AUDITS

5.4.1 FREQUENCY

- 1) The CB shall ensure that for each certified organization at least one surveillance audit is undertaken unannounced after the initial certification audit and within each three (3) year period thereafter.
- 2) The certified organization can voluntarily choose to replace all surveillance audits by unannounced annual surveillance audits. Recertification audits may be conducted unannounced at the request of the certified organization.
- 3) The initial certification audit (stage 1 and stage 2) cannot be performed unannounced.

5.4.2 EXECUTION

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

- 8) If the certified organization refuses to participate in the unannounced audit, the certificate shall be suspended immediately, and the CB shall withdraw the certificate if the unannounced audit is not conducted within a six-month timeframe from the date refusal.
- 9) The audit of separate Head offices controlling certain FSMS processes pertinent to certification separate to the site(s) (see 5.2.1) shall be announced . Where Head Office activities are part of a site audit, they shall be unannounced.
- 10) Secondary sites (off-site activities) and off-site storage, warehouses and distribution facilities shall also be audited during the unannounced audit.

5.5 USE OF INFORMATION AND COMMUNICATION TECHNOLOGY

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

- 1) For conducting interviews with people and review of policies, procedures, or records as part of the on-site audit;
- 2) When utilizing the ICT Audit Approach as set out in Annex 9.

5.6 TRANSFER OF CERTIFICATION

The CB shall follow the requirements of IAF MD2 for the transfer of certified organizations from another CB.

5.7 UPGRADE AUDITS

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

The CB shall:

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

5.8 TRANSITION AUDITS

- 1) Transition audits are allowed from ISO 22000 and GFSI recognized certification programs with equivalent scopes. For FSSC 22000-Quality, transition audits are allowed for organizations holding a valid ISO 22000, FSSC 22000 and a valid ISO 9001 certificate (see section 4.3.5 for audit duration).
- 2) Transition audits are the start of a new certification cycle and shall therefore be a stage 2 audit (a stage 1 may be performed at the discretion of the CB).
- 3) The FSSC 22000 certificate/FSSC 22000-Quality certificate issued shall have a validity of 3 years.

5.9 ALLOCATION OF AUDIT TEAM

- 1) All audit team members shall meet the competence requirements set out by the Foundation in Part 4 chapter 3.
- 2) The audit team shall have the combined competence for the food chain sub-categories supporting the scope of the audit and following the requirements of ISO/IEC 17021-1.
- 3) The FSSC 22000-Quality audit is a fully integrated audit and the audit team shall meet the competence requirements set out by the Foundation in Part 4 of the Scheme.
- 4) The lead auditor shall always be a FSSC 22000 qualified auditor.
- 5) An auditor is not allowed to perform more than two 3-year certification cycles at the same certified site either as lead auditor or co-auditor. If an auditor starts auditing within a certification cycle, he/she will be rotated out after six (6) years for a minimum of one year.

5.10 MANAGEMENT OF SERIOUS EVENTS

- 1) The CB shall have a process to review planned audits when a serious event affects a certified organization, and the audit cannot be performed as planned.
- 2) The CB shall assess the risks of continuing certification and establish a documented policy and process, outlining the steps it will take in the event a certified organization is affected by a serious event to ensure the integrity of certification is maintained. The minimum content of the risk assessment shall cover the aspects listed in IAF ID3, section 3.
- 3) The outcome of the Risk Assessment and planned actions shall be recorded. Deviations from the audit program and their justification for changes shall be recorded. CBs shall establish in consultation with certified organizations a reasonable planned course of action.
- 4) In cases where the annual surveillance audit cannot take place within the calendar year as a result of a serious event, an exemption shall be requested from the Foundation or the certificate shall be suspended.

6 AUDIT REPORT

6.1 WRITTEN REPORT

The CB shall provide a written report for each audit.

- a) The audit report is to be treated confidentially by the CB but shall be made available to Food Safety Authorities after approval of the organization.
- b) The audit report shall confirm that all Scheme requirements are assessed, reported and a statement of (non) conformity given. Furthermore, it shall comply with all relevant requirements of ISO/IEC 17021-1. The content shall comply with the requirements of Annex 2 or Annex 3 in the case of FSSC 22000-Quality.
- c) Both the procedural and operational conditions of the food safety management system shall be verified to assess the effectiveness of the food safety management system meeting the Scheme requirements and reported.
- d) In exceptional cases, a requirement can be deemed not applicable. Where a requirement is deemed to be N/A then suitable justification shall be recorded in the relevant section of the audit report.
- e) Exclusions from scope shall be assessed and justified in the audit report.
- f) Deviations from the audit plan shall be motivated in the report.

- g) Auditors shall report all nonconformities (NCs) at all audits. For each nonconformity (NC), a clear concise statement of the requirement, the NC, grade of the NC and the objective evidence shall be written.
- h) Corrections, corrective action plans and their approval shall be included as per Annex 2 or Annex 3 in the case of FSSC 22000-Quality.
- i) A Head Office report shall contain as a minimum the NCs found at the HO. This report shall be uploaded. At each site audit the implementation of the corrective actions shall be verified and reported.
- j) The full audit report meeting the minimum requirements as set out by the Scheme, shall be sent to the (certified) organization within 2 weeks of the certification decision for all audits conducted.
- k) It is the Foundation's requirement that audit reports are written in English. Where an organization requests the report to be written in the language the audit was conducted in (if other than English), this is allowed based on mutual agreement between the CB and the organization. However, the mandatory fields in the portal shall always be completed in English. In all instances where CBs are translating audit reports, the CB shall have verification procedures in place to ensure the translations are accurate.

6.2 NONCONFORMITIES

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

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

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

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

The Scheme does not allow "Opportunities for Improvement".

6.2.1 MINOR NONCONFORMITY

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

- 1) The organization shall provide the CB with objective evidence of the correction, evidence of an investigation into causative factors, exposed risks, and the proposed corrective action plan (CAP);

- 2) The CB shall review the corrective action plan and the evidence of correction and approve it when acceptable. The CB approval shall be completed within 28 calendar days after the last day of the audit. Exceeding this timeframe shall result in a suspension of the certificate;
- 3) Corrective action(s) (CA) shall be implemented by the organization within the timeframe agreed with the CB;
- 4) Effectiveness of implementation of the corrective action plan shall be reviewed, at the latest, at the next scheduled audit. Failure to address a minor nonconformity from the previous audit could lead to a major nonconformity being raised at the next scheduled audit.

6.2.2 MAJOR NONCONFORMITY

A major nonconformity shall be issued when the finding affects the capability of the management system to achieve the intended results:

- 1) The organization shall provide the CB with objective evidence of an investigation into causative factors, exposed risks, and evidence of effective implementation;
- 2) The CB shall review the corrective action plan and conduct an on-site follow-up audit to verify the implementation of the CA to close the major nonconformity. In cases where documentary evidence is sufficient to close out the major nonconformity, the CB may decide to perform a desk review. This follow-up shall be done within 28 calendar days from the last day of the audit;
- 3) The major nonconformity shall be closed by the CB within 28 calendar days from the last day of the audit. When the major cannot be closed in this timeframe, the certificate shall be suspended;
- 4) Where completion of corrective actions might take more time, the CAP shall include any temporary measures or controls necessary to mitigate the risk until the permanent corrective action is implemented.

