



# FSSC DEVELOPMENT PROGRAM

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## TRANSLATIONS

Please be aware that in case of translations of the FSSC Development Program documents, the English version is the valid and binding version.

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## INTRODUCTION

With a growing world population, there is an increasing need for affordable, safe, and good quality food products. To fulfill this need, Foundation FSSC provides a trusted brand assurance platform to the food industry. The FSSC Development Program (hereafter: the Program) fits the needs of organizations in the food supply chain and their customers to achieve a conforming food safety system.

## ABOUT THE PROGRAM

The Program consists of four Parts and two Appendices, which are bundled in this document. Furthermore, there are three Annexes. All these documents also contain mandatory Program requirements. Guidance documents, where available, can be downloaded for free from the FSSC website.

## HOW THE PROGRAM IS ORGANIZED

### **PART 1      PROGRAM OVERVIEW**

This part describes the Program context and details, including its applicable scopes.

### **PART 2      REQUIREMENTS FOR ORGANIZATIONS TO BE ASSESSED**

This part describes the Program requirements against which licensed conformity assessment bodies shall assess the food safety systems of organizations in the supply chain in order to achieve or maintain Program conformity.

### **PART 3      REQUIREMENTS FOR THE ASSESSMENT PROCESS**

This part describes the requirements for the execution of the assessment process to be conducted by licensed conformity assessment bodies.

### **PART 4      REQUIREMENTS FOR CONFORMITY ASSESSMENT BODIES**

This part describes the requirements for licensed conformity assessment bodies that provide Program assessment services to organizations.

### **APPENDIX 1 DEFINITIONS**

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

### **APPENDIX 2 REFERENCES**

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

### **ANNEXES**

There are three Annexes which are mandatory and necessary for proper implementation of the Program:

- Annex 1 Conformity statement scope wording
- Annex 2 CAB Conformity statement templates
- Annex 3 HACCP (CCP/OPRP) Decision tree

# **PART 1** **PROGRAM** **OVERVIEW**

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# 1. INTRODUCTION

## 1.1 THE PROGRAM

The Program outlines the requirements for organizations in the food supply chain and their customers to achieve a conforming food safety system (FSS).

The Program provides a voluntary assessment model that can be used in the food manufacturing supply chain linked to the food chain category description as defined in ISO 22003-1: 2022 Annex A and section 3 – scope of this document.

The Program's assessments are performed unaccredited. The assessments are subsequently registered in the FSSC Register of conforming organizations. This register is publicly available. Registration indicates that the organization's food safety system is in conformance with the Program requirements and that the organization is able to maintain conformance with these requirements.

When the Foundation (hereafter FSSC) decides that updates or changes to the Program are necessary, requirements for communication and implementation will be published separately.

## 1.2 OWNERSHIP AND GOVERNANCE

FSSC retains the ownership and the copyright of all Program related documentation and also holds the agreements with all involved conformity assessment bodies.

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

## 1.3 LANGUAGE

English is the official and valid version of the Program.

# 2. FEATURES

## 2.1 AIM AND OBJECTIVES

The aim of the Program is to ensure that it continuously meets international requirements resulting in trusted Conformity Statements being issued by licensed conformity assessment bodies (CABs) to assure the provision of safe products to consumers worldwide.

The specific Program objectives are to:

- a) Establish and maintain an accurate and reliable Register of conforming organizations that have demonstrated compliance with the Program requirements;
- b) Promote the accurate application of food safety systems;
- c) Promote national and international recognition and general acceptance of food safety systems;
- d) Provide information and campaigns on food safety systems;

- e) Provide support for the assessment of food safety systems;
- f) Provide market access for conforming organizations;
- g) Provide a tool for supplier development and assessment against a minimum set of food safety requirements.

## 2.2 NATURE OF THE PROGRAM

The Program provides an independent third-party assessment of food safety, covering the majority of the sectors in the food supply chain.

The Program:

- a) Is based on elements of ISO22000 and the relevant technical specifications for the sector (e.g., ISO/TS 22002-x; PAS xyz);
- b) Provides a pathway to achieving FSSC 22000 certification;
- c) Is governed by a non-profit Foundation and managed by an independent Board of Stakeholders;
- d) Increases transparency throughout the food supply chain;
- e) Offers a “Register of conforming organizations” that is publicly available on the FSSC website.



### 3. SCOPE

The Program is intended for the assessment and registration of organizations for the following food chain (sub)categories (in line with ISO 22003-1:2022) as indicated in Table 1 below:

**Table 1. Overview of (Sub)Categories**

Category	Subcategory	Description	Example of included activities and products	Normative Program requirements
<b>B</b>	BIII	Pre-process handling of plant products	Activities on harvested plants that do not transform the product from original whole form, including horticultural products and hydrophytes for food. These include cleaning, washing, rinsing, fluming, sorting, grading, trimming, bundling, cooling, hydro-cooling, waxing, drenching, aeration, preparing for storage or processing, packing, repacking, staging, storing, and loading.	Assessment Requirements for Food and Feed manufacturing
	C0	Animal – Primary conversion	Conversion of animal carcasses intended for further processing including lairage, slaughter, evisceration, bulk chilling, bulk freezing, bulk storage of animals and game gutting, bulk freezing of fish and storage of game.	Assessment Requirements for Food and Feed manufacturing
<b>C</b>	CI	Processing of perishable animal products	Processing and packaging including fish, fish products, seafood, meat, eggs, and dairy requiring chilled or frozen temperature control. Processing pet food from animal products only.	Assessment Requirements for Food and Feed manufacturing
	CII	Processing of perishable plant products	Processing and packaging including fruits and fresh juices, vegetables, grains, nuts, pulses, frozen water-based products, plant-based meat, and dairy substitutes. Processing pet food from plant products only.	Assessment Requirements for Food and Feed manufacturing
	CIII	Processing of perishable animal and plant products (mixed products)	Processing and packaging including pizza, lasagna, sandwiches, dumplings, and ready-to-eat meals. Includes off-site catering kitchens. Includes products of industrial kitchens not offered for immediate consumption. Processing perishable pet food from mixed products.	Assessment Requirements for Food and Feed manufacturing

	CIV	Processing of ambient stable products	Processing and packaging of products stored and sold at ambient temperature including canned foods, biscuits, snacks, oil, drinking water, beverages, pasta, flour, sugar, and food-grade salt. Processing ambient stable pet food.	Assessment Requirements for Food and Feed manufacturing
<b>D</b>	D	Processing of feed and animal food	Processing feed material intended for food and non-food producing animals not kept in households, e.g., meal from grain, oilseeds, by-products of food production. Processing feed mixtures, with or without additives, intended for food-producing animals, e.g. premixes, medicated feed, compound feeds.	Assessment Requirements for Food and Feed manufacturing
<b>E</b>	E	Catering/food service	Open exposed food activities such as cooking, mixing, and blending, preparation of components and products for on-site direct consumer consumption or take away. Examples include restaurants, hotels, food trucks, institutions, workplaces (school or factory cafeteria), including retail with on-site preparation (e.g., rotisserie chicken). Includes reheating of food, event catering, coffee shops and pubs.	Assessment Requirements for Catering and Food Service
<b>F</b>	FI	Retail /Wholesale /E-commerce	Storage and provision of finished products to customers and consumers (retail outlets, shops, wholesalers). Includes minor processing activities, e.g., slicing, portioning, reheating.	Assessment Requirements for Retail and wholesale
<b>G</b>	G	Transport and storage services	Storage facilities and distribution vehicles for perishable food and feed where temperature integrity shall be maintained. Storage facilities and distribution vehicles for ambient stable food and feed. Relabelling/repackaging excluding open exposed product materials. Storage facilities and distribution vehicles for food packaging material.	Assessment Requirements for Transport and Storage services
<b>I</b>	I	Production of packaging material.	Production of packaging material in contact with food, feed, and animal food.	Assessment Requirements for Packaging manufacturing
<b>K</b>	K	Production of Bio/chemicals	Production of food and feed processing aids, additives (e.g., flavorings, vitamins), gases and minerals. Production of bio-cultures and enzymes.	Assessment Requirements for Food and Feed manufacturing

