



## 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, FSSC 22000 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 based on a stepwise approach.

The Program is aligned with the Codex Recommended International Code of Practice General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003) and the Global Food Safety Initiative (GFSI) Global Markets Program.

## 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 22000 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 requirements for Conformity Assessment Bodies to assess food safety systems of organizations in the supply chain and to guarantee its integrity. The Conformity Statement indicates that the organizations' food safety system is in conformance with the requirements outlined in the Program.

### 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 Assessment report
- Annex 3 CAB Conformity statement templates

# PART 1 PROGRAM OVERVIEW

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# 1 INTRODUCTION

## THE PROGRAM

The FSSC Development Program (hereafter the Program) outlines the requirements for organizations in the food supply chain and their customers to achieve a conforming food safety system (FSS) based on Level 1 and Level 2 food safety requirements. The conformity statement confirms that the organization's FSS is in conformance with the Program requirements.

The Program provides an assessment model that can be used in the food manufacturing supply chain following the food chain category description as defined in ISO/TS 22003: 2013.

The FSSC Development Program follows a stepwise approach, however it also allows organizations to remain at Level 1 meeting the food safety requirements aligned with the GFSI Global Markets Program Basic Level supplemented by Codex HACCP. The Level 2 requirements are in accordance with the GFSI Global Markets Program Foundation Level.

The Program's Level 1 and Level 2 assessments are performed unaccredited although the FSSC Integrity Program does monitor assessment quality.

The assessments are subsequently registered in the FSSC Development Register of Conforming Organizations. This register is publicly available. Registration indicates that the organizations' food safety system is in conformance with the Program requirements and that the organization is able to maintain conformance with these requirements. The added value for a conforming organization lies in the oversight by the Foundation to ensure the integrity of the entire assessment process is in line with the Program requirements.

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

The Program provides a voluntary model that can be applied across the defined food supply chain categories. The food chain category description used by this Program is defined according to ISO/TS 22003:2013 (see section 3 - scope).

## OWNERSHIP

The Foundation FSSC 22000 (hereafter the Foundation) retains the ownership and the copyright of all Program related documentation and also holds the agreements for all involved Conformity Assessment Bodies.

## LANGUAGE

English is the original 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 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 to comply 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

### 2.2 NATURE OF THE PROGRAM

The Program provides an independent Codex-based Program for third party assessment.

The Program:

- a) Is aligned with the Codex Recommended International Code of Practice General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003) and the Global Food Safety Initiative (GFSI) Global Markets Program;
- b) Is based on elements of ISO22000 and the ISO/TS22002-1 requirements;
- c) Provides a pathway to achieving FSSC22000 certification;
- 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 Conforming Organizations" that is publicly available.

### 3 SCOPE

The Program is intended for the assessment and registration of organizations for the following food chain (sub)categories (in line with ISO/TS 22003:2013) as indicated in Table 1 below:

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

| Category | Sub category | Description   | Example of included activities and products  |
|----------|--------------|---|--|
| <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.<br>Final product examples: fish, meat, poultry, eggs, frozen and/or chilled dairy products and fish/seafood products.  |
| <b>C</b> | 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.<br>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)                                 |
|          | CIII         | Processing of perishable animal and plant products (mixed products) | Mixing, cooking, packing, ensemble cooling, chilling, freezing<br>Final products e.g. mixed products, pizza, lasagna, sandwich, dumplings, ready-to-eat meals.   |
|          | CIV          | Processing of ambient stable products                               | Mixing, cooking, packing, bottling, brewing, drying, pressing, milling, blending, roasting, refining, ensemble, distilling, drying, canning, pasteurizing, sterilization.<br>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. |
| <b>D</b> | DIIa         | Production of pet food (only for dogs and cats)                     | Production of single or multiple products, whether processed, semi-processed or raw, which are intended to be fed to non-food producing animals being dogs and cats.   |
| <b>K</b> | K            | Production of Bio-chemicals   | Mixing, cooking, packing, distilling, drying, canning, sterilization for all products at ambient, chilled and frozen temperatures.<br>Final products: e.g. food and feed additives, vitamins, minerals, bio-cultures, flavorings, enzymes and processing aids, gases as ingredients and/or packaging gas.  |

### 3.1 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, pulses and rice
- 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.

