FSSC 22000

FOOD SAFETY SYSTEM CERTIFICATION 22000

Part 0: Definitions
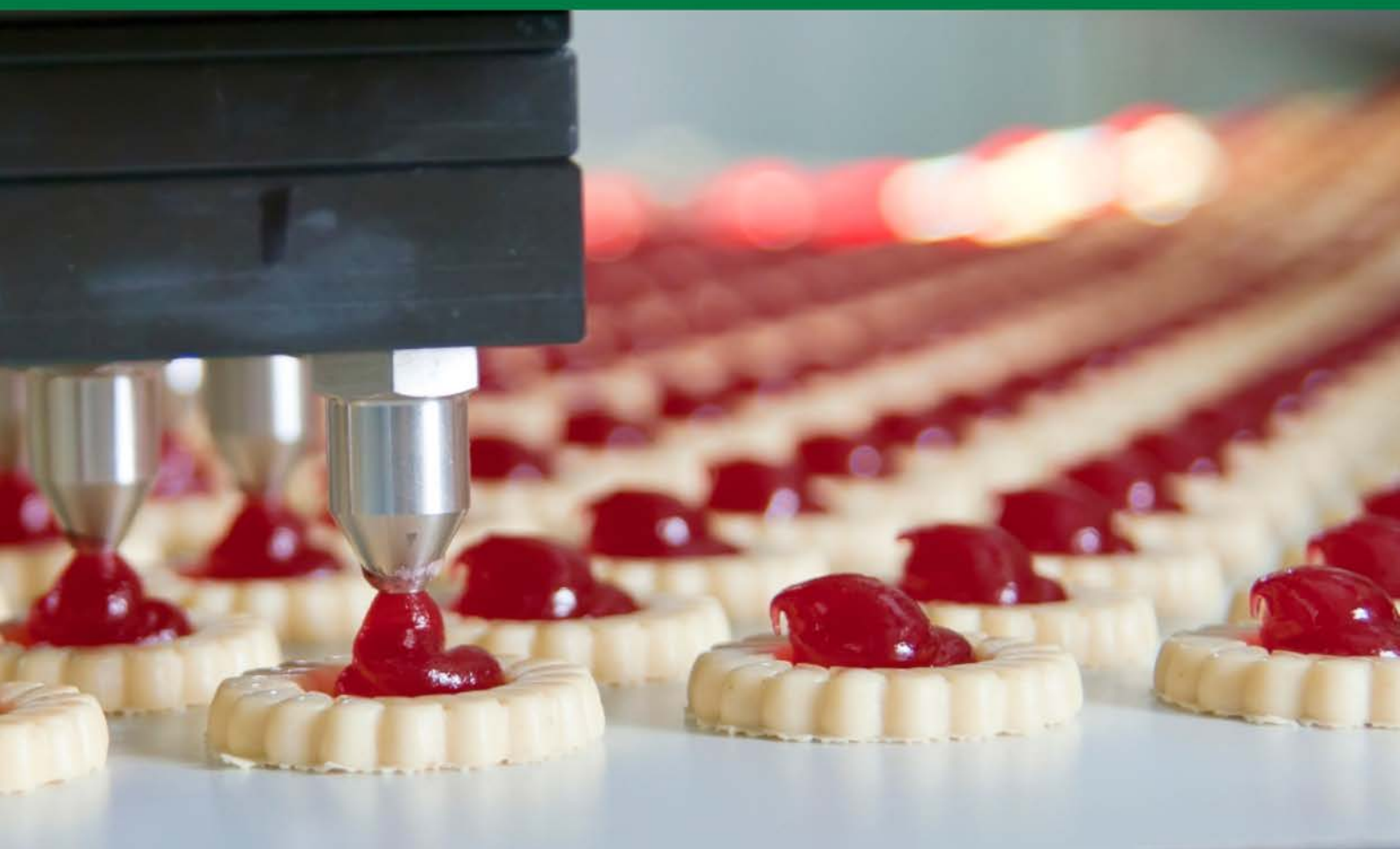
Version 4: January 2017

Part 0: Definitions

Contents

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1 Definitions applicable throughout the Scheme

The following definitions apply to the terminology used in all FSSC 22000 Scheme documentation.

Accreditation

An attestation by an accreditation body that a certification body meets the requirements set out by the Foundation to carry out FSSC 22000 certification.

Accreditation body

An accreditation body (AB) is an appointed body that provides accreditation to certification bodies providing conformity assessment services.

Active materials and articles

1) Active materials and articles are materials and articles that are intended to
   a) extend the shelf-life, or
   b) maintain, or
   c) 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).