6.2.3 CRITICAL NONCONFORMITY

A critical nonconformity is issued when a direct food safety impact without appropriate action by the organization is observed during the audit or when legality and/or certification integrity are at stake:

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

7 CERTIFICATION DECISION PROCESS

7.1 GENERAL

- 1) CBs shall conduct a technical review for all audits to agree with the audit reports content and outcome, NC's (objective evidence and grading) and effectiveness of corrections and corrective action plans. Following each technical review, CB's shall make a decision on the certification status of the organization (e.g., certify, continue certification, suspend, withdraw).
- 2) The CB shall keep documented information of decisions on certification status that have been considered and by whom. This information shall include: the names of those making each decision, and the date the decision was made.
Note: not all decisions may lead to issuing a new certificate.
- 3) The maximum certificate validity period is 3 years from the date of initial certification decision, with subsequent 3-year cycles.

7.2 CERTIFICATE DESIGN AND CONTENT

- 1) The CB shall issue FSSC 22000 and FSSC 22000-Quality certificates in accordance with the scope rules and certificate templates set out by the Foundation (see Annex 1 and Annex 4).
- 2) The certificate shall be in English and correspond with the certificate in the portal and the details on the public register. It is possible to include a translation of the scope statement following the English statement on the certificate.
- 3) The FSSC 22000 logo shall be used by the CB on its certificates.
- 4) Head Office details shall be included, where applicable.
- 5) Where applicable Off site and Multi-site locations shall be listed, (including name, address, and activities); details may be provided in an Annex to the certificate.
- 6) Dates on the certificates shall be as follows:
 - a) Certificate decision date: date at which a new decision is made after a certification or recertification audit (excluding regular surveillance audits).
New certificate decision dates are also required in situations such as version changes of the Scheme and/or scope extensions/reductions. In these cases, the valid until date remains unchanged;
 - b) Initial certification date (i.e., the certification decision date after the initial audit). This is a fixed date that is maintained as long as the organization is linked to the CB and holds a valid FSSC 22000 certificate;
 - c) Issue date: date certificate is issued to the client; or re-issue date when a new certificate is issued (e.g., because of version change, scope extension etc.);
 - d) Valid until date: certificate expiry date (e.g., original certification decision date + 3 years for the initial cycle).

7.3 CERTIFICATE SUSPENSION, WITHDRAWAL OR SCOPE REDUCTION

- 1) *Suspension*: the CB shall immediately suspend certification when a critical nonconformity is issued and/or there is evidence that their client is either unable or unwilling to establish and maintain conformity with Scheme requirements.
- 2) *Withdrawal*: the CB shall withdraw a certificate when:
 - a) The status of suspension cannot be lifted within six (6) months;
 - b) The organization ceases its FSSC 22000 certification activities;
 - c) Any other situation where the integrity of the certificate or audit process is severely compromised.
- 3) *Scope reduction*: When the CB has evidence that their client holds a certificate whose scope exceeds their capability or capacity to meet Scheme requirements, the CB shall reduce the certification scope accordingly. The CB shall not exclude activities, processes, products, or services from the scope of certification when those activities, processes, products, or services can have an influence on the food safety of the end products as defined in the scope of certification.

7.3.1 ACTION UPON SUSPENSION, WITHDRAWAL AND SCOPE REDUCTION

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

8 PORTAL DATA AND DOCUMENTATION

8.1 DATA OWNERSHIP

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

8.2 DATA UPLOAD REQUIREMENTS

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

8.3 DATA QUALITY CONTROL

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

- a) Completeness: All the mandatory data has been registered in the Portal;
- b) Timeliness: All the data has been registered in the Portal within the required timelines;
- c) Validity: The registered data values meet the Scheme requirements;
- d) Accuracy: The data is a true representation of the actual facts relating to the complete audit and the certification process;
- e) Consistency: The registered data in the Portal is a true representation of the data stored in the CBs internal system(s).

8.4 CB PORTAL

- a) When requested by the certified organization, CBs shall actively provide the Certified Organization access to the associated Organization Profile, Audit and Certification data registered in the CB Portal using the available functionality.
- b) CBs shall ensure that Certified Organization access is only granted to authorized individual(s).

PART 4

REQUIREMENTS FOR CERTIFICATION BODIES

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1 PURPOSE

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

Where reference to FSSC 22000 requirements is made, this is also applicable for FSSC 22000-Quality unless stated otherwise.

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

2 RELATION WITH THE FOUNDATION

2.1 LICENSING

- 1) As a prerequisite for the license application, the CB shall hold a valid ISO/IEC 17021-1:2015 accreditation including ISO/TS 22003:2013.
- 2) For the Scheme Requirements, the accreditation shall cover the applicable food chain categories and sub-categories in which it supplies its FSSC 22000 certification services. The CB shall provide the Foundation with information and documentation related to its accreditation to the Scheme when requested.
- 3) The Foundation is entitled to request information from the Accreditation Body related to the CB accreditation.
- 4) The CB may hold more than one accreditation for the main location which shall be covered by a single license. In case the CB has multiple locations holding their own accreditation, a separate license is required for each location.

2.1.1 LICENSE APPLICATION PROCESS

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

2.1.2 LICENSES

2.1.2.1 LICENSE AGREEMENT (PROVISIONAL STATUS)

- 1) The CB shall submit an application to the Foundation specifying the food chain categories and sub-categories which they wish to provide certification services. As part of the application the CB shall submit the documentation required by the Integrity Program as part of the on-boarding process.
- 2) Upon review of the information and successful completion of the applicable stages of the Foundation’s Integrity Program, the CB shall be granted a license with provisional status and be listed as provisionally approved in the CB list on the FSSC 22000 website.

- 3) The CB shall then apply for accreditation with an AB accepted by the Foundation and submit the written confirmation of acceptance of the application to the Foundation.
- 4) The provisional status allows a CB to use the Scheme for unaccredited certification once authorization has been received from the Foundation as per the Integrity Program on-boarding process requirements. Unaccredited certificates shall be registered in the Portal. After accreditation is achieved, these unaccredited certificates may be replaced with an accredited certificate either immediately or following the next certification audit. If accreditation status is not achieved, the provisional license will be terminated and already issued certificates shall be withdrawn.
- 5) The provisional status of the license is valid for twelve (12) months from the date of signature by the Foundation and within this period of time the CB shall:
 - a) Achieve accreditation from an AB accepted by the Foundation for the categories and sub-categories covered in the license agreement. For FSSC 22000 requirements on the accreditation process see Part V of the Scheme;
 - b) Have at least five (5) audited organizations registered in the Portal.
 - c) Successfully complete the applicable stages of the Integrity Program on-boarding process.

2.1.2.2 LICENSE AGREEMENT (FULL STATUS)

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

- a) A copy of its accreditation certificate covering the categories and sub-categories in the license agreement;
- b) A copy of its AB assessment reports (office and witness assessments).

Upon successful completion of the applicable Integrity Program stages, the Foundation shall issue and/or modify the status of the license agreement of the CB listed on the FSSC 22000 website and in the Portal.

2.1.3 LICENSE MAINTENANCE

In order to maintain its license, the CB shall:

- a) Have at least fifty (50) certificates registered in the Portal with a minimum of one for each licensed food chain category. For new CBs, this shall be achieved as follows after receiving the full license: fifteen (15) certificates within 12 months, thirty-five (35) certificates within 24 months and fifty (50) certificates within 36 months.
- b) Comply with all the requirements of the FSSC 22000 certification Scheme for CBs;
- c) Meet the financial obligations to the Foundation.

