



# FSSC 22000 SCHEME VERSION 5

VERSION 5 | MAY 2019

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## TRANSLATIONS

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

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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 of the FSSC 22000 Scheme published in May 2019. The main factors that initiated the development of this version have been:

- publication of the new ISO 22000:2018 standard on 19 June 2018;
- transition period of 3 years for transition to the new ISO 22000:2018 standard as determined by the International Accreditation Forum (IAF) latest 29 June 2021;
- enable integrated management system audits for FSSC 22000-Quality;
- improvement of previous Scheme requirements;
- compliance with Global Food Safety Initiative (GFSI) Benchmarking Requirements;
- compliance with relevant Accreditation Body requirements.

## ABOUT THE SCHEME

The Scheme consists of six Parts and two Appendices which are bundled in this document. Furthermore, there are seven 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 REFERENCES

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

## ANNEXES

There are seven 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

PART 1

# SCHEME OVERVIEW

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# 1 INTRODUCTION

## 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.

## OWNERSHIP

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.

## LANGUAGE

English is the original 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 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	Sub category	Description	Example of included activities and products	Normative Documents
<b>A</b>	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, ISO/TS 22002-3, FSSC 22000 Additional requirements
	All	Farming of Fish and seafood	Raising fish and seafood used for meat production (associated farm packing and storage).	ISO 22000, ISO/TS 22002-3, FSSC 22000 Additional requirements
<b>C</b>	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
	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)	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	Sub category	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
<b>D</b>	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
	DIa	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 cates. 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
	DIb	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 cates. 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
<b>E</b>	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	Sub category	Description	Example of included activities and products	Normative Documents
<b>F</b>	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
<b>G</b>	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, NEN/NTA 8069:2016, FSSC 22000 Additional requirements
	GII	Provision of transport and storage services for ambient stable food and feed.	Transport and storage. Additional activities such as re-packing of packed product.	ISO 22000:2018, NEN/NTA 8069:2016, FSSC 22000 Additional requirements
<b>I</b>	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
<b>K</b>	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, 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 of this are:

- 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 logistic service providers who physically store and/or transport food, feed or food/feed packaging materials but do not take ownership of the product. It may include additional activities such as re-packing of packed products, freezing and thawing activities. Manufacturers that only store and/or transport their own product(s) do not provide a service to others and therefore shall not be audited under this category..

### 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.

### 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-Quality certificate.

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”.

## 4 GOVERNANCE AND INTEGRITY PROGRAM

### ARTICLE 1 FOUNDATION FSSC 22000

- 1.1 The Foundation has as its statutory objectives:
- a) Promoting the application of food safety and quality management systems;
  - b) Developing, designing, managing and amending food safety certification and inspection systems in the field of food safety and quality;
  - c) Promoting national and international recognition and general acceptance of systems it has developed for food safety and quality;
  - d) Running information campaigns and providing information on food safety and quality;
  - e) Providing support services for certification of food safety systems in the field of food safety and quality;
  - f) Performing all other actions that are related in the broadest possible sense with the aforementioned or that could in any way be beneficial to it.
- 1.2 The Foundation endeavors to achieve these objectives by:
- a) Entering into agreements with certification bodies;
  - b) Taking appropriate measures in the event of abuse or improper use of the certificates issued by accredited certification bodies;
  - c) Taking appropriate measures in the event of abuse or improper use of the Foundation's logo;
  - d) Supporting, supervising and financing of other foundations and organizations which strive to achieve similar or partially similar objectives as those mentioned in this Article.

### ARTICLE 2 THE MANAGEMENT BOARD

- 2.1 The Foundation's management board, hereinafter referred to as “the Board”, consists of at least three members
- 2.2 The Board may never consist of a majority of members who represent the interests of one of the stakeholder groups involved. Stakeholder groups in this context being stakeholders or certification bodies or certificate holders or organizations which are intended to be certificate holders.

- 2.3 The Board shall fill any vacancies that may arise with due observance of the aforementioned. Appointments are made by Board resolution.
- 2.4 Board members serve 5-year terms. They may be reappointed only twice. Thereof they only become eligible for appointment to the Board at least one year after their last term has expired. The Board shall use the prescribed term to draw up a retirement roster. Furthermore, the Board must ensure that end-of-term departures do not endanger its balanced operation.
- 2.5 The Board shall elect a chairman and a treasurer from among its members. The Board shall also appoint a secretary to carry out all necessary administrative activities. The same person may hold the position of secretary and treasurer. The Board can appoint deputies for the chairman, secretary and/or treasurer from among its members. The deputies perform these duties during the officers' absence or incapacity to act. If the secretary is not a member of the Board, he/she shall have only an advisory role.