Additive

1) Any substance, whether or not it has nutritive value, intentionally added to food or feed for technological (including organoleptic) purposes.
2) An additive substances is not normally
   a) consumed as a food or feed by itself or
   b) used as a typical ingredient of the food or feed.
3) Technological purposes include the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food.
4) The use of an additive 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 or feeds.
5) The term excludes "contaminants" or substances added to food or feed for maintaining or improving nutritional qualities.

Advisory Committee

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

Animal feed

1) Feed given to domesticated animals in the context of animal husbandry.
2) There are two basic types of feed namely;
    a) fodder and
    b) forage.

Note

Used alone, the word;

   a) *feed* usually means fodder fed to animals, whereas
   b) *forage* usually refers to feed that animals find for themselves.

Animal production

1) All operations related to activities carried out on farm premises (e.g. storage, sorting, cleaning, packing of unprocessed products, on-farm feed manufacturing, transport within the farm), to amongst others include both:
    a) the farming of living farm animals (e.g. cattle, poultry, pigs, fish/seafood, bees) and
    b) the handling of their products (e.g. milk, eggs, fish/seafood, honey).
2) The following activities are excluded:
    a) fishing, hunting, transportation of animals to or from the farm, and
    b) food processing activities carried out on farm premises (e.g. heating, smoking, curing, maturing, fermenting, drying, marinating, extraction, extrusion or a combination of those processes).

Audit

Systematic, independent, documented process for obtaining records, statements of fact or other relevant evidence and assessing them objectively to determine the extent to which specified requirements are fulfilled.

Auditor qualification

The process applied to confirm auditor competence.

Black-out days

Time periods shared by the applicant/certified organization with the certification body that prevents the unannounced audit occurring when the organization is not operating for legitimate business reasons.

Board of Stakeholders

The Board of Stakeholders (BoS) are a group of representatives appointed by the Scheme's key stakeholders who are responsible for oversight including all certification and accreditation requirements.

Catering

Preparation, storage and, where appropriate, delivery of food for consumption, at the place of preparation or a satellite unit.

Category

Food chain category for which a FSSC qualified auditor is qualified to conduct audits.

Certification body

A certification body (CB) is an organization providing conformity assessment services.

Computer aided audit techniques

Computer aided audit techniques (CAAT) are information technology based techniques such as webinars, telephone conferences, web-based access to documents (like records) used to access and gather evidence for use in audits.

Critical nonconformity

A nonconformity whereby food safety is directly impacted during the audit or when legality and/or certification integrity are at stake.

Facility

A building or structure that is used by an organization.

Feed

Any substance or product, whether processed or unprocessed, intended to be used for direct or indirect feeding of animals.

Feed Manufacturing

The manufacture (or processing) of materials intended to be consumed by animals and contribute energy and/or nutrients to their diet.

Food

1) Any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes amongst others:
   a) drink,
   b) chewing gum and
   c) any substance that has been used in the manufacture, preparation or treatment of "food".
2) The following are excluded from this definition:
   a) Cosmetics,
   b) Tobacco or
   c) Medicinal products, Over The Counter drugs (OTC), nutraceuticals and pharmaceuticals.

Food Defense

The process to prevent food and feed supply chains from all forms of ideologically or behaviourally motivated, intentional adulteration that might impact consumer health.

Food Fraud Prevention

The process to prevent food and feed supply chains from all forms of economically motivated, intentional adulteration that might impact consumer health.

Food/Feed Safety

The policies, processes and procedures, materials, facilities and monitoring systems applied to Food or Feed products to ensure they will not cause harm to humans or animals or adversely affect their health when utilised according to their intended purpose.

Food/Feed Safety Hazard

Biological, chemical, physical agent or allergen in food/feed, or condition of food/feed, with the potential to cause an adverse health effect to humans and/or animals (ISO 22000, section 3.3).

Foundation

The Foundation FSSC 22000.

GFSI

The Global Food Safety Initiative is an industry-driven initiative owned by the Consumer Goods Forum providing thought leadership and guidance on food safety management systems necessary for safety along the supply chain.

Ingredient

A processed or unprocessed component of food, feed or packaging.

Manufacturing/processing

The system of methods and techniques used to manufacture and supply food.

Management System

A management system of policies, processes, procedures, and records established and effectively implemented within an organization to ensure it consistently achieves its stated food safety and quality (if applicable) objectives.

Major nonconformity

A nonconformity that affects the capability of the management system to achieve the intended results.