2.1.4 LICENSE EXTENSION

- 1) The CB shall submit an application to the Foundation specifying the food chain sub-categories (or category if no subcategory) for which it requests an extension of the existing license.
- 2) The CB shall be granted a provisional status for the new sub-category (or category if no subcategory) following a review and registered in the Portal and displayed in the approved CB list on the FSSC 22000 website. The CB shall share with the Foundation the written AB confirmation of acceptance to start the accreditation process.
- 3) The provisional status allows a CB to issue unaccredited certification for the new sub-category (or category if no subcategory). Unaccredited certificates shall be registered in

the Portal. After accreditation, these certificates may be replaced with an accredited certificate.

- 4) The provisional status of the license is only valid for 12 months from the date of signature by the Foundation and within this period of time the CB must achieve accreditation from an AB accepted by the Foundation for the categories and sub-categories covered in the license agreement. For FSSC 22000-Quality the accreditation shall cover ISO 9001.
- 5) At least one certificate shall be listed in the Portal for the new category within the timelines defined.

2.1.5 SUSPENSION, TERMINATION AND REDUCTION

The Foundation has the right to suspend, terminate or limit the scope of the CB's license agreement. Reasons could be, amongst others:

- 1) Accreditation not achieved within one year;
- 2) Termination of the accreditation;
- 3) Not meeting the minimum number of certificates specified by the Foundation;
- 4) Sanction committee decision;
- 5) No payment of the fee to the Foundation;
- 6) Repetitive noncompliance with the Scheme requirements;
- 7) Noncompliance with the Integrity Program or components there-of.

2.1.5.1 SUSPENSION

- 1) When a CB's license is suspended by the Foundation, the Foundation will determine to which extent the CB will be allowed to maintain its auditing and certification activities for a defined period of time. The Foundation will publish suspensions on the FSSC 22000 website, and the Accreditation Body will be notified.
- 2) The Foundation will restore the suspended license when the CB has demonstrated that the issue which resulted in the suspension has been resolved and the conditions for lifting the suspension have been met.
- 3) Failure to resolve the issues that resulted in the suspension in a time established by the Foundation shall result in termination or reduction of the scope of the license as per the Integrity Program and Sanction Policy.

2.1.5.2 TERMINATION

- 1) When a CB's license is terminated by the Foundation, the CB is cannot apply for a new license within the time frame communicated by the Foundation.
- 2) The CB shall agree with the Foundation the transfer of its certified organizations following the requirements outlined in the license agreement.

2.2 ENGAGEMENT

2.2.1 COMMUNICATION

- 1) The CB shall appoint a FSSC 22000 contact person who is competent in the Scheme requirements and maintains contact with the Foundation.
- 2) This person shall be accountable for all aspects of Scheme implementation and ensure that the following responsibilities are defined and implemented within the CB:
 - a) Appoint a contact person for the FSSC 22000 IT systems;

- b) Appoint a responsible person for managing the Integrity Program;
 - c) Appoint a representative to attend the Harmonization Conference;
 - d) Keep up to date with the Scheme developments including IT developments;
 - e) Managing of other additional information required by the Foundation;
 - f) Communicate new information or changes regarding the requirements in the Scheme to those parties involved within one month unless specified otherwise by the Foundation.
- 3) The CB shall assign responsibility for the development, implementation and maintenance of the CBs quality system relating to the FSSC Scheme. This designated employee shall also have the responsibility for reporting on the performance of the quality system for the purposes of management review and continuous improvement.

The CB shall communicate the following to the Foundation:

- 1) Changes on the FSSC 22000 accreditation status: e.g., scope extension or scope reduction, suspension, or withdrawal, together with a written communication to the Foundation about the circumstances leading to this and any delays in obtaining accreditation that could impact the license;
- 2) Any significant changes in its ownership, legal status, management personnel, structure, or constitution that (potentially) impact the CB management of the Scheme in a timely manner;
- 3) Any possible conflict or problem which could result in bringing the Foundation or GFSI into disrepute;
- 4) Any public recall of a certified organization resulting in death and/or hospitalization or generating significant media coverage, within three days of the recall being notified to the CB;
- 5) Situations and/or serious events where the integrity of the FSSC 22000 certification is compromised as described in Part 3.

2.2.2 RESPONSIBILITIES

- 1) The CB shall cooperate with all requests from the Foundation to report information regarding all aspects in the performance and integrity of the Scheme.
- 2) In case the range of CB certification services offered is wider than those accredited, the CB shall ensure that the limits and scope of the accreditation shall be made clear and publicly available while any ambiguity in relation to the scope of services offered by the CB for the Scheme shall be resolved with the Foundation and certification services that are outside the scope of the accreditation shall be distinguished from those that are accredited.
- 3) The CB is responsible for the full application of these Scheme requirements and shall be prepared to demonstrate compliance at any time with all these requirements.
- 4) The CB shall attend the annual Harmonization conference and share the information to all relevant staff.
- 5) The CB shall participate in the Integrity Program.
- 6) The CB shall inform its AB(s) on any changes in the license status (e.g., reduced, extended, suspended, etc.) made by the Foundation.
- 7) The CB shall share information concerning the certified organization with the Foundation, GFSI and governmental authorities when required by law.
- 8) The CB shall take appropriate steps to assess the situation and have procedures in place to ensure the integrity of certification is maintained after a serious event and/or food safety incident notification and maintain records to support the decision made.

- 9) The CB shall ensure that all Scheme related data in Portal is complete, up to date, correct and meets the Scheme requirements.
- 10) Where the CB uses the FSSC 22000 logo, they shall comply with the requirements in Part 2 and are entitled to use it only when the CB has a signed license agreement.
- 11) An annual performance report shall be submitted by the CB to the Foundation with the minimum content as specified by the Foundation.

2.3 INTEGRITY PROGRAM

- 1) The CB shall participate in the Integrity Program which is the Foundation's system of ongoing monitoring. This program covers all activities of its licensed CBs to ensure compliance with all Scheme requirements. The CB shall provide any documentation requested by the Foundation for the Integrity Program.
- 2) The monitoring activities include but are not limited to:
 - a) Desk reviews of audit reports and additional information on the audit process;
 - b) Auditor assessment and registration;
 - c) Office assessments;
 - d) Witnessed audits;
 - e) Monitoring of agreed key performance indicators.

Further information can be found in the Integrity Program and Sanction Policy.

2.3.1 NONCONFORMITY

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

2.3.2 FOLLOW-UP

- 1) When a nonconformity is received, the CB shall:
 - a) Record and manage the nonconformity in its internal system,
 - b) Respond in the set timeframe and act to:
 - i. Restore conformity (i.e., implement corrections);
 - ii. Investigate to identify the causal factors;
 - iii. Perform an impact analysis;
 - iv. Provide a documented Corrective Action Plan (CAP) detailing the nonconformity, grading, cause analysis, correction, planned corrective action, responsible person, due date, measures of effectiveness, date closed.

- 2) Then:
 - a) take corrective actions to manage the identified causal factors so that the risks exposed by recurrence are reduced to an acceptable level, provide objective evidence;
 - b) use the opportunity to investigate how else and where else a similar nonconformity could occur;
 - c) take preventive action to manage these causal factors so that the risks exposed by occurrence are similarly reduced to an acceptable level.
- 3) Failure to meet the deadlines for nonconformities will result in the Integrity Program and Sanction Policy being initiated.

2.3.3 SANCTIONS

- 1) CBs that persistently fail to conform to the requirements of the Scheme or put the integrity of the Scheme at risk shall be investigated by the Foundation as per the Integrity Program and Sanction Policy.
- 2) Sanctions against non-compliant CBs could include:
 - a) Suspension of the license to issue certifications under the Scheme until discrepancies have been satisfactorily corrected;
 - b) Termination of the license to issue certifications under the Scheme.