### 3.2 PET FOOD PRODUCTION (CATEGORY DIIA)

Food chain category DIIa covers the production of pet food:

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

### 3.3 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.

## 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 assessment 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 assessment 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 conformity assessment bodies;

- b) Taking appropriate measures in the event of abuse or improper use of the conformity statements issued by licensed assessment 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 conformity assessment bodies or conformity statement holders or organizations which are intended to be conformity statement 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 Program 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 Development, Program assessment and promotion.

- 6.2 The BoS advises the Board on the design, development, changes and emendation of the Program, including interpretation of clauses, scopes, work methods, frequency and method with which conformity assessment bodies are inspected, complaints procedures and standards of expertise of assessors.
- 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 Conformity Assessment 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 conformity assessment 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 Program. 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:
- a) Standard contract with Conformity Assessment Bodies;
  - b) A program of KPI driven desk reviews of full assessment reports, as determined by the Board;
  - c) A program of KPI driven analysis of assessment reports, as determined by the Board,
  - d) Registration of all assessors qualified under the Program;
  - e) A program of office and witness assessments as determined by the Board;
  - f) All further programs, procedures and measures which at any time may be required by the current version of the requirements set out by The Program.
- 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 Program.
- 7.6. The Foundation shall maintain a public register for all conformity statements duly issued on the basis of the Program, safeguarding all information on conforming organizations which are to be treated as confidential.
- 7.7. The standard contract with assessment bodies as referred to above will contain provisions for the use of the FSSC Development logo and the Foundation's IT infrastructure supporting the assessment process and assessment 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 Program. 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 Program in as far as they may relate to the rights and obligations of direct and indirect stakeholders in 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 organizations' Food Safety System. By meeting the FSSC Development Program requirements the applicant organization, once assessed as conforming, will be included in the FSSC Development Register of Conforming Organizations.

# 2 REQUIREMENTS

## 2.1 GENERAL

Organizations shall develop, implement and maintain all the requirements outlined below and will be assessed by a licensed Conformity Assessment Body in order to receive a valid Statement of Conformity.

The Program requirements are global in nature, applicable to organizations in the food supply chain regardless of their size and complexity, whether profit-making or not and whether public or private.

The following food chain categories fall within the Program scope of conformity:

Table 1: Food chain categories (from ISO/TS 22003:2013)

| Category | Sub-category | Description   |
|----------|--------------|---|
| <b>C</b> | <b>CI</b>    | Processing of perishable animal products                            |
|          | <b>CII</b>   | Processing of perishable plant products                             |
|          | <b>CIII</b>  | Processing of perishable animal and plant products (mixed products) |
|          | <b>CIV</b>   | Processing of ambient stable products                               |
| <b>D</b> | <b>DIIa</b>  | Production of pet food for dogs and cats                            |
| <b>K</b> |              | Production of (bio)chemicals  |

## 2.2 OUTLINE OF PROGRAM REQUIREMENTS

This section provides an outline of the Program requirements to be met in order to achieve conformance. The Program requirements consist of two different levels:

- 1) Level 1 requirements
- 2) Level 2 requirements

Prior to deciding which level to apply for, the organization shall complete the self-evaluation which is available on the FSSC website free of charge.

### 2.2.1 LEVEL 1

The organization shall meet the Level 1 requirements to obtain the FSSC Development Level 1 conformance status. The requirements are documented in the mandatory FSSC Development Requirements and Reporting document. The requirements consist of three main components:

- Food Safety System requirements;
- Pre-requisite Program requirements;
- FSSC additional requirements.