### ARTICLE 3 REPRESENTATION

- 3.1 The Foundation is represented by the Board or two Board members acting together.
- 3.2 The Board can grant a Board member or a third party a power of attorney to represent the Foundation within the confines of the power of attorney and the limitations from this Part of the Scheme and/or applicable law.

### ARTICLE 4 BOARD MEETINGS

- 4.1 The Board shall meet at least once each year and, furthermore, as often as the chairman or at least two Board members consider necessary.
- 4.2 Board members are entitled to have another Board member represent them in a meeting after such written authorization is given which the chairman of the meeting deems sufficient. A Board member may only act as proxy for one other Board member.
- 4.3 If same has been mentioned in the summons, each Board member is entitled, in person or by way of written proxy, via an electronic means of communication, for instance via a conference or video call, to take part in the Board meeting, to take the floor in the meeting, and to exercise the right to vote, provided the Board member can be identified via the electronic means of communication, can take cognizance of the proceedings of the meeting directly and can participate in all deliberations.
- 4.4. The Board is authorized to set conditions for the use of electronic means of communication. If the Board exercises this authority, the conditions shall be published in the summons.

## ARTICLE 5 BOARD DECISION MAKING

5.1 The Board can pass resolutions in and outside meetings. Unless these articles stipulate otherwise, a resolution can only be passed in a meeting at which a majority of current members are present. A decision taken outside a meeting requires a unanimous written vote of all current Board members.

If the provisions of these articles concerning the summons to the meeting have been violated, the Board can still pass resolutions in a legally valid manner provided the Board members not present at the meeting have stated in writing prior to the meeting that they do not object to the decision-making.

5.2 Voting will be oral, unless a Board member requests a written vote.

5.3 Unless these articles state otherwise, the Board shall adopt motions by a simple majority of votes cast.

5.4 If there is no majority on the first ballot in case of voting on the appointment of persons, a new ballot will be held. If no majority is reached after the second ballot, an interim vote shall decide which persons will remain in the running.

If a ballot on persons results in a tied vote, lots will be drawn to decide who has been elected; if a ballot on other items results in a tied vote, the motion will be rejected.

## ARTICLE 6 BOARD OF STAKEHOLDERS

6.1 The Board appoints a Board of Stakeholders, hereinafter referred to as the “BoS”, of which it determines the number of members and shall appoint or reappoint its chairman. A Board member cannot be appointed as member of the BoS, but the Foundation secretary can act as Secretary of the BoS, having an advisory role, not having any voting rights. The chairman leads the meetings of the BoS and shall be independent. The BoS shall consist of representatives of stakeholders in the field of FSSC 22000 certification, accreditation and promotion.

6.2 The BoS advises the Board on the design, development, changes and emendation of the Scheme, including interpretation of clauses, scopes, accreditations, work methods, methods and frequency with which certification bodies are inspected, complaints procedures and standards of expertise of auditors.

6.3 The Board shall adopt the advice by the BoS referred to in paragraph 6.2 of this article, unless it is in conflict with any statutory provisions, or is in conflict with any requirement that the Foundation must meet in the context of accreditation, or if the Board is of the opinion that, taking into account all relevant interests of all stakeholders, the interests of the Foundation oppose the adoption of the advice. In such case the Foundation shall inform the BoS in writing, the BoS having the right to convene a meeting to discuss same.

6.4 With reference to Article 9, paragraph 3 of the Articles of Association of the Foundation the BoS shall from its members appoint a Sanction Committee, existing of at least 3 members and chaired by the independent chairman of the BoS. The Committee has the task to

decide on behalf of the BoS on sanctions to be imposed on licensed certification bodies in conformity with the Integrity Program & Sanction Policy as also to be established by the BoS.

- 6.5 The BoS can appoint an Advisory Committee which may include members of the BoS, outside experts, representatives of certification bodies group organizations, industry representatives, science and public institutions representatives, to advise the BoS on decisions to be taken regarding the contents and the application of the Scheme. The BoS shall in any case take such advice into consideration but is not bound to follow same.
- 6.6 The BoS will decide on Terms of Reference for both the Sanction and Advisory Committee(s).