### 3.1 HANDLING OF PLANTS (CATEGORY B)

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

### 3.2 FOOD MANUFACTURING (CATEGORY C)

Food chain category C involves the following food processing activities:

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

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

### 3.3 ANIMAL FEED PRODUCTION (CATEGORY D)

Food chain category D covers the production of animal feed:

- a) Processing of feed material intended for food and non-food producing animals not kept in households, e.g., meal from grain, oilseeds, by-products of food production.
- b) Processing of feed mixtures, with or without additives, intended for food-producing animals, e.g., premixes, medicated feed, compound feeds.

### 3.4 CATERING (CATEGORY E)

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

Examples include:

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

### 3.5 RETAIL, WHOLESALE AND E-COMMERCE (CATEGORY FI)

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

Retail is defined as selling goods to the final customer (i.e., consumer), in small quantities for consumption and not for the purpose of resale.

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

Retailers and wholesalers shall have physical buildings and facilities (i.e., shops, warehouses).

The retailer or wholesaler may offer internet sales or home deliveries (E-commerce) that may be included in the scope only when linked to the physical location but not as a stand-alone activity.

For both retail and wholesale, minor in-shop processing activities that only serve to give pre-prepared food a final process step may be included (e.g., reheating of ready to eat foods, cutting or portioning of meat or fish).

### 3.6 TRANSPORT AND STORAGE (CATEGORY G)

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

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

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

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

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

- a) Direct food contact surfaces or materials (i.e., physically touching the food or in contact with headspace) that will be in contact with the food during normal use of the food packaging, including labels and food desiccants with direct food contact and/or;
- b) Indirect food contact surfaces or materials that are not in direct contact with the food during normal use of the food packaging, but there is the possibility for substances to be transferred into the food, including labels applied to primary packaging.
- c) Closing packaging materials such as tape, plastic strips, or other can be included in Category I when the manufacturer can prove that it will be applied to a food or feed primary packaging material;
- d) Disposable tableware can only be included when it is sold together (and as part of) the food product. Examples are spoons that are packed with yoghurt, forks or chopsticks packed with ready-to-eat food. The intended use, including that it is sold together (and as

part of) the food product, shall be clearly specified in the scope statement. Disposable tableware that is intended for domestic (home) use is outside the scope of this Program.

- e) Napkins/serviettes can only be included where they are supplied specifically for use in food service. This intended use shall be clearly specified in the scope statement.
- f) Packaging materials, such as aluminum foil, baking paper and plastic wrap, which are intended to be used in the preparation of foodstuffs within the food industry may be included, in which case the scope statement shall indicate that it is for use within the food industry. Packaging materials of this nature that are not for use within the food industry or are intended for domestic (home) use, are excluded from the scope of the Program.
- g) Packaging activities limited to (inline) unfolding of packaging, blowing of bottle preforms, printing etc. are not considered as food packaging activities and are included in the food scope and therefore category I does not apply where linked with food manufacturing at the site.
- h) The in-line production of primary packaging where linked with food manufacturing at the site, such as bottles using resin to produce a preform and followed by the blowing of bottles, is considered a packaging activity and shall additionally be covered by the packaging scope. Therefore, category I shall apply.
- i) Packaging material used for personal care, pharmaceutical products or other non-food uses are outside the scope of the Program.

### **3.8 PRODUCTION OF BIO/CHEMICALS (CATEGORY K)**

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

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

# **PART 2**

# **REQUIREMENTS FOR ORGANIZATIONS TO BE ASSESSED**

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## 1. PURPOSE

This document states the requirements to be included in the design and implementation of an applicant organization's Food Safety System. By meeting the FSSC Development Program requirements, the applicant organization, once assessed as conforming, will be included in the FSSC Register of conforming organizations.

## 2. REQUIREMENTS

### 2.1 GENERAL

Organizations shall develop, implement, and maintain all the requirements outlined in the relevant assessment requirements of the Program and will be assessed by a licensed CAB in order to receive a valid conformity statement.

Sector requirements are normative and defined in the assessment requirements of the Program as set out in Part 1, Table 1. Based on the scope of the organization, the relevant sector requirements are determined against which an organization will be assessed.

### 2.2 PROGRAM CHANGES AND INTERPRETATION

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

FSSC publishes interpretation articles related to Program requirements that include further clarification on requirements and the application and/or implementation thereof. Conformity Assessment bodies (CAB) and conforming organizations (COs) need to adhere to these interpretation articles as applicable. It is the responsibility of the CAB contact person to keep up to date with the interpretation articles and communicate it to the relevant parties within the CAB or to the COs as appropriate.

### 2.3 LOGO USE

- a) COs and CABs shall use the FSSC Development Program logo only for marketing activities such as the organization's printed matter, website, and other promotional material.
- b) In case of using the logo, the organization shall request a copy of the latest FSSC Development Program logo from their CAB and comply with the following specifications:

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

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



- c) The CO is not allowed to use the FSSC Development Program logo, any statement or make reference to its conforming status on:
  - i. A product;
  - ii. Its labelling;
  - iii. Its packaging (primary, secondary or any other form, including certificates of analysis or certificates of conformance);
  - iv. In any other manner that implies that FSSC approves a product, process, or service; and
  - v. Where exclusions to the scope of the conformity assessment apply.

# **PART 3**

# **REQUIREMENTS FOR THE ASSESSMENT PROCESS**

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## 1. PURPOSE

This Part states the requirements for the execution of the conformity assessment process to be conducted by licensed conformity assessment bodies (CABs).

## 2. GENERAL

The CAB shall have procedures for the assessment process that confirm the compliance of the COs and run the Program based on Food Safety Management System (FSMS) accreditation principles. The CAB shall control all Program related documentation and records according to its own procedures.

## 3. RESOURCES

The CAB shall provide sufficient resources to enable the reliable supply of its FSSC Development Program service.

## 4. CONTRACT PROCESS

### 4.1 APPLICATION AND SELF-ASSESSMENT

The applicant organization shall select a CAB that is licensed by FSSC for the FSSC Development Program. The list containing FSSC Development Program licensed CABs is available on [www.fssc.com](http://www.fssc.com).

The applicant organization should conduct a self-assessment against the current version of the Program. The Program documents include a self-evaluation tool available on [www.fssc.com](http://www.fssc.com) that may be used for a preliminary self-assessment.