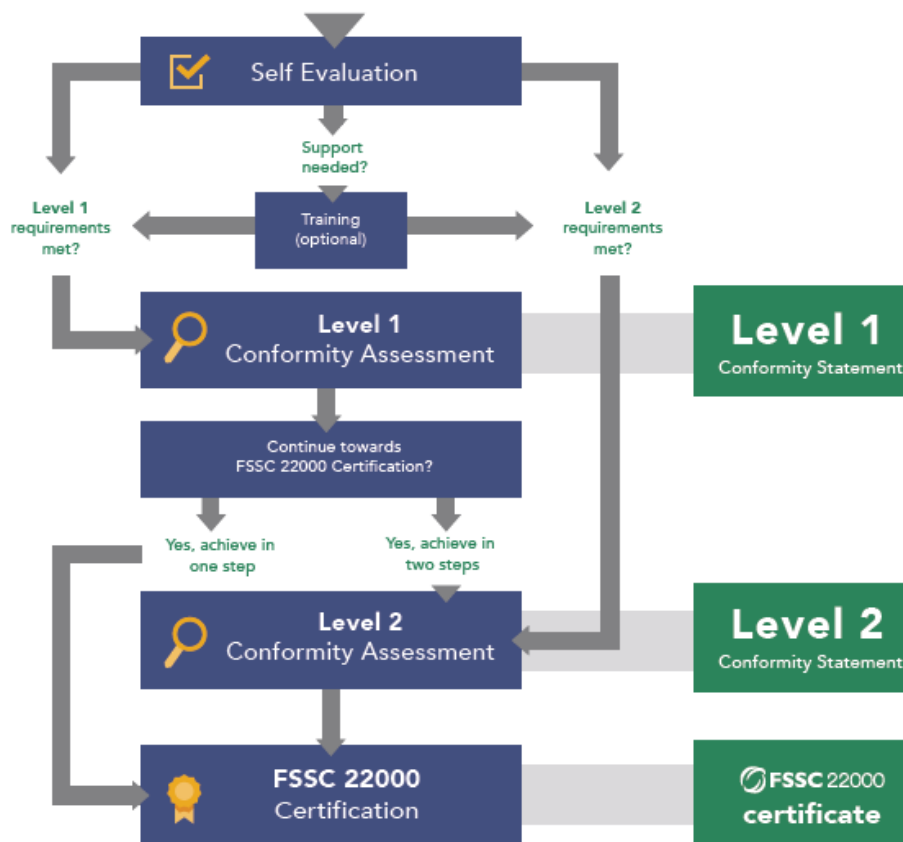
The organization can either remain at Level 1 and will have an annual re-assessment, or can decide to progress towards Level 2 or directly towards FSSC 22000 certification.

### 2.2.2 LEVEL 2

The organization shall meet the Level 2 requirements to obtain the FSSC Development Level 2 conformance status. The requirements are documented in the mandatory FSSC Development Requirements and Reporting document. The requirements consist of three main components:

- Food Safety System requirements;
- Pre-requisite Program requirements;
- FSSC additional requirements.

The organization can either remain at Level 2 and will have an annual re-assessment, or can decide to progress towards FSSC 22000 certification. It is not required to start with a Level 1 assessment to progress to a Level 2 assessment.



## 2.3 LOGO USE

- a) Conforming organizations and Conformity Assessment Bodies shall use the FSSC Development Program 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 conforming organization 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);
  - iv. In any other manner that implies The Foundation approves a product, process or service.



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 conforming organizations and run the Program based on 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 the Foundation.

The list containing FSSC Development Program licensed CABs is available on [www.fssc22000.com](http://www.fssc22000.com).