The CB shall respond to the sanctions as indicated in the sanction notification.

Details are provided in the Integrity Program and Sanction Policy.

3 COMPETENCE

3.1 GENERAL

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

3.2 TECHNICAL REVIEWER AND CERTIFICATION DECISION MAKER

3.2.1 TECHNICAL REVIEWER

The technical reviewer shall meet the same requirements as set out below for the certification decision maker with the exception of 3.2.2 – 1c. The technical review and certification decision functions may be separate, or the technical review and certification decision may be made by the same individual where the competency requirements are being met.

3.2.2 CERTIFICATION DECISION MAKER

- 1) Those making the decision to issue, maintain, extend, or reduce scope, suspend, or withdraw a certificate for registration in the FSSC 22000 Register of certified organizations shall have the following demonstrable competencies;
 - a) Meet the requirements of Annex C of ISO/TS 22003:2013;
 - b) Knowledge of Scheme requirements;
 - c) Knowledge of food safety management systems and ability to assess them.
- 2) In case of FSSC 22000-Quality the certification decision maker shall have knowledge of ISO 9001.

3.3 TECHNICAL EXPERT

- 1) When deemed necessary a technical expert can be assigned to the audit team.
- 2) The CB shall have in place a procedure for approval of technical experts who shall have demonstrable experience in the subcategory supporting the scope of the audit. The technical expert shall operate always under the direction of a qualified FSSC 22000 auditor.
- 3) Where a technical expert is used, the CB shall ensure that at least one auditor in the team has a qualification in the category.

3.4 WITNESSOR

- 1) Witnessed audits shall be undertaken by an auditor qualified for a GFSI recognized certification program that can demonstrate competence in the FSSC 22000 Scheme requirements, or by a CB FSSC 22000 technical certification person of equivalent competence and experience. Witnessors shall be assessed and qualified by the CB as suitable to undertake witnessed audits.
- 2) The witnessor has received training in witness audit techniques.
- 3) The witnessor plays no active part in the audit.
- 4) Witnessors shall have, as a minimum, the equivalent competency of the function being evaluated (see ISO/TS 22003:2013 Annex C).
- 5) A witness audit performed by the CB can only be substituted by an Accreditation Body (AB) witnessed audit if it is the first witnessed audit under a provisional license.

3.5 AUDITOR QUALIFICATION PROCESS

CB shall have a system and documented procedures for selecting, training, evaluating, (re) qualification and maintenance of qualification of the auditor.

3.5.1 INITIAL TRAINING AND EXPERIENCE

The CB shall ensure that trainee auditors or auditors transferring from other CBs are meeting the following initial training and experience requirements:

- 1) Work Experience

- a) Experience in the food or associated industry including at least 2 years' full-time work in quality assurance or food safety functions in food production or manufacturing, retailing, inspection or enforcement or the equivalent.
- 2) Education
- a) Education: A degree in a food related or bioscience discipline or, as a minimum, has successfully completed a food related or bioscience higher education course or equivalent.
- 3) Training
- a) Lead Auditor Course for FSMS or QMS – minimum 40 hours including exam;
 - b) HACCP training – minimum 16 hours including exam;
 - c) ISO 22000 Standard – minimum 8 hours including exam (if not included as part of Lead Auditor Training Course);
 - d) Food defense training covering food defense threat assessment methodology and possible mitigation measures (including exam);
 - e) Food fraud training covering food fraud vulnerability assessment methodology and possible mitigation measures (including exam);
 - f) Standards - all relevant Scheme requirements (including exam); ISO/TS 22003 (Annex C), ISO 19011 and ISO/IEC 17021-1 (as applicable to the auditing processes of the CB including exam);
 - g) Training in the relevant PRP standard (including exam).
- 4) Other
- a) Audits: a minimum of ten (10) audit days consisting of at least five (5) third-party food safety audits that cover elements of FSMS, HACCP and PRP requirements in the relevant industry sector. The five (5) audits shall include at least two (2) FSSC 22000 audits under supervision of a FSSC qualified auditor and one (1) FSSC 22000 witness audit. Where an already qualified FSSC 22000 auditor moves from another CB, the two (2) audits under supervision are not required, only the FSSC 22000 witness audit.
 - b) For Category I: a primary qualification, a degree or higher certificate in packaging technology and a relevant certificate in food technology, food hygiene or related science subject OR a primary qualification in food technology, food safety/ hygiene or related science subject and a training (minimum 30 hours) plus certificate in packaging technology that meets the requirements defined by WPO Packaging. This training shall include the following topics as a minimum:
 - i. Basics of packaging principles and concepts;
 - ii. Packaging legislation, standards, and regulations;
 - iii. Packaging materials manufacturing;
 - iv. Specifics to packaging of food/feed products;
 - v. Quality/food safety control and testing;
 - vi. Printing processes and printing inks;
 - vii. Packaging recycling and
 - viii. Design of packaging materials.
 - c) FSSC 22000-Quality: be a qualified auditor for ISO/IEC 17021-1 accredited ISO 9001 certification according to ISO/TS 22003 categories and ISO 9001 Food Sector codes.

3.5.2 INITIAL ASSESSMENT AND APPROVAL

- 1) The CB shall:
 - a) provide supervised training in food safety audits;
 - b) conduct a FSSC 22000 witnessed audit of the auditor to confirm competence is attained; and
 - c) document the sign-off of the satisfactory completion of the training program and witnessed audit.
- 2) The supervised training and the witnessed audit shall be conducted by an FSSC 22000 qualified auditor or a FSSC 22000 technical certification person of equivalent competence and experience.
- 3) Already qualified FSSC 22000 auditors moving from another CB shall always be subject to a witness audit by the new CB as part of the approval process. Where the new CB deems remote witnessing to be sufficiently robust, the new CB may use ICT to conduct the witness audit remotely to approve the FSSC 22000 auditor. Refer to Annex 9 for more information.
- 4) All FSSC 22000 auditors (including auditors in training) shall be registered in the Portal in accordance with the instructions of the Foundation.

3.5.3 ASSIGNMENT OF SUBCATEGORIES (INITIAL AND EXTENSION)

- 1) After the initial approval auditors shall be approved/qualified per subcategory (see Part 1 table 1). In order to assign subcategories to an auditor, the CB shall demonstrate that the auditor complies with the following requirements:
 - a) Experience:
 - i. Six (6) months' work experience in the subcategory (where food safety or quality consultancy work is used to demonstrate work experience, the number of man-days shall add up to six months) OR
 - ii. Five (5) audits against a GFSI approved or recognized standard, Dutch HACCP or ISO 22000 in the subcategory as a qualified auditor OR
 - iii. Five (5) audits against a GFSI approved or recognized standard, Dutch HACCP or ISO 22000 in the subcategory as a trainee under the supervision of a qualified auditor for the subcategory OR
 - iv. A combination of the above
 - b) demonstrated specific competence in the subcategory.
 - c) meeting the CB's own competency criteria for the subcategory
- 2) The CB shall have defined competency criteria for each subcategory to ensure knowledge of products, processes, practices and applicable laws and regulations of the relevant subcategory. Competence across the whole subcategory shall be demonstrated. Where the CB further split up subcategories, it shall be clear for which parts of the subcategory the auditor is qualified.

3.5.4 MAINTENANCE OF AUDITOR QUALIFICATION

3.5.4.1 AUDITS

- 1) Each auditor shall perform at least five (5) FSSC 22000 audits at different organizations each calendar year, either as a lead or co-auditor. In this context, stand-alone stage 1 audits and special audits do not count.

