

## **CERTIFICATION REGULATION** **FOOD SAFETY MANAGEMENT SYSTEM, FSSC 22000, Version 5.1**

### **Article 1**

#### *Regulation's Subject*

This Certification Regulation describes the assessment and certification procedures for the application of European and National standards. Moreover, it refers also at the European and national legislation, as they are nowadays applicable according to the FSSC 22000 certification scheme. As long as certification of FSSC 22000 Food Safety Management System is concerned, this regulation also clarifies the obligations of A CERT SA as well as the rights and obligations of its affiliated companies.

### **Article 2**

#### *Definitions*

The definitions apply to the terminology used to all FSSC 22000 Scheme documentation and they all shall comply with Appendix 1: Definitions, Version 5.1, November 2020

### **Article 3**

#### *Scheme Overview*

#### *1. The Scheme*

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

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

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

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

#### *2. Aim of the Scheme*

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

#### *3. Objective of the Scheme*

The specific Scheme objectives are to:

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

#### *4. Nature of the Scheme*

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

The Scheme:

- a) incorporates ISO standards, sector specific technical specifications for PRPs, market driven additional requirements as well as statutory and regulatory requirements;
- b) is recognized by the Global Food Safety Initiative;
- c) allows the integration with other management system standards such as those for quality,

environmental, health and safety etc.;

- d) is governed by a non-profit Foundation and managed by an independent Board of Stakeholders;
- e) increases transparency throughout the food supply chain;
- f) offers a "FSSC 22000 Register of certified organizations" which is publicly accessible.

#### 5. Scope

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

Category	Subcategory	Description	Normative documents
A	AI	Farming of animals for meat/milk/ eggs/honey;	ISO 22000: 2018, ISO/TS 22002-3, FSSC 22000 Additional requirements
	AII	Farming of Fish and seafood;	
C	CI	Processing of perishable animal products	ISO 22000:2018, ISO/TS 22002-1:2009, FSSC 22000 Additional requirements
	CII	Processing of perishable plant products	
	CIII	Processing of perishable animal and plant products (mixed products)	
	CIV	Processing of ambient stable products	
D	DI	Production of feed	ISO 22000:2018, ISO/TS 22002-6:2016, FSSC 22000 Additional requirements
	DIIa	Production of pet food (only for dogs and cats).	ISO 22000:2018, ISO/TS 22002-1:2009, FSSC 22000 Additional requirements
	DIIb	Production of pet food (for other pets).	ISO 22000:2018, ISO/TS 22002-6:2016, FSSC 22000 Additional requirements
E	EI	Catering	ISO 22000:2018, ISO/TS 22002-2:2013, FSSC 22000 Additional requirements
F	F1	Retail /Wholesale	ISO 22000:2018, BSI/PAS 221:2013, FSSC 22000 Additional requirements
G	GI	Provision of transport and storage services for perishable food and feed.	ISO 22000:2018, ISO/TS 22002-5:2019, FSSC 22000 Additional requirements
	GII	Provision of transport and storage services for ambient stable food and feed.	ISO 22000:2018, ISO/TS 22002-5:2019, FSSC 22000 Additional requirements
I	I	Production of food packaging and packaging materials.	ISO 22000:2018, ISO/TS 22002-4:2013, FSSC 22000 Additional requirements
K	K	Production of Bio-chemicals	ISO 22000:2018, ISO/TS 22002-1:2009, FSSC 22000 Additional requirements

#### FSSC 22000 - Quality

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

#### **Article 4**

##### *The Certification Body A CERT SA*

A CERT SA Certification and Audit Body (hereinafter referred to as A CERT or just a C.B.) was founded in 2005 and is based in Thessaloniki. A CERT is active in Product Control and Certification as well as in Quality and Food Safety Management Systems Certification.

1. Objectives of A CERT :

- Maintaining confidentiality, objectivity and impartiality
- Customer satisfaction
- Providing high quality services
- Development of human resources
- Continuous improvement
- Social responsibility

2. A CERT Operation Principles

a. Confidentiality-Confidentiality

A CERT is responsible for keeping the information it collects about businesses confidential through the audit and certification process. Information exchange between A CERT and a third party is subject to the written consent of the company. If the supervisory and supervisory authority is informed by the legislation in force, the enterprise shall be informed of the information provided.