The applicant organization shall conduct a self-assessment against the current version of the Program. The Program documents include a self-evaluation tool available on [www.fssc22000.com](http://www.fssc22000.com) that may be used for a preliminary self-assessment. Once the self-assessment has been completed, and observed gaps are addressed, the applicant organization can contact their selected CAB in order to receive an application form and agree on an FSSC Development Program assessment contract.

The CAB will require completion of an official application form, 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 (for example ISO 9001);
- f) When applicable, information regarding head office and central 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 in Annex I.

## 4.3 ASSESSMENT DURATION

The CAB shall calculate the assessment time 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; the effective on-site assessment duration does not include a lunch break (unless in contradiction with local legislation);
- b) The assessment time calculation shall be documented by the CAB, including justifications for addition of time based on the minimum assessment duration;
- c) The on-site assessment duration shall be stated in assessment or working hours indicating the time spent at the site and shall match the assessment plan and deviations shall be recorded (including motivations);
- d) The on-site assessment time does not include planning, reporting or travel activities, only actual on-site assessment time;
- e) The on-site assessment time shall only apply to assessors who are fully qualified, registered FSSC Development Program assessors;
- f) 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 TIME CALCULATION (SINGLE SITE)

The following minimum assessment duration applies:

- For small sites (1-30 employees and/or 1 – 3 production lines): 1 day
- For medium sites (31 – 100 employees and/or 4 – 6 manufacturing lines): 2 days
- For large sites (> 100 employees and/or > 6 manufacturing lines): 3 days

This applies to both Level 1 and Level 2 FSSC Development Program assessments for initial and annual assessments. The minimum assessment duration shall always be respected.

Preparation and reporting time shall be in addition to the on-site assessment time.

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

### 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 manufacturing site(s), the minimum

time shall be 0.5 assessor day (4 working hours) on-site to assess the functions pertinent to the Head Office.

- ii. When the responsible person from the Head Office attends the assessment at the manufacturing site, no extra assessment time is calculated.
- iii. A maximum of 20% assessment 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% assessment time reduction is applied to the minimum assessment time.

**b) Off-site activities**

Where off site manufacturing or service activities take place, a 50% assessment time reduction may be applied for each additional site OR the parameters of the off-site activities shall be included in the assessment calculation as under §4.3.1 and travel time between locations shall be included in the assessment plan.

For off-site storage: At least 0.25 assessor day (2 working hours) additional on-site assessment time shall be added to the main assessment time for each off-site storage facility.

## 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) At the request of food safety authorities, information related to the assessment and assessment process shall be shared;
- 3) Conditions under which the assessment contract can be terminated;
- 4) Conditions under which the conformity statement can be used by the conforming organization;
- 5) Terms of confidentiality in relation to information gathered by the CAB during the assessment process;
- 6) The conforming organization allows the CAB 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 conformity status of the organization on the FSSC website;
- 10) Cooperation in allowing witness assessments by the Foundation when requested;
- 11) Communication obligations of conforming organizations 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 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) 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 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 carried out on-site at the premises of the organization and is a full assessment against all Program requirements related to either Level 1 or Level 2.
- 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 are 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) Where one manufacturing or service process is split across more than one physical address, all locations may be covered in one assessment provided that the different addresses are part of the same legal entity, under the same FSS and that they are the sole receiver/customer of each other.
- 2) Storage facilities at another location shall also be included in the same assessment provided they meet the requirements mentioned above.
- 3) The scope statement shall show the assessed locations with activities per location (on the conformity statement or as an Annex to the conformity statement).
- 4) 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 database.