- 2) In the event when the requirement in (1) cannot be met, the CB shall ensure that the auditor has performed at least five (5) audits against an approved GFSI scheme (post-farm gate only except for food chain category A) of which at least one (1) FSSC 22000 audit either as a lead or co-auditor. The CB shall mark this auditor in the Portal as working under a temporary exemption arrangement with an appropriate justification. An exemption can be applied in the following cases:
 - a) long term sickness of the auditor;
 - b) extended leave (e.g., maternity, paternity, sabbatical);
 - c) lack of clients in the region/country*
 - d) due to a serious event

* For lack of clients the temporary exemption cannot be applied more than one year for the same auditor.
- 3) In case an auditor has demonstrated he/she performed FSSC 22000 audits for another CB, these are also allowed to be included. In the event of point 2 or 3 above, the CB shall upload evidence of the audits in the Portal.

3.5.4.2 ONGOING TRAINING

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

3.5.4.3 WITNESSED AUDIT

- 1) At least one (1) FSSC 22000 witnessed audit shall be conducted every three (3) years to confirm acceptable auditor performance. The witness audit shall be conducted at a full FSSC certification audit. Stand-alone Stage 1, Follow-Up and Special Audits cannot be used as witness audits.
- 2) A witness audit assessment report shall be completed by the witnessor to confirm performance of – as a minimum- the elements described for auditing activities in ISO/TS 22003:2013 Table C1.

3.5.4.4 AUDITOR REQUALIFICATION

- 1) The overall auditor performance shall be evaluated every three (3) years in order to confirm the continued competence of the auditor. The following aspects shall be evaluated by the appointed supervisor of the CB prior to requalification:
 - a) the auditor audit log;
 - b) the auditor training log;
 - c) result of the witness audit.
- 2) The evaluation shall consider the auditor's overall performance, including complaints from clients.
- 3) Documented sign-off of the satisfactory completion of the entire requalification process shall be uploaded in the Portal.

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

PART 5
REQUIREMENTS
FOR
ACCREDITATION
BODIES

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1 PURPOSE

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

1.1 MEMBERSHIP OF THE IAF

- 1) ABs providing accreditation to CBs for FSSC 22000 certification and/or FSSC 22000-Quality certification shall be a current member of the International Accreditation Forum (IAF) and:
 - a) Be a signatory to the IAF Multilateral Recognition Arrangement (MLA) for Food Safety Management Systems (FSMS) to cover FSSC 22000 accreditation services; and
 - b) Be a signatory to the IAF MLA for FSSC 22000 (once available) to cover FSSC 22000 accreditation services and
 - c) Be a signatory to the IAF MLA for Quality Management System (QMS) to cover FSSC 22000-Quality accreditation services.

1.2 COMMUNICATION AND RESPONSIBILITIES

- 1) The AB shall appoint a primary and secondary contact person for communication with the Foundation.
- 2) The AB shall notify the Foundation in a timely manner of any changes in contact persons, its ownership, legal status, or any other issues that are relevant for accreditation. Changes in the IAF MLA status of the AB shall be communicated to the Foundation within 3 working days.
- 3) At least one AB contact person or assessor shall attend the annual Harmonization Conference.
- 4) Communication on changes to the Scheme requirements and other related information shared with the ABs via webinars and technical newsletters, shall be shared by the AB with all its assessors for the Scheme and records of such training shall be retained.
- 5) The AB shall inform the Foundation without undue delay in case the accreditation status of the CB changes (e.g., granted, extension, reduction, re-instate, suspension or withdrawal).
- 6) Upon request, the AB shall cooperate with the Foundation in relation to information requests related the performance of its accredited CBs.

2 ACCREDITATION

2.1 LICENSE AGREEMENT

- 1) The AB shall verify that the CB has signed a (provisional) license agreement with the Foundation to certify for a predefined ISO/TS 22003:2013 food chain sub-category (or category if no subcategory) as set out in Annex 5 and/or for FSSC 22000-Quality.
- 2) The AB shall not issue an accreditation certificate for a category or sub-category (where there is no (provisional) license with the Foundation, this includes scope extensions for new sub-categories (or category if no subcategory).

2.2 ACCREDITATION PROCESS

2.2.1 GENERAL

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

2.2.2 SCOPE OF ACCREDITATION

- 1) The scope of accreditation shall be clearly defined and be part of the accreditation certificate as defined below and summarized in Annex 5 to this part:
 - a) Food Safety System Certification (FSSC) 22000 version 5; or
 - b) Food Safety and Quality System Certification (FSSC) 22000-Quality version 5;
 - c) Normative documents for providing certification:
 - i. ISO 22000;
 - ii. ISO 9001 (applicable for FSSC 22000-Quality only);
 - iii. Sector specific PRPs;
 - iv. Additional FSSC 22000 requirements.
 - d) Food chain clusters, categories and sub-categories as indicated in Annex A of ISO/TS 22003:2013;
 - e) IAF ID 1 sector codes as indicated in Annex 5 Auditor competence (applicable for FSSC 22000-Quality only); and
 - f) Locations covered under CB accreditation.
- 2) The accreditation certificate shall include the initial accreditation and expiry date.

2.2.3 WITNESSED AUDITS

- 1) The witnessed audits shall meet the requirements for witnessing activities for the Accreditation of Management Systems Certification Bodies as set out in section 7.5.6 of IAF MD 16:2015 with the below FSSC 22000 Scheme specific requirements:
 - a) Initial and scope extension assessments shall require at least one (1) FSSC 22000 witnessed audit of each category (as defined in ISO/TS 22003:2013) detailed on the provisional or full CB license agreement;
 - b) The AB shall conduct FSSC 22000 witnessed audits covering all categories included in the CB accreditation scope during the AB accreditation cycle.

- c) For the purposes of CB witnessing, FSSC 22000-Quality is considered a category.

2.3 INTEGRITY PROGRAM

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

PART 6

REQUIREMENTS FOR TRAINING ORGANIZATIONS

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1 PURPOSE

This Part states the requirements for licensed training organizations (TOs) who wish to provide approved FSSC 22000 training courses.

2 RELATION WITH THE FOUNDATION

2.1 LICENSE

The TO shall supply FSSC 22000 training services only when it holds a valid (full) license from the Foundation for the relevant training scope.

2.1.1 APPLICATION

- 1) The TO shall submit an application to the Foundation specifying the type of FSSC 22000 training they wish to apply for. The application form is available on the FSSC 22000 website. Information required includes:
 - a) contact information;
 - b) TO operation;
 - c) regional activity;
 - d) types of FSSC 22000 courses provided;
 - e) FSSC 22000 trainers.
- 2) The application form provides details on what documents are to be provided for each stage of the process (provisional and full license agreement).

2.1.2 LICENSE AGREEMENT

2.1.2.1 LICENSE AGREEMENT (PROVISIONAL)

- 1) Upon successful review of the application and the payment of the required fee to the Foundation, the applicant shall be granted a license agreement with a provisional status.
- 2) The signed license agreement (provisional) allows the Training Organization to have access to the FSSC 22000 training materials, which can be used as a basis for the development of their own training materials. The TO shall not deliver or market any FSSC 22000 courses as approved by the Foundation until a full license agreement has been granted.
- 3) The license agreement (provisional) is valid for 12 months from the date of signature by the Foundation and during this period the TO shall upgrade the status of their license agreement to full following the steps in the next section.