b. Impartiality-Objectivity

A CERT is not involved in the design and promotion of systems of the type it certifies. A CERT Certification Authority and its affiliates do not provide any kind of general or specialized consulting services, either alone or in combination with other services or in the context of other services to any natural or legal person. A CERT's staff and external partners are free from any commercial, financial and other pressures that could affect their judgment. A CERT provides interested companies with information on the interpretation of certification requirements. The overall operation and content of the A CERT certification system is monitored by the supervisory / supervisory authority. Internal Audit is overseen by the Independence Audit Committee (EEA), which is a collective body set up at the invitation of A CERT to all interested parties, acts as an independent internal audit body and holds one (1) once a year, in accordance with its Rules of Procedure. Its composition is such that no individual interest prevails, while at the same time making it possible to involve all the major stakeholders. In addition to its audit work, EEA contributes to the creation of policies and principles regarding the content and operation of the certification system.

A CERT categorically states that its job is to carry out impartial, independent and objective certification. The activities of his relatives,

- do not in any way bind it and in any way affect its objectivity, impartiality and orthodoxy and therefore the accuracy and validity of the results of the certification process; and
- do not make the certification process simpler, easier or cheaper in any way and for any reason.

In this context, A CERT cannot accept an application for certification of a subsidiary or a directly related company.

c. Transparency

The procedures that A CERT implements ensure transparency through a series of publications accessible to all concerned. Publications include, among other things, this Certification Regulation and the Certified Business Register. In addition, the published documents and any information required are submitted to the competent authorities in order to ensure compliance with A CERT's obligations under the existing legislation.

3. A CERT reviews continuously the decisions of the Board of FSSC 22000 Stakeholders as it is available on the Foundations website and incorporates all requirements into its procedures as appropriate.

#### **Article 5**

##### *Requirements for Certification by an applicant/certified organization*

The requirements to be included in the design and implementation of the Food Safety Management System claimed to conform with the requirements of the Scheme by an applicant/certified organization seeking to be included in the FSSC 22000 Register of Certified Organizations shall be in compliance with Part 2: Requirements for organizations to be audited, FSSC 22000, version 5.1

## Article 6

### Requirements for Certification Process

#### 1. Purpose

This article states the requirements for the execution of the certification process to be conducted by A CERT. Where reference to FSSC 22000 requirements is made, this is also applicable for FSSC 22000- Quality unless stated otherwise.

#### 2. General

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

A CERT controls all Scheme related documentation and records according to its own procedures.

A CERT has procedures of certification that confirm the compliance of the certified organizations.

#### 3. Resources

A CERT provides its resources to enable the reliable supply of its FSSC 22000 certification service.

#### 4. Contract process

##### 4.1 Application

A CERT collects and documents the information from the applicant organization in an application form which details the minimum information as required in the ISO/IEC 17021-1 and ISO/TS 22003, and additional Scheme requirements.

##### 4.2 Scope

A CERT assesses the scope proposed by the organization on the application form and review it against the requirements in Annex I (CB Certificate scope statements), FSSC 22000, Version 5.1.

##### 4.3 Audit duration

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

- a) the duration of an audit day normally is eight (8) hours; the effective on-site audit duration does not include a lunch break (unless in contradiction with local legislation);
- b) the audit duration calculation for FSSC 22000 shall be documented by the CB, including justifications for reduction or addition of time based on the minimum audit duration;
- c) the on-site audit duration shall be stated in auditor working hours indicating the time spent at the site and shall match the audit plan and deviations shall be recorded (including motivations);
- d) the on-site audit duration does not include planning, reporting or travel activities, only actual on-site auditing time;
- e) the on-site audit time shall only apply to auditors that are fully qualified, registered FSSC 22000 auditors;
- f) where the FSSC 22000 audit is undertaken in combination or integration with other food safety audits as a combined audit, the audit time stated in the report shall be of the total combined audit and match the audit plan. Total audit duration is then longer than for FSSC 22000 alone. This is considered as an increase in audit duration and the reason for this shall be justified.

##### 4.3.1 Basic audit time calculation (single site)

The total on-site audit time (for a single site) is defined as  $T_S + T_{FSSC}$  where:

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

When properly documented and justified, a reduction of the  $T_S$  audit time can be made in accordance with ISO/TS 22003:2013, Annex B. The reduction in  $T_S$  audit time can never be more than 0,25 auditor day (2 working hours) and the  $T_S$  cannot be reduced below 1 day. The reduction cannot be applied on  $T_{FSSC}$ .

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

- a) At least 0.25 auditor day (2 working hours) shall be added to the FSSC 22000 on-site audit time for

audit preparation.