The CAB will require completion of an official application form, and assessment contract signed by an authorized representative of the applicant organization. It is the responsibility of the applicant organization to ensure that adequate and accurate information is shared with the CAB about the details of the applicant organization.

The details shall include at least the following:

- a) The proposed scope of the assessment;
- b) The number of workers in management and production;
- c) Details of shifts and number of production lines;
- d) Number of HACCP studies;
- e) Details of other food safety systems or certifications held;
- f) When applicable, information regarding head office and functions controlled by the head office;

### 4.2 SCOPE

The CAB shall assess the scope proposed by the organization on the application form and review it against the requirements of the Program.

## 4.3 ASSESSMENT DURATION

The CAB shall determine the assessment duration based on the information gathered from the organization's application and following the requirements as set out below.

- a) The duration of an assessment day normally is eight (8) hours and only includes effective assessment time. In exceptional circumstances an assessment day may be longer than 8 hours but shall never exceed ten (10) hours and then only in accordance with the relevant International Labor Organization (ILO) and national legislative requirements;
- b) The assessment duration determination shall be documented by the CAB, including justifications for addition of time based on the minimum assessment duration;
- c) The site assessment duration shall be stated in working hours indicating the effective assessment time based on the assessment plan. Deviations to the assessment durations and assessment plan shall be recorded (including motivations);
- d) The assessment duration does not include planning, reporting or travel activities, only actual assessment time;
- e) The assessment duration shall only apply to assessors who are fully qualified, registered FSSC Development Program assessors, and not to other team members(s) not assigned as an assessor (e.g., technical experts, interpreters, observers, witnesses, and trainee auditors);
- f) A minimum of 50% of the total assessment duration shall be spent on assessing the operational food safety planning and the implementation of PRPs and control measures. This includes time spent assessing the facilities, conducting the traceability exercise(s) and reviewing the relevant records.
- g) Where the Program assessment is undertaken in combination or integration with other food safety assessments as a combined assessment, the assessment time stated in the report shall be of the total combined assessment and match the assessment plan. Total assessment duration is then longer than for FSSC Development Program alone. This is considered as an increase in assessment duration and the reason for this shall be justified.

### 4.3.1 BASIC ASSESSMENT DURATION CALCULATION (SINGLE SITE)

The following minimum assessment duration applies and shall always be respected:

- 1.0 auditor day (8 working hours) when the company has less than 100 FTE and 1 or 2 HACCP studies.
- 1.5 auditor days (12 working hours) when the organization has 100 FTE or more; or 3 HACCP studies or more.

The number of employees involved in any aspect of food safety shall be expressed as the number of full-time equivalent employees (FTE). When an organization deploys workers in shifts and the products/processes are similar, the FTE number will be calculated based on employees on the main shift (including seasonal workers) plus office workers.

A HACCP study corresponds to a hazard analysis for a family of products/services with similar hazards and similar production technology, and, where relevant, similar storage technology.

Preparation and reporting time shall be in addition to the assessment duration.

The CAB shall in all instances ensure that the assessment duration allows for an effective assessment based on the scope and complexity of the organization, and therefore more time

might need to be added, e.g. where the organizations scope covers more than one food chain category with different PRP requirements.

### 4.3.2 ADDITIONAL ASSESSMENT TIME

Additional time shall be required for the following situations:

**a) Separate Head Office**

- i. For organizations where some functions pertinent to the assessment are controlled by a Head Office separate to the site(s), the minimum time shall be 0.25 assessor day (2 working hours) to assess the functions pertinent to the Head Office.
- ii. When the Head Office functions are assessed as part of, and at the same time as the assessment at the site, no additional assessment time is required.
- iii. A maximum of 20% assessment time reduction can be allowed for each of the single sites belonging to the group where the shared functions are controlled by the (off-site) Head Office. The 20% assessment time reduction is applied to the minimum assessment duration.

**b) Off-site storage activities**

At least 0.25 assessor day (2 working hours) additional assessment time shall be added to the main assessment time for each off-site storage facility. Additional time shall be allocated for planning and travelling between the site and the off-site storage facility.

**c) Use of Interpreters**

An interpreter may be added to the assessment team to support members of the assessment team. The interpreter shall be assigned by the CAB and be independent of the organization assessed. Where an interpreter is required to support the assessment team, the assessment duration shall be increased by at least 20% to allow for the translation process.

## 4.4 CONTRACT

An assessment contract shall be in place between the CAB and the organization applying for the conformity assessment, detailing the scope of the assessment, and referring to all relevant Program requirements. This contract shall detail or have reference to the agreements between the CAB and the organization which shall include but are not limited to:

- 1) Ownership of the conformity statement and the assessment report content shall be held by the CAB;
- 2) Conditions under which the assessment contract can be terminated;
- 3) Conditions under which the conformity statement can be used by the CO;
- 4) Terms of confidentiality in relation to information gathered by the CAB during the assessment process;
- 5) The CO allows the CAB to share information when required by law with governmental and food safety authorities and FSSC;
- 6) Procedures for nonconformity management;
- 7) Procedures for complaints and appeals;
- 8) Inclusion of information on the conformity status of the organization on the FSSC website;
- 9) Cooperation in allowing witness assessments by the CAB and FSSC when requested;
- 10) Communication obligations of the CO to the CAB within 3 working days related to the following:

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

## 5. PLANNING AND MANAGING ASSESSMENTS

### 5.1 GENERAL

- 1) Annual assessments shall take place to ensure continued conformity validity.
- 2) The initial and annual assessments shall be a full assessment against all Program requirements.
- 3) The assessment shall be carried out in a mutually agreed language. An interpreter may be added to the team by the CAB to support members of the assessment team.
- 4) The CAB is expected to operate discretely in case of emergencies (e.g., fire, major catastrophic event, another assessment on-going).

### 5.2 MULTIPLE FUNCTIONS ACROSS MORE THAN ONE SITE

#### 5.2.1 HEAD OFFICE FUNCTIONS

- 1) In all cases where functions pertinent to the assessment are controlled by a Head Office (such as procurement, supplier approval, quality assurance etc.), the Program requires that those functions be assessed, including interviewing the personnel described in the food safety system as having the (delegated) authority and responsibility for these functions. This Head Office assessment shall be documented.
- 2) The functions at the Head Office shall be assessed separately, where they are not part of a site being assessed.
- 3) Every site belonging to the group shall have a:

- a. Separate assessment,
  - b. Separate report and a
  - c. Separate Conformity statement.
- 4) The Head Office assessment shall be carried out prior to the site assessment(s).
- 5) The subsequent assessment 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 assessment reports, and conformity statements shall show which Food Safety functions and/or processes have been assessed at the Head Office.
- 7) All individual sites shall be assessed within a time frame of 3 months from the assessment of the Head Office.
- 8) The Head Office cannot receive a separate conformity statement.
- 9) The Head Office is mentioned on the site conformity statement by use of wording such as *"This assessment included the following central Food Safety System processes managed by (name and location of Head Office): (describe FSS processes assessed at the Head Office)"*

### 5.2.2 OFF-SITE ACTIVITIES

- 1) Storage facilities at another location shall be included in the same assessment provided they are part of the same legal entity and under the same food safety system (FSS). Storage facilities are limited to those only used for and directly linked to the storage of the site's products.
- 2) The scope statement shall show the assessed locations with activities per location (on the conformity statement or as an Annex to the conformity statement).
- 3) The assessment report shall include all relevant requirements at all locations and allow assessment findings to be identified as site specific.