## 5.4 ALLOCATION OF ASSESSMENT TEAM

- 1) All assessment team members shall meet the competence requirements set out by the Foundation in Part 4 and be registered with 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, 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 COMPUTER AIDED ASSESSMENT TECHNIQUES (CAAT)

Computer aided assessment techniques (CAAT) may be used during FSSC Development Program assessments only under the following conditions:

- 1) CAAT shall be only be used for interviews with people and review of policies, procedures or records;

- 2) CAAT shall not replace physical assessments of e.g. sites and processes;
- 3) The CAB shall establish, document and maintain a procedure for the use of CAAT during on site assessments;
- 4) The CAB shall:
  - a) Establish criteria for its use of CAAT;
  - b) Ensure its assessors are able to apply with these criteria consistently.
- 5) The CAB shall ensure that the functions that have been assessed remotely are effectively implemented at the site;
- 6) The assessor shall include in the assessment report:
  - a) Which CAAT techniques were used;
  - b) The assessment report shall clearly show:
    - i) Which functions were assessed using CAAT;
    - ii) Their relationships with the related assessment findings.

## 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;
- 3) 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 concludes 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 conforming organization 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 conforming organization is affected by a serious event.
- 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 conforming organizations a reasonable planned course of action.

## 6 ASSESSMENT REPORT

### 6.1 WRITTEN 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 assessment report shall confirm that all Program requirements are assessed, reported and a statement of (non) conformity given. The content shall comply with the requirements of Annex 2.
- 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 relevant level i.e. Level 1 or Level 2 and is always carried out at the production site of the organization.
- 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, grade of the NC and the objective evidence shall be written.
- i) Corrections, corrective action plans and their approval shall be included as per Annex 2.
- j) A Head Office report shall contain as a minimum the NCs found at the HO. This report shall be included in the documentation supplied to The Foundation. At each site assessment the implementation of the corrective actions shall be verified and reported.

### 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.

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.

#### 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 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 on-site 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 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 shall be done within 28 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.

Note:

- a) The completion of corrective and actions might take more time depending on the potential severity of the major nonconformity and the amount of work necessary to eliminate the causal factors.

- b) In such cases the corrective action plan shall include any temporary measures or controls necessary to mitigate the risk until the permanent corrective action is implemented.
- c) 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 a direct food safety impact without appropriate action by the organization is observed during the assessment or when legality and/or assessment/conformity integrity are at stake:

- 1) When a critical nonconformity is issued at a conforming organization, the conformity statement shall be immediately suspended 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 CAP. This shall be provided to the CAB within 14 days after the assessment;
- 3) A separate assessment shall be conducted by the CAB between six (6) weeks to six (6) month 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 The Foundation;
- 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.

## 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, NC's (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. issue statement of conformity or non-conformity, suspend, withdraw).
- 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) Subsequent assessments should be planned and conducted within a suitable timeframe to enable timely renewal of the Conformity statement before the expiry date.
- 5) The purpose of the re-assessment is to confirm the continuing conformity of the food safety system as a whole with all the relevant Level Program requirements.

- 6) The re-assessment also includes a review of the food safety system over the period since the previous assessment.
- 7) The CAB decides on renewal of the conformity status on the basis of the re-assessment which must meet the same requirements as an initial assessment. In exceptional cases where the assessment is conducted after the expiry date on 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 the Foundation (see Annex III)
- 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 activities shall be listed, (including name, address and activities); details may be provided in an Annex to the conformity statement.
- 6) 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).

## 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 within 3 working days:
  - a) Communicate the change the status of the organization with The Foundation 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 within 3 working days of the decision date:
  - a) Communicate the change in scope of the organization with The Foundation 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

For all assessment types, the required data and documentation shall be submitted to The Foundation at the latest 28 calendar days after the conformity decision with a maximum of 2 months after the last day of the assessment.

PART 4

# REQUIREMENTS FOR CONFORMITY ASSESSMENT BODIES

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# 1 PURPOSE

This document states the requirements for licensed conformity assessment bodies (CABs) who 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 THE FOUNDATION

## 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 a FSSC Development Program license the CAB shall have a valid full licence for FSSC 22000 certification in the appropriate food chain category issued by the Foundation. The CAB shall supply its FSSC Development Program services only whilst it holds a valid FSSC Development Program licence to do so from the Foundation.