Minor nonconformity

A nonconformity that does not affect the capability of the management system to achieve the intended results.

Organization in the food chain

The food or feed chain partner that is responsible for ensuring that products meet and, if applicable, continue to meet, the requirements on which the certification is based.

Pet food for dogs and cats

1) Any commercial food prepared and distributed for consumption by dogs and cats.
2) The definition includes;
   a) supplements or
   b) a food intended as a sole ration composed of vegetal (plant) or animal material.

Pet food for other pets

1) Any commercial food prepared and distributed for consumption by pet animals, other than cats or dogs, that may be kept at home as pets e.g. turtles, rabbits, birds, poultry'
2) The definition includes;
   a) supplements or
   b) a food intended as a sole ration composed of vegetal (plant) or animal material
3) This definition also includes food produced for exotic and zoo-animals.

Quality

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

Raw Material

A component of food, feed or packaging that has not undergone processing.

Recall

Removal of products from the market by public means, that are expected to cause adverse health effects to humans and/or animals as they do not meet food safety requirements.

Retail

Preparation, packaging, storage, serving, vending, selling or otherwise providing food for consumption direct to the public.

Rework

The re-utilisation of food or feed, ingredients or raw materials.

Risk

The product of the probability of an adverse health effect and the severity of that effect, consequential to hazard in food when prepared and consumed according to its intended use.

Sanction Committee

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

Scope

The Scheme is intended for the audit, certification and registration of food safety management systems for the following scopes and product categories:

1) Manufacturing of food products
2) Manufacturing of food packaging and packaging material
3) Manufacturing of food and feed for animals
4) Animal farming
5) Transport and Storage
6) Catering
7) Retail

Standard

A set of requirements against which something can be measured, judged or evaluated.

Tableware

Consumer good products that come in contact with food and food packaging materials based on the definition included in ISO/TS 22002-4.

The Board

Foundation's management board.

The Scheme

The FSSC 22000 certification Scheme for food safety management systems.

Unannounced audit

A full on-site surveillance audit that is conducted at the facility of the certified organization without prior notification of the audit date.

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.

Witnessed audit

Periodic on-site observation of an auditor by the approved supervisor of the CB in order to monitor and evaluate the performance of the auditor.

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Part 1: Scheme Overview
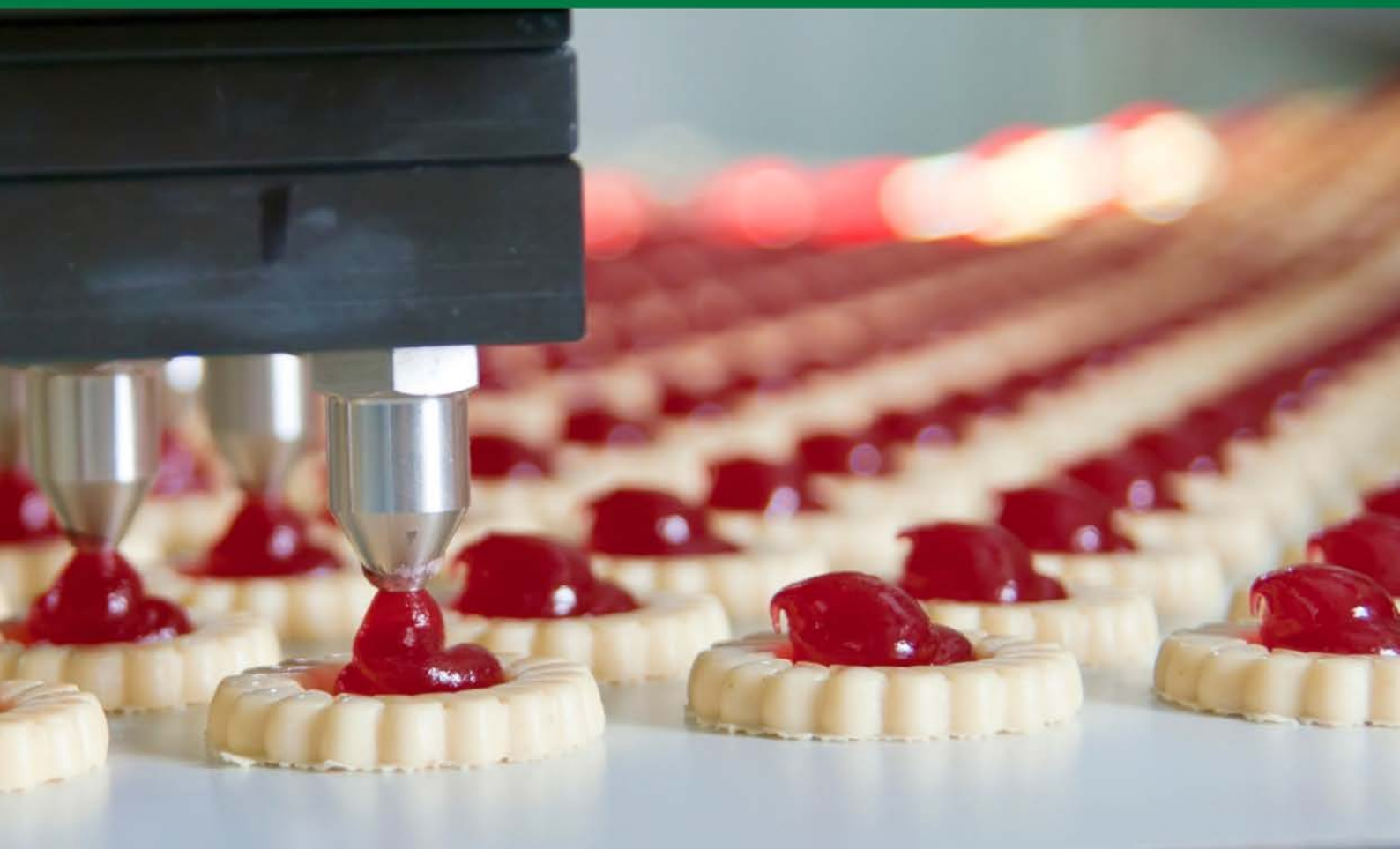
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Part 1: Scheme Overview