## 5.3 MULTI-SITE ASSESSMENTS

Multi-site assessment and sampling is not applicable to the FSSC Development Program. The Program requires that every site shall have:

- a. A separate assessment,
- b. A separate report,
- c. A separate Conformity statement, and
- d. Every site shall be entered separately in the FSSC database.

## 5.4 ALLOCATION OF ASSESSMENT TEAM

- 1) All assessment team members shall meet the competence requirements set out in Part 4 of this document, and information shall be provided to FSSC as specified by FSSC.
- 2) The assessment team shall have the combined competence for the food chain sub-categories supporting the scope of the assessment. Other team members may be attending for training and familiarity purposes, or as a technical expert, but their contribution shall not be considered in the assessment time.
- 3) An assessor is not allowed to perform more than 6 consecutive assessments at the same organization. A minimum break of one year is required in this case.



## 5.5 USE OF INFORMATION AND COMMUNICATIONS TECHNOLOGY

The standard method for conducting assessments is on-site. Information and Communication Technology (ICT) may be utilized as a remote auditing tool during assessments under certain circumstances, with the following applications and meeting the applicable requirements of IAF MD4:

- 1) For conducting interviews with people and review of policies, procedures, or records as part of the on-site assessment;
- 2) When utilizing the ICT Audit Approach as set out in Annex 5 of the FSSC 22000 Scheme;
- 3) When conducting Full remote assessments as set out in the FSSC 22000 Full Remote Audit Addendum in the case of a serious event.

In (2) and (3) above the following terminology shall be interpreted as having the same meaning:

Audit = assessment

Auditor = assessor

CB = CAB

Scheme = Program

Certificate = Conformity statement

## 5.6 MANAGEMENT OF SIGNIFICANT CHANGES

Once the Conformity Statement has been granted, any significant changes that affect the fulfilment of the requirements of the Program shall be communicated to the CAB within three working days as stipulated in the assessment contract.

Significant changes include:

- 1) Any significant changes that affect the compliance with the Program requirements and obtain advice of the CAB in cases where there is doubt over the significance of a change;
- 2) Changes to organization name, contact address and site details;
- 3) Changes to organization (e.g., legal, commercial, organizational status or ownership) and management (e.g., key managerial, decision-making, or technical staff);
- 4) Changes to the food safety system, scope of operations and product categories covered by the food safety system;
- 5) any other change that renders the information on the Conformity Statement inaccurate.

The CAB shall review the reported changes, decide upon the significance and consequences for conformity with the Program requirements, and conclude whether or not additional verification activities are necessary, or the status of the conformity statement is impacted i.e., whether it is necessary to suspend or withdraw the conformity statement.

The CAB decides also whether or not changes to the Conformity scope shall be granted.

If granted, the current Conformity statement shall be superseded by a new Conformity Statement using the same expiry date as detailed in the original Conformity Statement.

The organization's entry in the FSSC Register of conforming organizations shall be updated accordingly.

## 5.7 MANAGEMENT OF SERIOUS EVENTS

- 1) The CAB shall have a process to review planned assessments when a serious event affects a CO, and the assessment cannot be performed as planned.
- 2) The CAB shall assess the risks of maintaining the conformity statement and establish a documented policy and process, outlining the steps it will take in the event a CO is affected by a serious event to ensure the integrity of the assessment is maintained. The minimum content of the risk assessment shall cover the aspects listed in IAF ID3, section 3.
- 3) The outcome of the Risk Assessment and planned actions shall be recorded. Deviations from the assessment program and their justification for changes shall be recorded. CABs shall establish in consultation with COs a reasonable planned course of action.
- 4) In the case of a serious event, a full remote assessment may be conducted if the conditions as set out in the Full Remote Audit Addendum for FSSC 22000 Scheme are met. Where a full remote assessment has been conducted, the assessment delivery method shall be referenced on the conformity statement, as per the requirements of Annex 2.

## 5.8 UPGRADE ASSESSMENTS

FSSC will issue instructions when upgrade assessments are required. This typically occurs when there is a significant change to the Program requirements e.g., a Version change.

The CAB shall:

- 1) Follow the upgrade requirements as issued by FSSC;
- 2) Ensure all staff and assessors are familiar with the upgrade process;
- 3) Assessment duration shall be recalculated, documented and advised to the clients where applicable;
- 4) Following the successful upgrade assessment (including closure of nonconformities) the conformity statement will be issued to the new (sub)version as required as part of the upgrade process.

# 6. ASSESSMENT DOCUMENTATION

## 6.1 WRITTEN ASSESSMENT REPORT

The CAB shall provide a written report for each assessment.

- a) The assessment report is to be treated confidentially by the CAB but shall be made available to Food Safety Authorities after approval of the organization if required.
- b) The mandatory assessment reports as provided by FSSC shall be completed and shall confirm that all Program requirements have been assessed, reported on and a statement of (non) conformity given with supporting evidence.
- c) Both the procedural and operational conditions of the food safety system shall be verified to assess the effectiveness of the food safety system meeting the Program requirements and reported.
- d) Each assessment is a full assessment against all the requirements of the Program and is always carried out at the production site of the organization (on-site or via the ICT approach).
- e) In certain cases, a requirement can be deemed not applicable. The justification shall be documented in the report for the relevant requirement.
- f) Exclusions from scope shall be assessed and justified in the assessment report.

- g) Deviations from the assessment plan shall be motivated in the report.
- h) Assessors shall report all nonconformities (NCs) at all assessments. For each nonconformity (NC), a clear concise statement of the requirement, the NC statement, grade of the NC and the objective evidence shall be recorded in the assessment report.
- i) Corrections, corrective action plans and their approval shall be included in the CABs nonconformity report.
- j) A Head Office (HO) report shall contain as a minimum the NCs found at the HO. This report shall be included in the documentation supplied to FSSC. At each site assessment the implementation of the corrective actions shall be verified and reported.
- k) The full assessment report (on the FSSC template) shall be sent to the (conforming) organization within 2 weeks of the conformity decision for all assessments conducted.
- l) It is the requirement of FSSC that assessment reports are written in English. Where an organization requests the report to be written in the language the assessment was conducted in (if other than English), this is allowed based on mutual agreement between the CAB and the organization. However, FSSC may request CABs to provide assessment reports in English in which case the CAB will provide the translated report in the defined timeline. In all instances where CABs are translating assessment reports, the CAB shall have verification procedures in place to ensure the translations are accurate.

## 6.2 NONCONFORMITIES

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

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

Nonconformities shall always be written to the most relevant Program requirement linked to the specific assessment criteria and not be grouped unless a systemic issue is identified.

In case of nonconformities noticed in a Head Office assessment, these are assumed to have an impact on the equivalent procedures applicable to all sites. Corrective actions shall therefore address issues of communication across the conforming sites and appropriate actions for impacted sites. Such nonconformities and corrective actions shall be clearly identified in the relevant section of the site assessment report and shall be cleared in accordance with the CAB procedures before issuing the site conformity statement.

The Program does not allow “Opportunities for Improvement”.