2.1.2.2 LICENSE AGREEMENT (FULL)

- 1) To change the status of the license agreement (provisional) to a (full) license agreement the TO shall:
 - a) submit the Training Materials and Trainers Qualifications for a Desk Review as part of the Scheme Integrity Program (IP). Files submitted shall be for all the courses specified in the application (one per type of training, refer section 3). A sample of the trainers'

- files will also be requested to assess their competence. All files shall be in digital format;
- b) close out satisfactorily the nonconformities issued during the Desk Reviews by demonstrating effective corrective actions (refer to 2.3.2).
 - 2) Upon review and approval, the Foundation shall modify the status of the license agreement to full and include the information of the TO and its courses on the FSSC 22000 website.
 - 3) With the granting of a full license agreement, the TO is entitled to use the FSSC 22000 logo on their training certificates, training materials, brochures, and website (requirements for use are defined in Part 2) and to provide the approved training courses mentioned on the FSSC 22000 website.
 - 4) If full status is not granted 12 months after the signature of the license agreement (provisional), the license shall be terminated (refer 2.1.5). The TO can re-apply following the application process above.

2.1.3 LICENSE MAINTENANCE

The TO shall provide the following information on an annual basis:

- 1) An overview of FSSC 22000 trainings performed in the previous year;
- 2) The planned FSSC 22000 trainings for the current year;
- 3) Changes in TO organization/management.

2.1.4 EXTENSION OF LICENSE

Where an initial license does not cover all four types of training (refer section 3) the TO shall submit an application including the new FSSC 22000 training materials for an extension of the license, along with an updated qualification record for the trainers. Steps in section 2.1.2 for full status shall be followed.

2.1.5 TERMINATION OF LICENSE

- 1) The Foundation reserves the right to terminate the license of a TO. Refer to Sanctions in 2.3.3.
- 2) The FSSC 22000 logo shall be removed from any documentation and the TOs website (if applicable). The TO shall not make use of the FSSC 22000 training materials anymore.
- 3) The name of the TO and their courses will be removed from the FSSC 22000 website.

2.2 RESPONSIBILITIES AND COMMUNICATION

- 1) At least one TO representative shall participate at the annual Harmonization Conference and the FSSC 22000 technical webinars;
- 2) The information that has been acquired through the Harmonization Conference and the technical webinars shall be shared and harmonized within the TO;
- 3) The training schedule shall be shared with the Foundation on an annual basis for updating on the FSSC 22000 website;

- 4) The FSSC 22000 logo (or any other statements made) shall be used in accordance with the Scheme requirements (see Part 2 for logo use requirements);
- 5) Comply with all relevant Scheme requirements;
- 6) Participate in the Integrity Program of the Foundation;
- 7) Payment of fees to the Foundation in a timely manner;
- 8) The TO shall appoint a contact person and a back-up for communication with the Foundation;
- 9) Significant changes shall be communicated to the Foundation. These include:
 - a) Contact details,
 - b) Organizational changes,
 - c) Updates to training programs.

2.3 INTEGRITY PROGRAM

- 1) The TO shall participate in the Integrity Program which is the Foundation's system of ongoing monitoring. This program covers all activities of its licensed TOs to ensure compliance with the Scheme requirements. The TO shall provide any documentation requested by the Foundation for the Integrity Program.
- 2) The monitoring activities include but are not limited to:
 - a) desk reviews of training materials, trainer qualification and experience, results of training. Desk reviews can be planned as remote assessments if necessary;
 - b) TO Office assessments;
 - c) witnessed assessments of training;
 - d) monitoring of agreed key performance indicators.

The IP also includes activities related to the follow up of complaints and/or nonconformities reported to the Foundation.

2.3.1 NONCONFORMITY

- 1) The Foundation's Integrity Program defines a "nonconformity" as any breach of Scheme requirements.
- 2) Nonconformities ("NCs") requiring a response from the TO shall be raised by the Foundation in relation to:
 - a) any discrepancy raised by the Integrity Program;
 - b) feedback from trainees;
 - c) any other feedback deemed credible.

2.3.2 FOLLOW-UP

- 1) When a NC is issued by the Foundation, the TO shall:
 - a) record and manage the nonconformity in its internal system;
 - b) respond in the set timeframe and act to:
 - i. restore conformity (i.e., implement corrections);
 - ii. investigate to identify the causal factors (i.e., undertake corrective action);
 - iii. identify the risks to effective FSSC 22000 training;

- iv. provide a documented Corrective Action Plan (CAP) detailing the nonconformity, grading, cause analysis, correction, planned corrective action, responsible person, due date, measures of effectiveness, date closed;
 - v. provide objective evidence that the nonconformity has been effectively closed.
 - 2) Then:
 - a) take corrective actions to manage the identified causal factors so that the risks exposed by recurrence are reduced to an acceptable level;
 - b) use the opportunity to investigate how else and where else a similar nonconformity could occur;
 - c) take preventive action to manage these causal factors so that the risks exposed by occurrence are similarly reduced to an acceptable level.
 - 3) Failure to meet the deadlines for nonconformities will result in the Foundations' Sanction Policy being initiated.

2.3.3 SANCTIONS

- 1) A TO that consistently fails to comply with the requirements of the Scheme or puts the integrity of the Scheme at risk, shall be investigated by the Foundation as per its Integrity Program and Sanction Policy.
- 2) The TO shall respond to the sanctions as determined by the Foundation. Failure to comply with the sanctions will result in the termination of the license with the TO.

3 TYPES OF TRAINING

There are four (4) general categories of training for FSSC 22000. Specifications for these training courses are detailed in section 4.2 and Annex 6. Online webinars are allowed for types 3.1 and 3.2 with an equivalent duration and are considered as E-learning. The Internal Auditor training may be delivered via VILT training and the Lead Auditor Course may be delivered as a blended course. The requirements as set out in Annex 8 applies to all E-learning courses delivered by the TO.

3.1 UNDERSTANDING FSSC 22000

A course for organizations, CBs, consultants, and others that are interested in a general knowledge of the Scheme requirements and understand how it can be applicable in different food chain organizations. Duration typically 1-3 days, depending on target audience and learning objectives.

3.2 IMPLEMENTING FSSC 22000

A course for organizations, consultants and others that builds on 3.1 above, and demonstrates how the Scheme can be implemented within various food chain categories. Duration typically 1-3 days, depending on target audience and learning objectives.

3.3 FSSC 22000 INTERNAL AUDITOR COURSE

Designed for organizations that are implementing FSSC 22000 to meet the training requirements for internal auditors. Duration typically 1-2 days, depending on target audience and learning objectives. The training shall address all elements specified in ISO 19011:2018.

3.4 FSSC 22000 LEAD AUDITOR COURSE

Designed for CB personnel/employees to become qualified lead auditors. May also be applicable to organizations wishing to further develop their internal auditing skills and for consultants. The minimum duration of the course is 40 hours. Prerequisite knowledge of FSSC 22000 required. The training shall address all elements specified in ISO 19011:2018, ISO/IEC 17021-1:2015 and ISO/TS 22003:2013 and shall include exercises (e.g., case studies) and a written exam. Where a delegate does not take the exam, this will be considered as a “failed exam” and only a certificate of attendance may be issued.

4 OPERATIONAL PROCESSES

4.1 LEARNING NEEDS

- 1) Preceding each training the TO shall determine the target audience and the accompanying learning objectives.
- 2) The TO shall specify the course pre-requisites detailing minimum level of education/experience for its course delegates.