## ARTICLE 7 FSSC 22000 INTEGRITY PROGRAM

- 7.1 The FSSC 22000 Integrity program consists of the following elements:
- Standard contract with certification bodies;
  - A program of KPI driven desk reviews of full audit reports, as determined by the Board;
  - A program of KPI driven analysis of audit reports, as determined by the Board,
  - Registration of all auditors qualified under the Scheme;
  - A program of office and witness audits as determined by the Board;
  - A program for obligatory unannounced audits by contracted certification bodies, as determined by the Board;
  - All further programs, procedures and measures which at any time may be required by the current version of the requirements set by the Global Food Safety Initiative.
- 7.2 The Foundation shall appoint an independent expert assessing the results of the above mentioned programs, reporting same to the Board.
- 7.3 The Board shall maintain a sanction policy consisting of a system of written warnings, and yellow and red cards, based on major and minor findings in the programs.
- 7.4 Directly interested parties may appeal in writing against sanction decisions made by the Board.
- 7.5 The Board will make public the way on which any interested third party may file complaints against any of the aspects of the Scheme.
- 7.6 The Foundation shall maintain a public register for all certificates duly issued on basis of the Scheme, safeguarding all information on certified organizations which are to be treated as confidential.
- 7.7 The Board may, in consultation with the BoS, decide on specific provisions on accreditation of CBs and memoranda of understanding between the Foundation and accreditation bodies, which may go beyond the provisions laid down in the Scheme.

- 7.8 The standard contract with certification bodies as referred to above will contain provisions for the use of the FSSC 22000 logo and the Foundation's IT infrastructure supporting the audit process and audit registration process.

## ARTICLE 8 FURTHER STATUTORY PROVISIONS AND REQUIREMENTS

The Foundations 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.

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.

### 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 prerequisite programs (PRPs) as referenced in clause 8.2 of ISO 22000:2018. These PRP

requirements are specified in the ISO/TS 22002-x series, NEN/NTA 8059 and/or the BSI/PAS 221 standards.

## 2.5 FSSC 22000 ADDITIONAL REQUIREMENTS

### 2.5.1 MANAGEMENT OF SERVICES

In addition to clause 7.1.6 of ISO 22000:2018, the organization shall ensure that in case external laboratory analysis services are used for the verification and/or validation of food safety, these shall be conducted by a competent laboratory 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).

### 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 food safety (including allergens) statutory and regulatory requirements in the country of intended sale.

### 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.

PART 3

# REQUIREMENTS FOR THE CERTIFICATION PROCESS

## CONTENTS 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 I.

### 4.3 AUDIT DURATION

The CB shall calculate the audit time 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 on-site audit duration does not include a lunch break (unless in contradiction with local legislation);
- b) the audit time 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 on-site audit duration shall be stated in auditor working hours indicating the time spent at the site and shall match the audit plan and deviations shall be recorded (including motivations);
- d) the on-site audit time does not include planning, reporting or travel activities, only actual on-site auditing time;
- e) the on-site 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 time stated in the report shall be of the total combined audit and match 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 on-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) on-site when the company has less than 250 FTE and 1 or 2 HACCP studies.
  - ii) 1.0 auditor day (8 working hours) on-site 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). The reduction cannot be applied on  $T_{FSSC}$ .

Exemption: Further reduction is only allowed for sites with simple processes, having 5 FTE or less and maximum 1 HACCP study. For such sites, a reduction in on-site audit time ( $T_{FSSC}$ ) can be made but the total time  $T_s + T_{FSSC}$  shall be minimum one day.

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

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

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

#### 4.3.2 SURVEILLANCE AND RECERTIFICATION AUDITS

- a) Surveillance audits: on-site audit duration shall be (one-third of  $T_s$ ) + ( $T_{FSSC}$ ), plus any other additional audit time (as per §4.3.3 below).
- b) Recertification audits: on-site audit duration shall be (two-thirds of  $T_s$ ) + ( $T_{FSSC}$ ), plus any other additional audit time (as per §4.3.3 below).

In both types of audits, the minimum duration for  $T_s$  is 1 day as per ISO/TS 22003, Annex B. This makes a minimum basic FSSC 22000 audit duration of 1.5 days regardless of the audit type.

Note: For subcategory A ISO/TS 22003:2013 states a minimum audit duration of 0.5 days, the minimum FSSC 22000 audit duration will for this category be 1 day).