### 6.2.1 MINOR NONCONFORMITY

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

- 1) When a minor nonconformity is issued during an assessment, the organization shall provide the CAB with objective evidence of the correction, evidence of an investigation into causative factors, exposed risks, and the proposed corrective action plan (CAP);
- 2) The CAB shall review the corrective action plan and the evidence of correction and approve it when acceptable. The CAB approval shall be completed within 28 calendar days after the last day of the assessment. Exceeding this timeframe shall result in a

- suspension of the conformity statement or in the case of an initial assessment, result in a full new assessment;
- 3) Corrective action(s) (CA) shall be implemented by the organization within the timeframe agreed with the CAB;
  - 4) Effectiveness of implementation of the corrective action plan shall be reviewed, at the latest, at the next scheduled assessment. Failure to address a minor nonconformity from the previous assessment could lead to a major nonconformity being raised at the next scheduled assessment.

### **6.2.2 MAJOR NONCONFORMITY**

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

- 1) When a major nonconformity is issued during an assessment, the organization shall provide the CAB with objective evidence of an investigation into causative factors, exposed risks, and evidence of effective implementation;
- 2) The CAB shall review the corrective action plan (CAP) and conduct an on-site follow-up assessment 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 CAB may decide to perform a desk review. This follow-up assessment shall be done within 28 calendar days from the last day of the assessment;
- 3) The major nonconformity shall be closed by the CAB within 28 calendar days from the last day of the assessment. When the major cannot be closed in this timeframe, the conformity statement 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. Supporting evidence of the temporary measures or controls shall be submitted to the CAB for review and acceptance within 28 calendar days from the last day of the assessment.
- 5) In the case of initial assessments, where the organization has failed to close out nonconformities within the required timelines, a full new assessment is required.

### **6.2.3 CRITICAL NONCONFORMITY**

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

- 1) When a critical nonconformity is issued at a CO, the conformity statement shall be suspended within 3 working days of being issued, for a maximum period of six (6) months;
- 2) When a critical nonconformity is issued during an assessment, the organization shall provide the CAB with objective evidence of an investigation into causative factors, exposed risks, and the proposed corrective action plan (CAP). This shall be provided to the CAB within 14 calendar days after the assessment. The CAB shall review and approve the CAP if acceptable;
- 3) A separate assessment shall be conducted by the CAB between six (6) weeks to six (6) months after the regular assessment to verify the effective implementation of the corrective actions. This assessment shall be a full on-site assessment (with a minimum on-site duration of one day). After a successful follow-up assessment, the conformity statement and the current assessment cycle will be restored, and the next assessment shall take place as originally planned (the follow-up assessment is additional and does not

replace an annual assessment). This assessment shall be documented, and the report included in the documentation supplied to FSSC;

- 4) The conformity statement shall be withdrawn when the critical nonconformity is not effectively resolved within the six (6) month timeframe;
- 5) In case of an initial assessment, the full assessment shall be repeated.

### 6.3 ADDITIONAL ASSESSMENT DOCUMENTATION

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

- 1) An attendance register (or similar document) that confirms the actual presence of the assessor(s) and organization representatives during the assessment. This document shall:
  - Be signed by a representative of the organization being assessed and the lead assessor;
  - Indicate the start time, lunch break duration and end time of each day and
  - Be included as part of the mandatory assessment documentation supplied to FSSC for each assessment.
- 2) A signed integrity declaration by the senior representative of the organization and the assessor(s) confirming that all of the below has been met:
  - a. No actual or perceived conflict of interest exists to ensure the impartiality of the assessment;
  - b. The integrity of the assessment or the assessment process has not been compromised in any way, and
  - c. The assessment was conducted in an ethical manner.

## 7. CONFORMITY DECISION PROCESS

### 7.1 GENERAL

- 1) CABs shall conduct a technical review for all assessments to agree with the assessment reports content and outcome, NCs (objective evidence and grading) and effectiveness of corrections and corrective action plans. Following each technical review, CAB's shall make a decision on the conformity status of the organization (e.g., conforming, non-conforming, suspended, withdrawn).
- 2) The CAB shall keep documented information of decisions on conformity 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.
- 3) The CAB will issue the conformity statement within 28 calendar days from the date of the conformity decision. The conformity statement expires 1 year after the date of the initial conformity decision.
- 4) The maximum conformity statement validity period is 1 year from the date of initial conformity decision, with subsequent 1-year cycles.
- 5) Subsequent assessments should be planned and conducted within a suitable timeframe to enable timely renewal of the Conformity statement before the expiry date.
- 6) The purpose of the re-assessment is to confirm the continuing conformity of the food safety system as a whole with all the Program requirements.
- 7) The re-assessment also includes a review of the food safety system over the period since the previous assessment.

- 8) The CAB decides on renewal of the conformity status on the basis of the re-assessment which shall meet the same requirements as an initial assessment. In exceptional cases where the assessment is conducted after the expiry date of the Conformity Statement or the CAB is unable to issue a new Conformity Statement prior to the expiry date, then a new 12-month Conformity Statement will be issued that is valid from the Date of Conformity Decision.

Note: not all decisions may lead to issuing a new conformity statement

## 7.2 CONFORMITY STATEMENT DESIGN AND CONTENT

- 1) The CAB shall issue the conformity statement in accordance with the scope rules and conformity statement templates as set out by FSSC (see Annex 2)
- 2) Conformity statements shall be issued in English. It is possible to add a scope translation in which case the scope shall be displayed in English, followed by the translation in the relevant language.
- 3) The FSSC Development Program logo shall be used by the CAB on its conformity statements.
- 4) Head Office details shall be included, where applicable.
- 5) Where applicable Off-site storage activities shall be listed, (including name, address, and activities); details may be provided in an Annex to the conformity statement.
- 6) The Conforming Organizations Identification Code (COID) provided by FSSC shall be included.
- 7) Dates on the conformity statement shall be as follows:
  - a) Conformity statement date: date at which a new decision is made after a conformity assessment.  
New conformity decision dates are also required in situations such as scope extensions/reductions. In these cases, the valid until date remains unchanged;
  - b) Issue date: date conformity statement is issued to the client; or re-issue date when a new conformity statement is issued (e.g., because of scope extension);
  - c) Valid until date: date conformity statement expires (maximum duration is 12 months minus 1 day).

## 7.3 CONFORMITY STATEMENT SUSPENSION, WITHDRAWAL, OR SCOPE REDUCTION

- 1) *Suspension*: the CAB shall suspend the conformity statement within 3 working days 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 the Program requirements.
- 2) *Withdrawal*: the CAB shall withdraw a conformity statement when:
  - a) The status of suspension cannot be lifted within six (6) months;
  - b) The organization ceases its FSSC Development Program activities;
  - c) any other situation where the integrity of the conformity statement or assessment process is severely compromised.
- 3) *Scope reduction*: When the CAB has evidence that their client holds a conformity statement where the scope exceeds their capability or capacity to meet program requirements, the CAB shall reduce the conformity scope accordingly. The CAB shall not exclude activities, processes, products, or services from the scope of conformity 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 conformity.

### **7.3.1 ACTION UPON SUSPENSION, WITHDRAWAL, AND SCOPE REDUCTION**

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

## **8. DATA AND DOCUMENTATION**

### **8.1 DATA OWNERSHIP**

- a) A (conforming) organization is the owner of an assessment report, whilst the CAB is responsible for the report data.
- b) A (conforming) organization is the conformity statement holder, not the owner. The CAB is the data owner of the conformity statement data.