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

If after the calculation the result is a decimal number, the exact hours may be used or where rounding is applied to the number of days, this shall be rounded upwards to the nearest half day. Additional time shall be considered in case an interpreter is required to support the audit team.

#### 4.3.2 Surveillance and recertification audits

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

Additional (special) audits may be performed on top – but never as a replacement of the annual surveillance/recertification audits.

#### 4.3.3 Minimum Audit Duration

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

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

The following exemptions apply to the minimum audit durations:

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

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

#### 4.3.4 Additional audit time

Additional time shall be required for the following situations:

- a) Separate Head Office

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

- b) Off-site activities

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

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

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

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

#### 4.3.3 FSSC 22000-Quality

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

#### 4.3.3 Transition to FSSC 22000

- 1) When transitioning from Dutch HACCP, ISO 22000 or an equivalent GFSI recognized certification to

FSSC 22000 certification, the minimum FSSC 22000 certification on-site audit time shall be two-thirds of the initial certification audit time, with a minimum of 1 auditor day (8 working hours) on-site plus TFSSC as defined in §4.3.1.

The transition audit shall result in an FSSC 22000 certificate with a validity of three (3) years.

- 2) Transition to FSSC 22000-Quality is only possible when the organization has a valid ISO 22000 or FSSC 22000 certificate AND a valid ISO 9001 certificate. In this case, the audit duration is two-thirds of the initial combined audit time (see 4.3.4.) plus TFSSC.

#### 4.4 Contract

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

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

- 1) ownership of the certificate and the audit report content shall be held by the A CERT;
- 2) at the request of food safety authorities, information related to the certification and auditing process shall be shared;
- 3) conditions under which the certification contract can be terminated;
- 4) conditions under which the certificate can be used by the certified organization;
- 5) terms of confidentiality in relation to information gathered by the CB during the certification process;
- 6) the certified organization allows the CB to share information when required by law from governmental authorities and/or the Foundation and GFSI;
- 7) procedures for nonconformity management;
- 8) procedures for complaints and appeals;
- 9) inclusion of information on the certified status of the organization on the FSSC 22000 website and in the Portal;
- 10) cooperation in allowing witness assessments by the AB and/or the Foundation when requested;
- 11) communication obligations of certified organizations to the CB within 3 working days related to the following:
  - a) any significant changes that affect the compliance with the Scheme requirements and obtain advice of the CB in cases where there is doubt over the significance of a change;
  - b) serious events that impact the FSMS or FSQMS, legality and/or the integrity of the certification which include legal proceedings, prosecutions, situations which pose major threats to food safety, quality or certification integrity as a result of natural or man-made disasters (e.g. war, strike, terrorism, crime, flood, earthquake, malicious computer hacking, etc.);
  - c) public food safety events (such as e.g. public recalls, calamities, food safety outbreaks, etc.);
  - d) changes to organization name, contact address and site details;
  - e) changes to organization (e.g. legal, commercial, organizational status or ownership) and management (e.g. key managerial, decision-making or technical staff);
  - f) changes to the management system, scope of operations and product categories covered by the certified management system;
  - g) any other change that renders the information on the certificate inaccurate.

#### 5 Planning and managing audits

##### 5.1 General

- 1) Annual audits shall take place to ensure certificate validity or that recertification is granted before the expiry date of the certificate.
- 2) The annual audit shall be carried out at the premises of the organization and is a full audit against all Scheme requirements. Surveillance audits shall be conducted within the calendar year as per the requirements of ISO/IEC 17021-1.
- 3) The audit shall be conducted over a continuous number of days in accordance with the audit duration calculated. Where the ICT Audit Approach is utilized, the requirements of Annex 9 apply. FSSC 22000 Version 5.1 | November 2020
- 4) The audit shall be carried out in a mutually agreed language. An interpreter may be added to the team by the CB to support members of the audit team.
- 5) A CERT is expected to operate discretely in case of emergencies (e.g. fire, major catastrophic event, another audit on-going).
- 6) A CERT shall perform the stage 1 and stage 2 audits for initial certification according to the requirements of ISO/IEC 17021-1.
- 7) The interval between stage 1 and stage 2 audits shall not be longer than 6 months. Stage 1 shall be repeated if a longer interval is needed. Where separate stage 1 and stage 2 audits are conducted, the

relevant sections of the template are used as separate reports.

- 8) The 3-year certification cycle (ISO/IEC 17021-1 §9.1.3) shall be respected at all times.