If after the calculation the result is a decimal number, the number of days should be adjusted to the nearest half day (e.g. 5.3 audit days becomes 5.5).

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.

The minimum audit duration for the annual audits shall always be respected.

### 4.3.3 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) on-site 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 on-site audit time shall be added to the FSSC 22000 audit time for each off-site storage facility.

### 4.3.4 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.

### 4.3.5 TRANSITION TO FSSC 22000

- 1) When transitioning from Dutch HACCP, ISO 22000 or an equivalent GFSI recognized certification to FSSC 22000 certification, the minimum FSSC 22000 certification on-site audit time shall be two-thirds of the initial certification audit time, with a minimum of 1 auditor day (8 working hours) on-site 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 4.3.4.) 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) at the request of food safety authorities, information related to the certification and auditing process shall be shared;
- 3) conditions under which the certification contract can be terminated;
- 4) conditions under which the certificate can be used by the certified organization;
- 5) terms of confidentiality in relation to information gathered by the CB during the certification process;
- 6) the certified organization allows the CB to share information when required by law from governmental authorities and/or the Foundation;
- 7) procedures for nonconformity management;
- 8) procedures for complaints and appeals;
- 9) inclusion of information on the certified status of the organization on the FSSC 22000 website and in the Portal;
- 10) cooperation in allowing witness assessments by the AB and/or the Foundation when requested;
- 11) communication obligations of certified organizations to the CB within 3 working days related to the following:
  - a) any significant changes that affect the compliance with the Scheme requirements and obtain advice of the CB in cases where there is doubt over the significance of a change;
  - b) serious events that impact the FSMS 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 on-site at the premises of the organization and is a full audit against all Scheme requirements.
- 3) 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.
- 4) The CB is expected to operate discretely in case of emergencies (e.g. fire, major catastrophic event, another audit on-going).
- 5) The CB shall perform the stage 1 and stage 2 audits for initial certification according to the requirements of ISO/IEC 17021-1.
- 6) The interval between stage 1 and stage 2 audits shall not be longer than 6 months. Stage 1 shall be repeated if a longer interval is needed.
- 7) The 3-year certification cycle (ISO/IEC 17021-1 §9.1.3) shall be respected at all times.

### 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 are 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

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

- 1) A – Animal Farming
- 2) E – Catering
- 3) FI – Retail/wholesale
- 4) G – Storage and distribution.

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.

Each site (plus the central function) shall have its own report (see section 6). The certificate shall be a group certificate.

## 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 sets the date of the unannounced audit typically between 8-12 months after the previous audit (but respecting recertification planning). The consequence of this may be that the audit is not conducted annually (as required by §5.1).

- 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.
- 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.
- 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 REMOTE AUDITS

Computer aided audit techniques (CAAT) may be used as a remote audit tool during FSSC 22000 audits provided the requirements of IAF MD4 are met.

## 5.6 TRANSFER OF CERTIFICATION

The CB shall follow the requirements of IAF MD2 for 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.

## 5.8 TRANSITION AUDITS

- 1) Transition audits are allowed from Dutch HACCP, 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 section 4 of this Part.
- 4) Audit teams conducting integrated FSSC 22000 and ISO 9001 audits (FSSC 22000-Quality) shall collectively meet the relevant FSSC 22000-Quality auditor specifications.
- 5) The lead auditor shall always be a FSSC 22000 qualified auditor.
- 6) 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.
- 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) This includes situations where due to security and/or visa issues in the Country, an audit cannot be performed as unannounced (e.g. when an auditor requires to be in contact with the organization at all times, due to security reasons or a visa must be requested in advance).

## 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.
- 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 but only when the requirements of ISO/TS 22003:2013, clause 9.1.2 are met. N/As shall be motivated in the 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.
- 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.

### 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.

In case of non-conformities noticed in a Head Office audit, these are assumed to have 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.

#### 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 three (3) months 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 on-site 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 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 issued at a certified site the certificate shall be immediately suspended 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 days after the audit;
- 3) a separate audit shall be conducted by the CB between six (6) weeks to six (6) month 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.

### 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 I and Annex VI).
- 2) The FSSC 22000 logo shall be used by the CB on its certificates.
- 3) Head Office details shall be included, where applicable.
- 4) 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.
- 5) Dates on the certificates shall be as follows:
  - a) certificate decision date: date of 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);
  - 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 expires (maximum duration is 3 years).