### **8.2 DATA AND DOCUMENT UPLOAD/SUBMISSION REQUIREMENTS**

For all assessment types, the required data and documentation (assessment report, assessment plan, additional assessment documentation, and conformity statement) shall be submitted to FSSC at the latest 28 calendar days after the conformity decision and with a maximum of 2 months after the last day of the assessment.



## 8.3 QUALITY CONTROL PROCESS

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

- a) Completeness: All relevant documentation shall be duly completed;
- b) Timeliness: All the relevant documentation shall be submitted to FSSC within the required timelines;
- c) Validity: The documentation shall meet the requirements of the Program;
- d) Accuracy: The data is a true representation of the actual facts relating to the complete assessment and the conformity process;
- e) Consistency: The documentation submitted to FSSC is a true representation of the documentation stored in the CAB's internal system(s).



**PART 4**

# **REQUIREMENTS FOR CONFORMITY ASSESSMENT BODIES**

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## 1. PURPOSE

This document states the requirements for licensed conformity assessment bodies (CABs) that wish to provide Program conformity assessments to organizations.

Where the term “Program Requirements” is used, this refers to the FSSC Development Program requirements and the Board of Stakeholders (BoS) decision list.

## 2. RELATION WITH FSSC

### 2.1 LICENSING

The CAB is responsible for the full application of and the demonstration of compliance to the Program requirements for CABs at all times. To apply for an FSSC Development Program license the CAB shall have a valid full license for FSSC 22000 certification issued by FSSC. Having a full FSSC 22000 license for food chain category C enables the CAB to deliver Development Program assessments in categories BIII, C, D, E, FI, G and K, and holding a full FSSC 22000 license for food chain category I is a pre-requisite for delivering packaging (category I) assessments for the Development Program. The CAB shall supply its FSSC Development Program services only whilst it holds a valid FSSC Development Program license from FSSC.

#### 2.1.1 LICENSE APPLICATION PROCESS

- 1) CABs shall apply for obtaining a license with FSSC to be eligible to perform valid and recognized FSSC Development program conformity activities. Licenses are issued for specified CAB office location(s) as requested in the license application form. In case of outsourcing of any assessment related activities this shall also be described in the application.
- 2) A license may cover multiple Food Chain Categories for the FSSC Development Program.
- 3) With the application, the CAB commits themselves to the implementation of all Program requirements and any other obligations outlined in the license agreement.

#### 2.1.2 LICENSE AGREEMENT

- 1) The CAB shall submit an application to FSSC specifying the food chain categories and sub-categories which they wish to provide conformity services.
- 2) Upon successful review of the information the CAB will be granted a license agreement and be listed in the approved CAB list on the FSSC website.

#### 2.1.3 LICENSE MAINTENANCE

In order to maintain its license, the CAB shall:

- a) In the first 12 months from being granted a license, have at least 2 assessed organizations including submission to FSSC;
- b) For subsequent years have at least five (5) assessed organizations and submitted to FSSC;
- c) Comply with all the requirements of the FSSC Development Program for CABs;
- d) Meet the financial obligations to FSSC.

### 2.1.4 LICENSE EXTENSION

- 1) The CAB shall submit an application to FSSC specifying the food chain categories and sub-categories for which it requests an extension of the existing license.
- 2) Upon successful review by FSSC, the sub-category (or category if no subcategory) will be registered and displayed in the approved CAB list on the FSSC website.
- 3) At least one assessed organization shall be registered with FSSC for the new category or per category in the case of multiple category extension within 12 months of approval by FSSC.

### 2.1.5 SUSPENSION, TERMINATION, AND REDUCTION

FSSC has the right to suspend, terminate or limit the scope of the CAB's license agreement. The reasons could be, amongst others:

- 1) Not meeting the minimum number of conformity assessments;
- 2) Sanction committee decision;
- 3) Non-payment of the fee to FSSC;
- 4) Repetitive noncompliance with the Program requirements.
- 5) Situations where FSSC might be brought into disrepute and/or the integrity of the assessment might be at risk;
- 6) Contractual breaches.

#### 2.1.5.1 SUSPENSION

- 1) When a CAB's license is suspended by FSSC, FSSC will determine to what extent the CAB will be allowed to maintain its assessment activities for a defined period of time. FSSC will publish suspensions on the FSSC website.
- 2) FSSC will restore the suspended license when the CAB 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 FSSC shall result in termination or reduction of the scope of the license.

#### 2.1.5.2 TERMINATION

- 1) When a CAB's license is terminated by FSSC, the CAB cannot apply for a new license within the time frame communicated by FSSC.
- 2) The CAB shall execute subsequent actions as defined by FSSC and the requirements outlined in the license agreement.

## 2.2 ENGAGEMENT

### 2.2.1 COMMUNICATION

- 1) The CAB shall appoint an FSSC Development program contact person who is competent in the Program requirements and maintains contact with FSSC.
- 2) This person shall be accountable for all aspects of Program implementation and ensure that the following responsibilities are defined and implemented within the CAB:
  - a) Appoint a contact person for the FSSC Development program IT systems;
  - b) Appoint a responsible person for managing the Program;
  - c) Appoint a representative to attend mandatory FSSC related event/s;
  - d) Keep up to date with the Program developments including IT developments;
  - e) Managing of other additional information required by FSSC;

- f) Communicate new information or changes regarding the requirements in the Program to those parties involved within one month unless specified otherwise by FSSC.

The CAB shall communicate the following to FSSC within three working days:

- 1) Any significant changes in its ownership, legal status, management personnel, structure, or constitution that (potentially) impact the CAB management of the Program in a timely manner;
- 2) Any possible conflict or problem which could result in bringing FSSC into disrepute;
- 3) Any public recall of a CO resulting in death and/or hospitalization or generating significant media coverage, within three working days of the recall being notified to the CAB;
- 4) Situations and/or serious events where the integrity of the FSSC Development program may be compromised as described in Part 3.

### **2.2.2 RESPONSIBILITIES**

- 1) The CAB shall cooperate with all requests from FSSC to report information regarding all aspects in the performance and integrity of the Program.
- 2) The CAB is responsible for the full application of these Program requirements and shall be prepared to demonstrate compliance at any time with all these requirements.
- 3) The CAB shall participate in mandatory FSSC, harmonization and calibration events as defined by FSSC, and shall share the applicable information to all relevant staff.
- 4) The CAB shall participate in monitoring and verification activities as defined by FSSC and act on any issues identified by FSSC within the defined timelines. Failure to meet timelines or address issues, may result in sanctions.
- 5) The CAB shall share information concerning the CO with FSSC and governmental authorities when required by law.
- 6) The CAB shall ensure that all Program related data supplied to FSSC is complete, up to date, correct and meets the Program requirements.
- 7) Where the CAB uses the FSSC Development Program logo, they shall comply with the requirements in Part 2 and are entitled to use it only when the CAB has a signed license agreement with FSSC.
- 8) The CAB commits to operating in accordance with the FSSC Code of Ethics, which is publicly available on the FSSC website.