## 5.2 Multiply functions across more than one site

### 5.2.1 Head Office functions

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

### 5.2.2 Off-site activities

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

## 5.3 Multi-site certification

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

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

b) When applying multi-site certification all requirements of IAF MD 1 shall be met, except:

- paragraph 6.1.3 (size of sample). This IAF MD 1 paragraph shall be replaced by the ISO/TS 22003:2013 sampling regime paragraph 9.1.5.4.
- paragraph 7.3: For audit time calculation see 4.3.3 where the same principles for a Head Office can be used for the central function.

c) A multi-site organization need not be a unique legal entity, but all sites shall have a legal or contractual link with the central function of the organization and be subject to a single management system, which is laid down, established and subject to continuous surveillance and internal audits by the central function.

d) The central function shall be audited at least annually and before the audits of the (sampled) sites. If necessary, a small number of the sample sites may be audited prior to the audit of the central function.

e) One audit report may be produced for the multi-site organization, including the central function information, specific information about each site audited and complying with the content of Annex 2 or Annex 3 (FSSC 22000-Quality). The summary sections of the audit report shall clearly reflect what was audited at each site with supporting objective evidence. Alternatively, separate reports may be produced for the Central function

and each of the sites respectively.

f) The certificate shall be a group certificate.

#### 5.3.2 Sampling Methodology

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

#### 5.3.3. Requirements for the central Function

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

#### 5.3.4 Nonconformities management

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

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

### 5.4 Unannounced audits

#### 5.4.1 Frequency

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

#### 5.4.2 Execution

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

- 7) The A-Cert decides which of the surveillance audits shall be chosen for the unannounced audit, taking into consideration the requirement that unannounced audits shall be conducted at least once every 3 years and adhering to the calendar year requirement.
- 8) If the certified organization refuses to participate in the unannounced audit, the certificate shall be suspended immediately, and the CB shall withdraw the certificate if the unannounced audit is not conducted within a six-month timeframe from the date refusal.
- 9) The audit of separate Head offices controlling certain FSMS processes pertinent to certification separate to the site(s) (see 5.2.1) shall be announced. Where Head Office activities are part of a site audit, they shall be unannounced.
- 10) Secondary sites (off-site activities) and off-site storage, warehouses and distribution facilities shall also be audited during the unannounced audit.

#### 5.5 Use of Information and Communication Technology (ICT)

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

- 1) For conducting interviews with people and review of policies, procedures or records as part of the on-site audit;
- 2) When utilizing the ICT Audit Approach as set out in Annex 9 FSSC 22000 Version 5.1 | November 2020.

#### 5.6 Transfer of certification

A CERT follows the requirements of IAF MD2 for transfer of certified organizations from another CB.

#### 5.7 Upgrade audits

A CERT:

- 1) follows the upgrade requirements as issued by the Foundation;
- 2) ensures all staff and auditors are familiar with the upgrade process;
- 3) additional audit time are being recalculated and advised to the clients where applicable;
- 4) following the successful upgrade audit (including closure of nonconformities the certificate gets re-issued when required as part of the upgrade requirements

#### 5.8 Transition audits

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

#### 5.9 Allocation of the audit team

- 1) All audit team members shall meet the competence requirements set out by the Foundation in Part 4 chapter 3, version 5.1.
- 2) The audit team shall have the combined competence for the food chain sub-categories supporting the scope of the audit and following the requirements of ISO/IEC 17021-1.
- 3) The FSSC 22000-Quality audit is a fully integrated audit and the audit team shall meet the competence requirements set in Part 4 of the Scheme.
- 4) Audit teams conducting integrated FSSC 22000 and ISO 9001 audits (FSSC 22000-Quality) shall collectively meet the relevant FSSC 22000-Quality auditor specifications.
- 5) The lead auditor shall always be a FSSC 22000 qualified auditor.
- 6) An auditor is not allowed to perform more than two 3-year certification cycles at the same certified site either as lead auditor or co-auditor. If an auditor starts auditing within a certification cycle he/she will be rotated out after six (6) years for a minimum of one year.

#### 5.10 Management of serious events

- 1) A CERT has a process to review planned audits when a serious event affects a certified organization and the audit cannot be performed as planned.
- 2) A CERT assesses the risks of continuing certification and establishes a documented policy and process, outlining the steps it will take in the event a certified organization is affected by a serious event to ensure the integrity of certification is maintained. The minimum content of the risk assessment shall cover the aspects listed in IAF ID3, section 3.
- 3) The outcome of the Risk Assessment and planned actions shall be recorded. Deviations from the audit program and their justification for changes shall be recorded. A CERT shall establish in consultation with certified organizations a reasonable planned course of action.