### 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:
  - a) immediately 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 within three (3) days after the decision was made;
  - 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:
  - a) immediately 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 within three (3) days after the decision of change;
  - c) instruct the organization to take appropriate steps in order to inform its interested parties.

## 8 PORTAL DATA AND DOCUMENTATION

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 4 months after the last day of the audit.

PART 4

# REQUIREMENTS FOR CERTIFICATION BODIES

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# 1 PURPOSE

This document states 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) The CB shall hold a valid ISO/IEC 17021-1:2015 accreditation including ISO/TS 22003:2013 for the Scheme and applicable food chain 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.
- 2) The Foundation is entitled to request information from the Accreditation Body related to the CB accreditation.
- 3) 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 which they wish to provide certification services. As part of the application, the CB shall submit a completed self-assessment in the FSSC 22000 provided format against the Scheme requirements.
- 2) Upon successful review of the information the CB shall be granted a license agreement with a 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. Unaccredited certificates shall be registered in the Portal. After accreditation is achieved, these unaccredited certificates shall be replaced with an accredited certificate. 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 (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 two (2) certified organizations registered in the Portal.

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

Upon review and approval, the Foundation shall issue and/or modify the status of the license agreement CB list 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 five (5) audited organizations registered in the Portal with a minimum of one for each licensed food chain category. For new CBs this shall be achieved within 12 months after receiving the full license status;
- 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 categories for which it requests an extension of the existing license.
- 2) The CB shall be granted a provisional status for the new category 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 category. Unaccredited certificates shall be registered in the Portal. After accreditation these certificates shall 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 subcategories 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.

## 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 (five) 5;
- 4) sanction committee decision;
- 5) no payment of the fee to the Foundation;
- 6) repetitive noncompliance with the Scheme requirements.

### 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 an 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.

The CB shall communicate the following to the Foundation:

- 1) changes on the FSSC 22000 accreditation status: e.g. suspension or withdrawal, together with a written communication to the Foundation about the circumstances leading to this;
- 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 and governmental authorities when required by law.
- 8) The CB shall ensure that all Scheme related data in Portal is complete, up-to-date, correct and meets the Scheme requirements.
- 9) Where the CB uses the FSSC 22000 logo, they shall comply with the requirements in Part II and are entitled to use it only when the CB has a signed license agreement.

## 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 IP 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 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 audit them.
- 2) In case of FSSC 22000-Quality the certification decision maker must 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.
  
- 4) Other
  - a) Audits: at least ten (10) audit days and five (5) ISO 22000 or GFSI recognized scheme audits relevant to the specific industry sector including at least one (1) FSSC 22000 audit.
  - b) GFSI Exam: all auditors shall complete the GFSI exam within the timeframe given by the Foundation. For new auditors this shall be completed prior to qualification as an FSSC 22000 auditor.
  - c) 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 meeting the requirements defined by WPO Packaging.

- d) 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 an FSSC 22000 technical certification person of equivalent competence and experience.
- 3) 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 I table 1). In order to assign subcategories to an auditor, the CB shall demonstrate that the auditor complies with the following requirements:
  - a) six (6) months' work experience in the subcategory OR five (5) audits against a GFSI recognized scheme in the new sub category (post-farm gate only except for food chain category A) as a trainee or co-auditor under the supervision of an auditor qualified for the subcategory. At least one (1) of these five (5) audits shall be an FSSC 22000 audit (stage 2, surveillance or re-certification audits).  
Where consultancy work is used to demonstrate work experience, the amount of consultancy days shall add up to six (6) months.
  - 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) on-site 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. Maximum two (2) of the five (5) can be FSSC 22000 audits as a witnessor.
- 2) In the event when this requirement 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\*

\* 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, and at least one event 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) on-site FSSC 22000 witnessed audit shall be conducted every three (3) years to confirm acceptable auditor performance.
- 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 document specifies the requirements against which the Foundation will recognize Accreditation Bodies (ABs) that provide accreditation services to licensed Certification Bodies.

## 1.1 MEMBERSHIP OF THE IAF

- 1) ABs providing accreditation to CBs seeking to offer FSSC 22000 certification and/or FSSC 22000-Quality certification shall:
  - a) be a current member of the International Accreditation Forum (IAF) and inform the Foundation in case of changes to its membership status; and
  - b) be a signatory to the IAF Multilateral Recognition Arrangement (MLA) for Food Safety Management System (FSMS) certification for FSSC 22000 accreditation; and
  - c) be a signatory to the IAF Multilateral Recognition Arrangement (MLA) for Quality Management System (QMS) certification for FSSC 22000-Quality accreditation.