4.2 DEVELOPMENT OF TRAINING MATERIALS

- 1) The design of all courses shall include the following elements:
 - a) content;
 - b) purpose;
 - c) target audience;
 - d) course prerequisites;
 - e) learning objectives;
 - f) training plan/course agenda;
 - g) tutor notes;
 - h) delegate notes;
 - i) handouts (as required);
 - j) assessment methodology;
 - k) training resources.
- 2) The training materials shall provide a clear explanation of the FSSC 22000 Scheme requirements:
 - a) ISO 22000 (FSMS, hazard control);
 - b) PRPs, OPRPs and CCPs;
 - c) Additional Scheme specific requirements;
 - d) Board of Stakeholders decision list.

- 3) Annex 6 contains the additional specifications applicable to each type of training course.
- 4) The training materials shall respect the copyright of the Foundation owning the FSSC 22000 Scheme. This means that there is an acknowledgement included with every text or image/figure from the Foundation that has been copied into training material or presentations.

4.3 LEARNING ENVIRONMENT AND RESOURCES

- 1) The TO shall ensure that:
 - a) all resources as defined in the curriculum are available;
 - b) all trainers responsible for delivering training have those resources available and are trained in their use;
 - c) all resources as defined in the curriculum can be accessed by the course delegates.
- 2) The TO shall ensure that the necessary staff, associates and learning resources are selected and deployed, taking into account any specific needs, and that the learning resources are maintained.

4.4 COURSE MEMBER EVALUATIONS

- 1) For courses that require evaluation of course delegates (on-going assessment, final assessment (exam) etc.) the TO shall:
 - a) describe general and specific evaluation goals and the scope of evaluation;
 - b) ensure that all evaluation methods and means employed by the TO, including their schedule and rationale, are recorded;
 - c) ensure that the evaluation procedures are planned, selected, and conducted in order to meet the intended objectives, and that they can be implemented in such a way as to provide value to the various interested parties;
 - d) ensure the evaluation is conducted legally and ethically, ensuring full compliance with relevant privacy legislation;
 - e) ensure the information collected for the TO evaluation is:
 - i. focused and sufficiently comprehensive to enable evaluation questions to be fully answered and the needs of learners to be properly addressed;
 - ii. systematically and accurately analyzed;
 - iii. valid, reliable, and meaningful.
- 2) The TO shall take reasonable steps to reduce bias in evaluations.

4.5 EFFECTIVENESS OF TRAINING

- 1) The TO shall keep track of the success rates of the course delegates who completed the training (numbers of course delegates passing and failing the course).
- 2) The TO shall evaluate whether the course delegates were satisfied with the training (and the exam, where applicable).
- 3) A customer satisfaction survey shall be performed by the TO after each training is conducted. Any needed actions shall be taken by the TO in order to make improvement in accordance with their continuous improvement program. Records of the survey shall be maintained.

4.6 FSSC 22000 TRAINING CERTIFICATES

- 1) The TO shall issue certificates to all participants as follows:
 - a) certificate of attendance, where no exam or participant failed exam.
 - b) certificate of achievement, where the exam and evaluations are passed.
- 2) The format of the certificates shall follow Annex 7 with regards to content (the design layout is at the discretion of the TO).

5 TRAINERS

5.1 TRAINER COMPETENCE

5.1.1 EXPERIENCE

- 1) The trainer shall have at least 3 years' work experience with Food Safety Management Systems (FSMS) as an auditor, consultant, or QA/Food Safety officer.
- 2) Training experience shall be a minimum of 3 training courses, totaling 10 days training (where a day is eight hours). A log shall be provided that demonstrates the training has been in the area of food safety (for example: ISO 22000, other GFSI food safety standards, HACCP etc.)
- 3) The training experience can be achieved via participation under supervision in training courses.

5.1.2 QUALIFICATIONS

- 1) The trainer shall have the following adequate knowledge, demonstrated through training records and/or experience:
 - a) Trainers qualified to provide introduction and implementation courses:
 - i. Scheme requirements, relevant normative documents, FSSC 22000 Guidance documents with a minimum duration of 16 hours .
 - b) Trainers qualified to provide auditing courses:
 - i. Scheme requirements, relevant normative documents, FSSC 22000 Guidance documents with a minimum duration of 16 hours
 - ii. audit principles, practices, and techniques (internal auditor trainers) with a minimum duration of 8 hours
 - iii. FSMS Lead Auditor Training (lead auditor trainers) with a minimum duration of 40 hours.

5.1.3 TRAIN THE TRAINER

All FSSC 22000 trainers shall successfully complete a train-the-trainer program to demonstrate the capability of delivering training.

5.1.4 PERSONAL SKILLS

- 1) The trainer shall have the following personal skills:

- a) listening and communicating effectively;
 - b) developing presentations;
 - c) motivating people;
 - d) facilitation;
 - e) managing conflicts;
 - f) continuous professional development;
 - g) using information technology effectively;
 - h) sensitivity to equality and diversity issues;
 - i) adherence to a conduct of conduct or statement of values;
 - j) intercultural competencies;
 - k) guiding, counselling, and mentoring.
- 2) The TO is responsible to ensure the trainers demonstrate these personal skills (for example: by observing training).

5.1.5 QUALIFICATION RECORD

The TO shall demonstrate the requirements of 5.1.1 – 5.1.4 by completing a Trainer Qualification record. The record shall be retained for the duration of qualification as an FSSC 22000 trainer.

5.1.6 RECORDS

Records of work experience, qualifications, and training shall be maintained by the TO for each FSSC 22000 trainer.

5.2 MAINTENANCE OF TRAINERS QUALIFICATION

- 1) The TO shall have a system to maintain the competence of the trainers.
- 2) The TO shall ensure that its trainers maintain an appropriate level of knowledge and education, by providing an internal program for continuous professional development (CPD).
- 3) Any changes to the Scheme requirements shall be communicated to the trainers prior to conducting training to the new Scheme requirements.
- 4) Annual training on Scheme updates and information shall be conducted by the TO following the Harmonization Conference.
- 5) In order to maintain their training skills, the trainer performs at least:
 - a) two (2) FSSC 22000 training courses every two years; OR
 - b) two (2) FSMS training courses per year that are equivalent to FSSC 22000 courses (GFSI approved/recognized).

6 MANAGEMENT SYSTEM

- 1) TO shall have a Management System for developing and delivering training including:
 - a) application for courses;

- b) acceptance of delegates;
 - c) selection and qualification of trainers;
 - d) development of training materials;
 - e) training resources;
 - f) delivery of training;
 - g) assessment of delegates;
 - h) assessment of courses;
 - i) issuing of certificates.
- 2) The TO shall implement at least the following basic elements in the organization:
- a) customer satisfaction;
 - b) complaints procedure;
 - c) management review;
 - d) continuous improvement;
 - e) internal audit;
 - f) change management.

6.1 DOCUMENT CONTROL

The TO shall have a system in place to ensure that only the most recent version of the Scheme documents are used, and that changes to the Scheme (communicated by the Foundation as per the Board of Stakeholders Decision List) shall be implemented as per Foundation requirements. The TO shall review and update the training materials following the publication of each Scheme update (including BoS Decisions) prior to the next training course delivery.

6.2 COMPLAINTS AND APPEALS

- 1) All complaints from course delegates, trainers or other involved parties shall be registered.
- 2) Complaints shall be investigated, corrective action taken to resolve the issue.
- 3) Records shall be maintained.
- 4) The TO has a right to appeal any decisions made through the Sanction Policy. Details are provided in the Sanction Policy.