- 4) In cases where the annual surveillance audit cannot take place within the calendar year as a result of a serious event, an exemption shall be requested from the Foundation or the certificate shall be suspended.

## 6. Audit report

### 6.1 Written report

A CERT provides a written report for each audit.

- a) The audit report is to be treated confidentially by A CERT but shall be made available to Food Safety Authorities after approval of the organization.
- b) The audit report shall confirm that all Scheme requirements are assessed, reported and a statement of (non) conformity given. Furthermore, it shall comply with all relevant requirements of ISO/IEC 17021-1. The content shall comply with the requirements of Annex 2 or Annex 3 in the case of FSSC 22000-Quality. FSSC 22000 Version 5.1 | November 2020
- c) Both the procedural and operational conditions of the food safety management system shall be verified to assess the effectiveness of the food safety management system meeting the Scheme requirements and reported.
- d) In exceptional cases, a requirement can be deemed not applicable. Where a requirement is deemed to be N/A then suitable justification shall be recorded in the relevant section of the audit report.
- e) Exclusions from scope shall be assessed and justified in the audit report.
- f) Deviations from the audit plan shall be motivated in the report.
- g) Auditors shall report all nonconformities (NCs) at all audits. For each nonconformity (NC), a clear concise statement of the requirement, the NC, grade of the NC and the objective evidence shall be written.
- h) Corrections, corrective action plans and their approval shall be included as per Annex 2, or Annex 3 in the case of FSSC 22000-Quality.FSSC 22000, version 5.1
- i) A Head Office report shall contain as a minimum the NCs found at the HO. This report shall be uploaded. At each site audit the implementation of the corrective actions shall be verified and reported.)
- j) The full audit report meeting the minimum requirements as set out by the Scheme (FSSC 22000 Version 5.1), shall be sent to the (certified) organization within 2 weeks of the certification decision for all audits conducted.
- k) It is the Foundation's requirement that audit reports are written in English. Where an organization requests the report to be written in the language the audit was conducted in (if other than English), this is allowed based on mutual agreement between A-Cert and the organization. However, the mandatory fields in the portal shall always be completed in English. In all instances where A-Cert are translating audit reports, the A-Cert have verification procedures in place to ensure the translations are accurate.

### 6.2 Nonconformities

In accordance with the definitions in the Scheme and as defined below, A CERT 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 requirement linked to the specific audit criteria in ISO 22000:2018; the specified PRP standard or the FSSC Additional Requirement.

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

Does not allow "Opportunities for Improvement".

#### 6.2.1 Minor Nonconformity

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

- 1) the organization shall provide the A CERT with objective evidence of the correction, evidence of an investigation into causative factors, exposed risks and the proposed corrective action plan (CAP);
- 2) A CERT shall review the corrective action plan and the evidence of correction and approve it when acceptable. The CB approval shall be completed within 28 calendar days after the last day of the

- audit. Exceeding this timeframe shall result in a suspension of the certificate;
- 3) Corrective action(s) (CA) shall be implemented by the organization within the timeframe agreed with A CERT;
  - 4) effectiveness of implementation of the corrective action plan shall be reviewed, at the latest, at the next scheduled audit. Failure to address a minor nonconformity from the previous audit could lead to a major nonconformity being raised at the next scheduled audit.

#### 6.2.2 Major Nonconformity

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

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

#### 6.2.3 Critical Nonconformity

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

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

### 7. Certification decision process

#### 7.1 General

- 1) A CERT conducts a technical review for all audits to agree with the audit reports content and outcome, NC's (objective evidence and grading) and effectiveness of corrections and corrective action plans. Following each technical review, A CERT shall make a decision on the certification status of the organization (e.g. certify, continue certification, suspend, withdraw).
- 2) A CERT keeps documented information of decisions on certification status that have been considered and by whom. This information shall include: the names of those making each decision, and the date the decision was made.

Note: not all decisions may lead to issuing a new certificate.

- 3) The maximum certificate validity period is 3 years from the date of initial certification decision, with subsequent 3 year cycles.