### 2.1.1 LICENSE APPLICATION PROCESS

- 1) CABs shall apply for obtaining a full license with the Foundation to be eligible to perform valid and recognized FSSC Development program conformity activities. Full 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 the Foundation specifying the food chain categories which they wish to provide conformity services. As part of the application, the CAB shall submit a completed self-assessment in the Foundation provided format against the Program requirements.
- 2) Upon successful review of the information the CAB shall be granted a full license agreement and be listed in the CAB list on the FSSC 22000 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 and submitted to The Foundation;
- b) For subsequent years have at least five (5) assessed organizations with a minimum of one for each licensed food chain category and submitted to the Foundation;
- c) Comply with all the requirements of the FSSC Development Program for CABs;
- d) Meet the financial obligations to the Foundation.

#### 2.1.4 LICENSE EXTENSION

- 1) The CAB shall submit an application to the Foundation specifying the food chain categories for which it requests an extension of the existing license.
- 2) Upon successful review by the Foundation, the new category/categories will be registered and displayed in the approved CAB list on the FSSC 22000 website.
- 3) At least one assessed organization shall be registered with The Foundation for the new category or per category in the case of multiple category extension within 12 months of approval by the Foundation.

#### 2.1.5 SUSPENSION, TERMINATION AND REDUCTION

The Foundation has the right to suspend, terminate or limit the scope of the CAB's license agreement. 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 the Foundation;
- 4) Repetitive noncompliance with the Program requirements.

##### 2.1.5.1 SUSPENSION

- 1) When a CAB's license is suspended by the Foundation, the Foundation will determine to which extent the CAB will be allowed to maintain its assessment activities for a defined period of time. The Foundation will publish suspensions on the FSSC 22000 website.
- 2) The Foundation 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 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 CAB's license is terminated by the Foundation, the CAB cannot apply for a new license within the time frame communicated by the Foundation.
- 2) The CAB shall agree with the Foundation the transfer of its conforming organizations following 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 the Foundation.
- 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 Integrity Program;
  - c) Appoint a representative to attend the Harmonization Conference;
  - d) Keep up to date with the Program 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 Program to those parties involved within one month unless specified otherwise by the Foundation.

The CAB shall communicate the following to the Foundation:

- 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 the Foundation into disrepute;
- 3) Any public recall of a conforming organization 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 is compromised as described in Part 3.

### 2.2.2 RESPONSIBILITIES

- 1) The CAB shall cooperate with all requests from the Foundation 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 attend the annual Harmonization conference and share the information to all relevant staff.
- 4) The CAB shall participate in the Integrity Program.
- 5) The CAB shall share information concerning the conforming organization with the Foundation and governmental authorities when required by law.
- 6) The CAB shall ensure that all Program related data supplied to The Foundation 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 II and are entitled to use it only when the CAB has a signed license agreement.

## 2.3 INTEGRITY PROGRAM (IP)

- 1) The CAB shall participate in the Integrity Program which is the Foundation's system of ongoing monitoring. This program covers all activities of its licensed CABs to ensure compliance with all Program requirements. The CAB 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 assessment reports and additional information on the assessment process;
  - b) Assessor approval and registration;
  - c) Office assessments;
  - d) Witnessed assessments;
  - e) Monitoring of the 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 Program requirements.
- 2) Nonconformities ("NCs") requiring a response from the CAB shall be raised by the Foundation in response to:
  - a) Any discrepancy raised by the Integrity Program;
  - b) Feedback from users of the Program;
  - c) Feedback from conforming organizations;
  - d) Feedback from governmental authorities;
  - e) Feedback from the media; and
  - f) Any other feedback 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, 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) 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 the Foundation as per the Integrity Program and Sanction Policy.
- 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 indicated in the sanction notification.  
Details are provided in the Integrity Program and Sanction Policy.