## **2.3 PROGRAM MONITORING & VERIFICATION ACTIVITIES**

- 1) The CAB shall participate in any monitoring and verification activities as determined by FSSC. These activities cover all activities of its licensed CABs to ensure compliance with the Program requirements. The CAB shall provide any documentation requested by FSSC in support of these monitoring and verification activities.
- 2) The monitoring and verification activities include but are not limited to:
  - a) Reviews of assessment documentation and the assessment process – the review may be conducted remotely or on-site;
  - b) Assessor approval and registration;
  - c) Monitoring of agreed key performance indicators.

### **2.3.1 NONCONFORMITY**

- 1) A nonconformity is defined as any breach of the Program requirements;
- 2) Nonconformities ("NCs") requiring a response from the CAB shall be raised by FSSC in response to:
  - a) Any discrepancy raised by FSSC;

- b) Feedback from users of the Program;
- c) Feedback from COs;
- d) Feedback from governmental authorities;
- e) Feedback from the media, and
- f) Any other feedback is deemed credible.

### **2.3.2 FOLLOW-UP**

- 1) When a nonconformity is received, the CAB 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, and 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 could result in warnings or sanctions.

### **2.3.3 SANCTIONS**

- 1) CABs that persistently fail to conform to the requirements of the Program or put the integrity of the Program at risk shall be investigated by FSSC.
- 2) Sanctions against non-compliant CABs could include:
  - a) Suspension of the license to issue conformity statements under the Program until discrepancies have been satisfactorily corrected;
  - b) Termination of the license to issue conformity statements under the Program.

The CAB shall respond to the sanctions as per the conditions in the sanction notification, including the timelines specified. CABs have the right to appeal to sanctions.

## 3. COMPETENCE

### 3.1 GENERAL

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

### 3.2 TECHNICAL REVIEWER AND CONFORMITY DECISION MAKER

#### 3.2.1 TECHNICAL REVIEWER

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

#### 3.2.2 CONFORMITY DECISION MAKER

- 1) Those making the decision to issue, maintain, extend, or reduce scope, suspend, or withdraw a conformity statement for registration in the FSSC Register of conforming organizations shall have the following demonstrable competencies;
  - a) Meet the requirements of Annex C of ISO 22003-1:2022;
  - b) Detailed knowledge of Program requirements;
  - c) Knowledge of food safety systems and the ability to assess them.
- 2) Assessment team members shall not be involved in the decision to issue or maintain conformity statements.

### 3.3 TECHNICAL EXPERT

- 1) When deemed necessary, a technical expert may be assigned to the assessment team.
- 2) The CAB shall have in place a procedure for approval of technical experts who shall have demonstrable experience in the sub-category supporting the scope of the assessment. The technical expert shall always operate under the direction of a qualified FSSC Development Program assessor.
- 3) Where a technical expert is used, the CAB shall ensure that at least one assessor in the team has a qualification in the category.
- 4) For the (sub)categories BIII, D, E, F, G and K, where the requirements of 3.3 (3) above cannot be met, at least one assessor in the team shall have a qualification in category C. This allowance does not apply to Category I.
- 5) In all instances, the CAB shall ensure that the assessment team meets the qualification requirements linked to the scope of the (conforming) organization.
- 6) Where a technical expert is used, the CAB shall ensure that the technical expert is registered in the assessment team table in the assessment report, with the role of technical expert.

### 3.4 WITNESSOR

- 1) Witnessed assessments shall be undertaken by an assessor who can demonstrate competence in the FSSC Development Program requirements, or by a CAB technical person with detailed knowledge of the FSSC Development program of equivalent competence and experience. Witnessors shall be assessed and qualified by the CAB as suitable to undertake witnessed assessments.
- 2) The witnessor has received training in witness assessment techniques.
- 3) The witnessor plays no active part in the assessment.
- 4) Witnessors shall have, as a minimum, the equivalent competency of the function being evaluated (see ISO 22003-1:2022 Annex C).

### 3.5 ASSESSOR QUALIFICATION PROCESS

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

General: Existing qualified FSSC 22000 auditors may conduct assessments to the Program based on their current FSSC 22000 qualifications, in which case no additional requirements apply as set out in this section (3.5) of the document. Specific training on the Program and the CAB procedures is however still required as defined under 3.5.1 (2)(b).

#### 3.5.1 INITIAL TRAINING AND EXPERIENCE

The CAB shall ensure that trainee assessors or assessors transferring from other CABs meet the following initial training and experience requirements:

- 1) Education and/or Work Experience
  - a) As a minimum, has successfully completed a food related or bio-science higher education;  
AND/OR
  - b) Minimum 2 years' full-time work experience in quality assurance and/or food safety related activities in a food related industry.
- 2) Training

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

  - a) Food safety assessment training – as a minimum in assessment techniques based on ISO 19011 principles (minimum 16 hours);
  - b) Training in the FSSC Development Program requirements (minimum 4 hours)
  - c) HACCP training – minimum 16 hours including exam;
  - d) Food fraud training – minimum 2 hours covering food fraud vulnerability assessment methodology and possible mitigation measures;
  - e) Food defense training – minimum 2 hours covering food defense threat assessment methodology and possible mitigation measures;
- 3) Other:
  - a) Audits: Complete at least 5 (five) post-farm gate second or third party food safety audits, amounting to 10 audit days, either as a trainee or an assessor. The food safety audits shall include HACCP and pre-requisite programs as a minimum in order to be considered.
  - b) Packaging (category I): In order to qualify for category I, the assessor shall meet at least one of the below in addition to meeting the requirements in 3.5.3:
    - i. Hold a higher education in a packaging discipline, OR
    - ii. Have at least 2 years' full-time work experience in quality assurance and/or food safety related activities in the food packaging industry, OR



- iii. Where a qualified FSSC Development Program food assessor wants to be approved for Category I, then they need to have undertaken a specific packaging technology training that meets the WPO requirements of at least 30 hours with an exam. This training shall include the following topics as a minimum and documented evidence thereof shall be available:
  - Basics of packaging principles and concepts;
  - Packaging legislation, standards, and regulations;
  - Packaging materials manufacturing;
  - Specifics to packaging of food/feed products;
  - Quality/food safety control and testing;
  - Printing processes and printing inks;
  - Packaging recycling and
  - Design of packaging materials.

### **3.5.2 INITIAL ASSESSMENT AND APPROVAL**

- 1) The CAB shall:
  - a) Conduct an on-site FSSC Development Program witnessed assessment of the assessor to confirm competence is attained (qualifying witnessed assessment) and
  - b) Document the sign-off of the satisfactory completion of the training program and witnessed assessment.
- 2) The witnessed assessment shall be conducted by an approved witnessor as specified in 3.4 above.
- 3) A witness audit assessment report shall be completed by the witnessor to confirm performance, including but not limited to:
  - The knowledge and skills as set out in Annex C of ISO 22003-1:2022 Table C.1, for auditing and leading the audit team;
  - An assessment of knowledge of the application of the FSSC Development Program requirements; and
  - An assessment of knowledge of the applicable laws and regulations.
- 4) All FSSC Development Program assessors shall be registered with FSSC in accordance with the instructions provided by FSSC. For assessors already qualified to FSSC 22000 only the additional information for this Program has to be registered.