#### 7.2 Certificate design and content

- 1) A CERT issues FSSC 22000 and FSSC 22000-Quality certificates in accordance with the scope rules and certificate templates set out in Annexes 1 and 4, FSSC 22000, version 5.1
- 2) The certificate is in English and correspond with the certificate in the portal and the details on the public register. It is possible to include a translation of the scope statement following the English statement on the certificate
- 3) The FSSC 22000 logo shall be used by A CERT on its certificates.
- 4) Head Office details shall be included, where applicable.
- 5) Where applicable Off site and Multi-site locations shall be listed, (including name, address and

activities); details may be provided in an Annex to the certificate.

- 6) Dates on the certificates shall be as follows:
  - a. certificate decision date: date of at which a new decision is made after a certification or recertification audit (excluding regular surveillance audits). New certificate decision dates are also required in situations such as version changes of the Scheme and/or scope extensions/reductions. In these cases, the valid until date remains unchanged;
  - b. initial certification date (i.e. the certification decision date after the initial audit). This is a fixed date that is maintained as long as the organization is linked to the A CERT and holds a valid FSSC 22000 certificate;
  - c. issue date: date certificate is issued to the client; or re-issue date when a new certificate is issued (e.g. because of version change, scope extension etc.);
  - d. valid until date: certificate expiry date ( e.g. original certification decision date + 3 years for the initial cycle).

### 7.3 Certificate suspension, withdrawal, or scope reduction

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

#### 7.3.1 Certificate Action upon suspension, withdrawal, or scope reduction

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

## 8. Portal data and documentation

### 8.1 Data ownership

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

### 8.2 Data Upload Requirements

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

### 8.3 Data Quality Control

A CERT has a data quality control process in place that provides assurance for Portal Data Quality. The

quality parameters include the following as a minimum:

- a) Completeness: All the mandatory data has been registered in the Portal;
- b) Timeliness: All the data has been registered in the Portal within the required timelines;
- c) Validity: The registered data values meet the Scheme requirements;
- d) Accuracy: The data is a true representation of the actual facts relating to the complete audit and the certification process;
- e) Consistency: The registered data in the Portal is a true representation of the data stored in the A-Cert internal system(s). CB PORTAL
- a) When requested by the certified organization, CBs shall actively provide the Certified Organization access to the associated Organization Profile, Audit and Certification data registered in the CB Portal using the available functionality.
- b) CBs shall ensure that Certified Organization access is only granted to authorised individual(s).

#### 8.4 A-Cert Portal

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

### **Article 7**

#### Complaints – Refugees - Appeals

The Agency receives complaints, which are made by telephone or written by e-mail concerning the Organization or its clients. The Agency shall be responsible for the collection and verification of information for the validation of complaints and for decisions at all levels concerning the handling of complaints. The Agency must examine the correctness of the allegations and take appropriate corrective, corrective or preventive actions. Additionally, investigating, and making decisions about the complaint do not in any way lead to discriminatory treatment of the one that addresses the complaint / complaint / complaint / appeal.

The audited undertakings, as well as third parties, have the right to appeal and appeal if and to the extent that they can justify their legitimate interest.

The objection may concern an act of the Agency's staff, or an appeal against the decision of the body's bodies by filling the special form available to the Agency for this purpose. In the case of an inspection, it would be useful to submit an objection by the inspector when carrying out the inspection or when notifying the company of its results.

Submission time is decided on a case-by-case basis by the Director-General, and if the interest is justified and the interest of the Agency is legal, you are referred to the appropriate Appeals and Appeals Committee.

The appeal shall be considered valid when submitted within fifteen (15) working days of the notification of the decision to the undertaking.

The Appeals and Appeals Committee shall meet within ten (10) working days of the filing of the appeal. The objector shall be informed in writing by the Body of the date of its examination and may request to attend the meeting. The Commission may require further clarification, if necessary, from the parties involved or request the involvement of experts in the investigation of the case under consideration. The Commission shall take a decision within fifteen (15) days of the filing of the complaint / appeal.

### **Article 8**

#### End of cooperation

The partnership between A CERT and the affiliate may end in the following ways:

- Over the period of time listed in the Private Agreement, and unless the company requests renewal.
- With the termination of the Private Agreement by the company. In this case, the Company must inform the Entity in writing, while undertaking to comply with the terms of the Agreement it has entered into with respect to its financial obligations to A CERT SA.
- With A CERT's termination of the Private Agreement. The reasons that may lead to a complaint by the

Agency include:

1. Failure to meet financial obligations
- 2 Non-compliance with the principles of the FSSC 22000 certification scheme
3. Improper use of marks and certificates

A CERT SA reserves the right to appeal to civil courts in order to defend its rights, as well as to seek prosecution for defamation by any means (document, traditional or digital media, radio, etc.).