## 3 COMPETENCE

### 3.1 GENERAL

- 1) The CAB shall follow the requirements described in Annex C of ISO/TS 22003: 2013 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 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 22000 Register of conforming organizations shall have the following demonstrable competencies;
  - a) Meet the requirements of Annex C of ISO/TS 22003:2013;
  - b) Detailed knowledge of Program requirements;
  - c) Knowledge of food safety systems and 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 can 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 operate always 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.

### 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/TS 22003:2013 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.

### 3.5.1 INITIAL TRAINING AND EXPERIENCE

The CAB shall ensure that trainee assessors or assessors transferring from other CABs are meeting 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 or equivalent  
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
  - a) Food safety assessment training – as a minimum, training by the CAB in assessment techniques;
  - b) Training in the FSSC Development Program requirements
  - c) HACCP training – minimum 16 hours including exam;
  - d) Complete at least 5 (five) post-farm gate food safety audits either as a trainee or an assessor.

### 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.
- 3) All FSSC Development Program assessors shall be registered with the Foundation in accordance with the instructions of the Foundation. For assessors already qualified to FSSC22000 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 I 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 including the associated PRPs, food safety hazards, risks and control measures. The knowledge can be obtained by 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 the Foundation if required.

#### **3.5.4.2 ONGOING TRAINING**

- 1) Assessors 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 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) on-site 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/TS 22003:2013 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.
- 3) Documented sign-off of the satisfactory completion of the entire requalification process shall be supplied to The Foundation.
- 4) The requalification of assessors may be combined with the requalification of FSSC22000 auditors.

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

- 1) Active materials and articles are materials and articles that are intended to:
  - c) extend the shelf-life; or
  - d) maintain; or
  - e) improve the condition of packaged food.
- 2) They are deliberately designed to incorporate components that would release or absorb substances into or from packaged food or the environment surrounding the food and examples are oxygen absorbers and desiccants.

Active materials and articles are food packaging based on the definition of food packaging (ISO/TS 22002-4, 3.7).

### 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 Program who advise 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.

### ASSESSOR

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

### BOARD OF STAKEHOLDERS

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

## CATEGORY

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

## COMPUTER AIDED ASSESSMENT TECHNIQUES (CAAT)

Information Technology based techniques such as webinars, telephone conferences, web-based access to documents (such as records) used to access and gather evidence for use in assessments.

## 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).

## 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 Conformity Assessment Body 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.

## 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 time-frame from the main assessment.

## 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 animal food. 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 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 22000

The legal owner of the FSSC Development Program.

## FSSC LOGO

Logo issued by the Foundation which can be used by licensed CABs and conforming organizations in accordance with FSSC Development Program 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 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.

## 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).

## 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

Product characteristics other than food safety such as size, colour, 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 upon information provided by the Foundation in case of unacceptable CAB performance.

## PROGRAM

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

## SCOPE

Extent and boundaries applicable of e.g. assessment or program activity.

## SERIOUS EVENT

Situation or event preventing a planned assessment to take place caused by humans (e.g. war, strike) or by nature (flood, storm).

## SPECIAL ASSESSMENTS

Assessments at conforming organizations that are performed on top of the annual assessments.

## 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

Periodic on-site observation of an assessor performance by a competent evaluator called the witnessor.

## APPENDIX 2

# REFERENCES

## APPENDIX 2: REFERENCES

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

- 1) GFSI Global Markets Program requirements
- 2) ISO 22000:2018, Food safety systems – Requirements for any organization in the food chain
- 3) ISO/TS 22002-1:2009, Prerequisite Programs for food safety – Part 1: Food manufacturing
- 4) ISO/TS 22003:2013, Food safety systems – Requirements for bodies providing assessment and assessment of food safety systems
- 5) ISO/IEC 17000:2004, Conformity assessment – Vocabulary and general principles
- 6) ISO/IEC 17011:2004, Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies
- 7) ISO/IEC 17021-1:2015, Conformity assessment – Requirements for bodies providing assessment and certification of management systems