### **3.5.3 ASSIGNMENT OF SUB-CATEGORIES (INITIAL AND EXTENSION)**

- 1) After the initial approval, assessors shall be approved/qualified per sub-category (see Part 1, table 1). In order to assign sub-categories to an assessor, the CAB shall demonstrate:
  - a) Specific competence in the sub-category including relevant knowledge of the processes of the applicable sub-category linked to the associated sector PRPs, food safety hazards, risks, and control measures. The knowledge can be obtained through e.g., education, training, cross training or working experience. The justification shall be documented.
  - b) Meeting the CAB's own competency criteria for the sub-category.
- 2) The CAB shall have defined competency criteria for each sub-category to ensure knowledge of products, processes, practices and applicable laws and regulations of the relevant sub-category. Competence across the whole sub-category shall be demonstrated. Where the CAB further split up sub-categories, it shall be clear for which parts of the sub-category the assessor is qualified.
- 3) For extension of the assessor qualification scope to a new category/sub-category, the CAB shall demonstrate that the assessor possesses the relevant competence as outlined in this document.

### **3.5.4 MAINTENANCE OF ASSESSOR QUALIFICATION**

#### **3.5.4.1 MAINTENANCE OF COMPETENCY**

- 1) The CAB shall ensure a system is in place to maintain assessor qualification according to the Program Requirements.
- 2) In case an assessor has demonstrated he/she performed FSSC Development Program assessments for another CAB, these are also allowed to be included. The CAB shall supply evidence of the assessments to FSSC if required.

#### **3.5.4.2 ONGOING TRAINING**

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

#### **3.5.4.3 WITNESSED ASSESSMENT**

- 1) At least one (1) FSSC Development Program witnessed assessment shall be conducted every three (3) years to confirm acceptable assessor performance.
- 2) A witness assessment report shall be completed by the witnessor to confirm performance of – as a minimum- the elements described for assessment activities in ISO 22003-1:2022 Table C1.

#### **3.5.4.4 ASSESSOR REQUALIFICATION**

- 1) The overall assessor performance shall be evaluated every three (3) years in order to confirm the continued competence of the assessor. The following aspects shall be evaluated by the appointed supervisor of the CAB prior to requalification:
  - a) The assessor assessment log – a minimum of 4 food safety related audits/assessments are required every 3 years;
  - b) The assessor training log;
  - c) Result of the witness assessment.
- 2) The evaluation shall consider the assessor's overall performance, including complaints from clients or other external or internal parties.
- 3) Documented sign-off of the satisfactory completion of the entire requalification process shall be supplied to FSSC.

Note: Only one witnessed assessment is required, irrespective of the number of categories/sub-categories that the assessor is qualified in.

# APPENDIX 1

# DEFINITIONS

## APPENDIX 1: DEFINITIONS

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

### ACTIVE MATERIALS AND ARTICLES

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

### 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 representative group of stakeholders, appointed by FSSC, that advises the Board of Stakeholders.

### ASSESSMENT

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

### APPEAL

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

### ASSESSOR

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

### BOARD OF STAKEHOLDERS

A group of representatives appointed by the Program's stakeholders who are responsible for oversight, including all conformity requirements.

### CATEGORY

Food chain category for which an FSSC assessor is qualified to conduct assessments.

## **CLEANING PROGRAM**

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

## **COMPETENCE**

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

## **COMPLAINT**

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

## **CONFORMITY ASSESSMENT BODY**

Organization providing assessment services.

## **CONFORMITY ASSESSMENT**

An assessment of a set of processes that demonstrate an organization is in conformance with the meets the requirements of the FSSC Development Program.

## **CONFORMITY STATEMENT**

A statement by a CAB confirming that the applicant organization meets the requirements of the FSSC Development Program.

## **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 conformity integrity are at stake.

## **DISINFECTION**

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

## **FACILITY**

A building or structure that is used by an organization to handle food.

## **FOLLOW UP ASSESSMENT**

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

## FEED

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

## 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 ADDITIVE

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

## FOOD DEFENSE

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

## FOOD FRAUD

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

## FOOD SAFETY 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.

## FOUNDATION FSSC

The legal owner of the FSSC Development Program.

## FSSC LOGO

Logo issued by FSSC which can be used by licensed CABs and COs in accordance with FSSC Development Program requirements.

## **HACCP STUDY**

Hazard analysis for a family of products/processes/services with similar hazards and similar processes and technology (e.g., production, packaging, storage or implementation of services) (ISO 22003-1:2022).

## **HYGIENIC DESIGN**

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

## **MANUFACTURING/PROCESSING**

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

## **MAJOR NONCONFORMITY**

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

## **MINOR NONCONFORMITY**

Nonconformity that does not affect the capability of the food safety 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 Program 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.

## **PRODUCT**

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

## **PRODUCT RECALL**

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

## **PRODUCT WITHDRAWAL**

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

## **PROCESS**

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

## **QUALITY**

Product characteristics other than food safety such as size, color, weight, taste, etc. to meet consumer expectations and applicable statutory and regulatory requirements.

## **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 on information provided by FSSC in case of unacceptable CAB performance.

## **SANITATION**

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

## **PROGRAM**

Set of rules and procedures that defines the objectives, specified requirements, and methodology for performing the conformity assessment.

## **SCOPE**

Extent and boundaries applicable to, e.g., assessment or program activity.

## **SERIOUS EVENT**

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



## **SITE**

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

## **SPECIAL ASSESSMENTS**

Assessments at COs that are performed on top of/or in addition to the annual assessments.

## **TABLEWEAR**

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.

## **VEHICLE**

Any device used for the conveyance of raw material, ingredients, food, feed, or packaging that is capable of being moved upon roadways, railways, waterways, or airways.

## **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 ASSESSMENT**

An activity performed by a competent CAB witnessor, whereby the performance of the CAB assessor is observed and evaluated, without interfering or influencing, at a complete FSSC Development Program audit performed by the CAB assessor.

# APPENDIX 2

# REFERENCES

## APPENDIX 2: REFERENCES

The Program is based on the following documents and their future versions:

- 1) ISO 22000:2018, Food safety systems – Requirements for any organization in the food chain
- 2) ISO/TS 22002-1:2009, Prerequisite Programs for food safety – Part 1: Food manufacturing
- 3) ISO/TS 22002-2:2013 Prerequisite programs for food safety – Part 2: Catering
- 4) ISO/TS 22002-4:2013 Prerequisite programs on food safety – Part 4: Food packaging manufacturing
- 5) ISO/TS 22002-5:2019 Prerequisite programs on food safety – Part 5: Transport and storage
- 6) ISO/TS 22002-6:2016 Prerequisite programs on food safety – Part 6: Feed and animal food production
  
- 7) BSI/PAS 221:2013 Prerequisite programs for food safety in food retail - specification
- 8) ISO 22003-1:2022, Food safety systems – Requirements for bodies providing audit and certification of management systems
- 9) ISO/IEC 17000:2004, Conformity assessment – Vocabulary and general principles
- 10) ISO/IEC 17011:2017 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies.
- 11) ISO/IEC 17021-1:2015, Conformity assessment – Requirements for bodies providing assessment and certification of management systems
- 12) IAF MD 4, The Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes (latest version)
- 13) IAF ID 3, Management of Extraordinary Events or Circumstances Affecting ABs, CABs, and Certified Organizations
- 14) FSSC 22000 Full Remote Audit Addendum
- 15) FSSC 22000 Annex 5: CB Requirements of the use of ICT
- 16) FSSC Code of Ethics