APPENDIX 1
DEFINITIONS

APPENDIX 1: DEFINITIONS

The following definitions apply to the terminology used in all Scheme documentation.

ACCREDITATION

Third-party attestation related to a certification body conveying formal demonstration of its competence to carry out specific conformity assessment tasks (ISO/IEC 17011:2004).

ACCREDITATION BODY

Authoritative body that performs accreditation (ISO/IEC 17011:2004).

ACCREDITATION CERTIFICATE

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

ACCREDITATION MARK

Mark issued by an accreditation body to be used by accredited CB's to indicate direct conformity of an entity against a set of requirements.

ADDITIVE

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

ADVISORY COMMITTEE

A group of stakeholders within the scope of the Scheme who advise the Board of Stakeholders.

AUDIT

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

APPEAL

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

AUDITOR

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

BLACK-OUT DAYS

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

BOARD OF STAKEHOLDERS

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

CERTIFICATION

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

CERTIFICATION BODY

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

CERTIFICATION DECISION

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

CERTIFICATION DECISION DATE

Date on which the certification decision is taken.

CERTIFICATION SCHEME

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

CERTIFICATE SUSPENSION

Declaration of certificate status as temporarily invalid.

CERTIFICATE WITHDRAWAL

Final inactivation of a certificate following a Certification decision.

CLEANING PROGRAM

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

COMPETENCE

Ability to apply knowledge and skills to achieve intended results (ISO 9000:2015).

COMPLAINT

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

CRITICAL NONCONFORMITY

Circumstance where there is a failure in the system with direct food safety impact and no appropriate action by the organization is observed or when legality and/or certification integrity are at stake.

CROSS DOCKING

Process by which goods (food, feed, animal food and packaging) are unloaded, sorted, consolidated, loaded, and shipped to the next destination.

DATA OWNERSHIP

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

DISINFECTION

Reduction by means of chemical agents and/or physical methods, of the number of microorganisms in the environment, to a level that does not compromise food safety.

ENVIRONMENTAL MONITORING

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

FEED

Any single or multiple products, whether processed, semi-processed or raw, which is intended to be fed to food producing animals.

FOOD

Product substance (ingredient), whether processed, semi-processed or raw, which is intended for consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of “food” but does not include cosmetics or tobacco or substances (ingredients) used as drugs (ISO 22000:2018). Food is intended for consumption by humans and animals, and includes feed and animal food:

- feed is intended to be fed to food-producing animals;
- animal food is intended to be fed to non-food-producing animals, such as pets.

FOOD DEFENSE

The process to ensure the security of food and drink from all forms of intentional malicious attack including ideologically motivated attack leading to contamination or unsafe product (GFSI v7.2:2018).

FOOD FRAUD

A collective term encompassing the deliberate and intentional substitution, addition, tampering or misrepresentation of food, food ingredients or food packaging, labelling, product information or false or misleading statements made about a product for economic gain that could impact consumer health (GFSI v7.2:2018).

FOOD SAFETY CULTURE

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

FOOD SAFETY MANAGEMENT SYSTEM

Set of interrelated or interacting elements to establish policy and objectives and to achieve those objectives, used to direct and control an organization with regard to food safety (ISO/TS 22003:2013).

FOUNDATION FSSC 22000

The legal owner of the FSSC 22000 Certification Scheme.

FOLLOW-UP AUDIT

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

FSSC LOGO

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

GFSI APPROVED STANDARDS

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

GFSI RECOGNIZED STANDARDS

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

HACCP STUDY

Hazard analysis for a family of products/services with similar hazards and similar production technology and, where relevant, similar storage technology (ISO/TS 22003:2013).

MANUFACTURING/PROCESSING

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

MAJOR NONCONFORMITY

Nonconformity that negatively affects the capability of the management system to achieve the intended results (ISO/IEC 17021-1:2015).

MINOR NONCONFORMITY

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

OUTSOURCE

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

ORGANIZATION

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

PERISHABLE PRODUCT

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

PET FOOD FOR DOGS AND CATS

Animal food intended to be fed to non-food-producing animals, limited to dogs and cats (ISO 22000:2018).

PET FOOD FOR OTHER PETS

Animal food intended to be fed to non-food-producing animals other than dogs and cats.

PORTAL

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

PORTAL DATA

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

PRODUCT

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

PRODUCT RECALL

The removal by a supplier of a product from the supply chain that has been deemed to be unsafe and has been sold to the end consumer and is available for sale (GFSI v7.2:2018).

PRODUCT WITHDRAWAL

The removal of a product by a supplier from the supply chain that has been deemed to be unsafe and which has not been placed in the market for purchase by the end consumer (GFSI v7.2:2018).

PROCESS

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

QUALITY MANAGEMENT SYSTEM

Set of interrelated or interacting elements to establish policy and objectives and to achieve those objectives, used to direct and control an organization with regard to quality.

RAW MATERIAL

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

REWORK

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

RISK

Effect of uncertainty (ISO 22000:2018).

SANCTION COMMITTEE

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

SANITATION

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

SCHEME

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

SCOPE

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

SERIOUS EVENT

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

SPECIAL AUDITS

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

TABLEWARE

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

THREAT

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

UNANNOUNCED AUDIT

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

VULNERABILITY

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

WITNESSED AUDIT

Periodic observation of an auditor performance during an audit, by a competent supervisor called the witnessor.

APPENDIX 2
REFERENCES

APPENDIX 2: NORMATIVE REFERENCES

- BSI/PAS 221:2013 Prerequisite programs for food safety in food retail
- GFSI Benchmarking Requirements (latest version)
- IAF ID 1 QMS and EMS Scopes of Accreditation (latest version)
- IAF MD 1 Audit and Certification of a Management System Operated by a Multi-Site Organization (latest version)
- IAF MD 2 Transfer of Accredited Certification of Management Systems (latest version)
- IAF ID 3 Management of Extraordinary Events or Circumstances Affecting ABs, CABs, and Certified Organizations
- IAF MD 4 The Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes (latest version)
- IAF MD 5 Determination of Audit Time of Quality and Environmental Management Systems (latest version)
- IAF MD11 Application of ISO/IEC 17021-1 for Audits of Integrated Management Systems (latest version)
- IAF MD 16 Application of ISO/IEC 17011 for the Accreditation of Food Safety Management System (FSMS) Certification Bodies (latest version)
- IAF MD 20 Generic Competence for AB Assessors: Application to ISO/IEC 17011 (latest version)
- ISO 9001:2015 Quality management systems – Requirements
- ISO 22000:2018 Food safety management systems – Requirements for any organization in the food chain
- ISO/IEC 17021-1:2015 Conformity assessment – Requirements for bodies providing audit and certification of management systems.
- ISO/TS 22003:2013 Food safety management systems – Requirements for bodies providing audit and certification of food safety management systems.
- ISO/IEC 17011:2018 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies.
- ISO/TS 22002-1:2009 Prerequisite programs for food safety – Part 1: Food manufacturing
- ISO/TS 22002-2:2013 Prerequisite programs for food safety – Part 2: Catering
- ISO/TS 22002-3:2011 Prerequisite programs for food safety – Part 3: Farming
- ISO/TS 22002-4: 2013 Prerequisite programs for food safety – Part 4: Food packaging manufacturing
- ISO/TS 22002-5:2019 Prerequisite programs for food safety – Part 5: Transport and storage
- ISO/TS 22002-6:2016 Prerequisite programs on food safety – Part 6: Feed and animal food production
- FSSC 22000 Integrity Program documentation