## 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.
- 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 FSSC 22000 information shared with the ABs via webinars and technical newsletters, shall be communicated to all its assessors for the Scheme and records of such training shall be retained.
- 5) The AB shall inform the Foundation in case the accreditation status of the CB changes (e.g. granted, extension, reduction, re-instate, suspension or withdrawal).
- 6) Evaluation that an AB meets the requirements of this document shall be monitored by the Foundation and the AB shall comply with the relevant Scheme requirements. Feedback on its performance shall be shared by the Foundation with the AB for discussion and action when appropriate.

# 2 ACCREDITATION OF CBS

## 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 category (Annex 4) and/or for FSSC 22000-Quality.
- 2) The AB shall not issue an accreditation certificate for a (sub)category where there is no (provisional) license with the Foundation, this includes scope extensions for new (sub)categories.

## 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) CBs undergoing the process of FSSC 22000 accreditation against ISO/IEC 17021-1:2015 and ISO/TS 22003:2013 may already carry out FSSC 22000 audits 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 4 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 PRP's;
    - iv. Additional FSSC 22000 requirements.
  - d) Food chain clusters and (sub)categories as indicated in Annex A of ISO/TS 22003:2013;
  - e) IAF ID 1 sector codes as indicated in Annex 4 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 Scheme specific requirements:
  - a) initial and scope extension assessments shall require at least one (1) 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 witnessed audits covering all categories included in the CB accreditation scope during the AB accreditation cycle.

## 2.3 INTEGRITY PROGRAM

- 1) The Foundation provides the AB access to all with 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 assessments undertaken by the Foundation at their accredited CBs.
- 3) The Foundation shall advise the AB on suspensions or terminations of its licensed CBs.

PART 6

# REQUIREMENTS FOR TRAINING ORGANIZATIONS

## CONTENTS PART 6 REQUIREMENTS FOR TRAINING ORGANIZATIONS

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# 1 PURPOSE

This document states the requirements for licensed training organizations (TOs) who wish to provide approved Scheme 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).

#### 2.2.2 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 TO 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 2.3.1).
- 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 II) 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 trainings performed in the previous year;
- 2) the planned 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 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 2.2.3.
- 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 II 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 IP 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.
  - d)

### 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.

### 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 CBs to become qualified lead auditors. May also be applicable to organizations wishing to further develop their internal auditing skills and for consultants. Duration 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.

## 4 OPERATIONAL PROCESSES

### 4.1 LEARNING NEEDS

- 1) Preceding each training the TO shall determine the target group and the accompanying learning goals.
- 2) The TO shall specify the minimal 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, OPRP's 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.
  - b) Trainers qualified to provide auditing courses:
    - i. Scheme requirements, relevant normative documents, FSSC 22000 Guidance documents.
    - ii. audit principles, practices and techniques (internal auditor trainers);
    - iii. FSMS Lead Auditor Training (lead auditor trainers).

#### 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).

## 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.

## 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.

## 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.

## 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.

## 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 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 time-frame from the main audit.

## 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.

## 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.

## 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.

## 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

Situation or event preventing a planned audit to take place caused by humans (e.g. war, strike) or by nature (flood, storm) which also includes situations where an unannounced audit is not possible (e.g. security reasons).

## SPECIAL AUDITS

Audits at certified organizations that are performed on top of 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 on-site observation of an auditor performance by a competent supervisor called witnessor.

# APPENDIX 2 REFERENCES

## APPENDIX 2: REFERENCES

In this appendix, all references to documents not included in the Scheme documents are listed:

- BSI/PAS 221:2013 Prerequisite programmes 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 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 programmes for food safety – Part 1: Food manufacturing
- ISO/TS 22002-2:2013 Prerequisite programmes for food safety – Part 2: Catering
- ISO/TS 22002-3:2011 Prerequisite programmes for food safety – Part 3: Farming
- ISO/TS 22002-4: 2013 Prerequisite programmes for food safety – Part 4: Food packaging manufacturing
- ISO/TS 22002-6:2016 Prerequisite programmes on food safety – Part 6: Feed and animal food production
- NEN/NTA 8059:2016 Prerequisite programs on food safety for transport and storage