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0 Introduction

The Scheme

FSSC 22000 is a certification Scheme for food and feed safety/quality management systems in compliance with ISO 22000/9001 requirements, sector specific Prerequisite Program (PRPs) requirements and additional Scheme requirements.

Ownership

The Foundation FSSC 22000 (hereafter the Foundation) retains the ownership and the copyright of all Scheme related documents and also holds the license agreements for all involved certification bodies.

Language

In all cases the English version of the Scheme is valid.

1 Background

1.1 Aim of the Scheme

The aim of the FSSC 22000 certification Scheme (hereafter the Scheme) is to ensure that the Scheme continuously meets international requirements resulting in certification that assures the provision of safe products to consumers worldwide.

1.2 Objective of the Scheme

The objective of the Scheme is to establish and maintain an accurate and reliable Register of Certified Organizations that have demonstrated to comply with the Scheme requirements.

1.3 Register of Certified Organizations

The Scheme outlines the requirements to comply, assess and certify management systems of organizations in the supply chain and to guarantee its integrity.

These certifications are subsequently registered in the FSSC 22000 Register of Certified Organizations. This register is publicly accessible.

Registration indicates that the organizations' management system is in conformance with the Scheme requirements and that the organization is able to maintain conformance with these requirements.

The value added for a certified organization lies in the oversight by the Foundation to ensure that the integrity of the entire certification process is in line with the Scheme requirements recognized by GFSI.

1.4 Nature of the Scheme

The Scheme is a complete certification Scheme for food and feed safety management systems, which are in compliance with the publicly available food safety management systems standard ISO 22000 'Requirements for any organization in the food chain', technical specifications for sector PRPs and additional Scheme requirements.

The Scheme provides a certification model that can be used in the whole food supply chain. It can cover sectors where such a technical specification for sector PRPs has been developed and accepted.

The Scheme follows the food chain category description as defined in ISO/TS 22003. As the development of new technical specifications for sector PRPs is ongoing the actual scope of the Scheme will follow these developments.

As of February 2010 the Scheme is a Global Food Safety Initiative (GFSI) recognized scheme.

2 Scope

The Scheme is intended for the audit, certification and registration of food safety management systems for the following scopes and product categories:

1) Farming of animals
   Farming of animals for meat, milk, eggs and honey but excluding trapping, hunting and fishing.
2) Manufacturing of food products
   a) Production of perishable animal products (e.g. meat, poultry, eggs, dairy and fish/seafood products).
   b) Production of perishable plant products (e.g. fruits, fresh juices, vegetables, grains, nuts and pulses).
   c) Processing of perishable animal and plant products (mixed products; e.g. pizza, lasagna, sandwich, dumpling, ready-to-eat meal).
   d) Production of products with long shelf life at ambient temperature (e.g. canned products, biscuits, snacks, oil, drinking water, beverages, pasta, flour, sugar, food-grade salt).
   e) Production of (bio)chemicals (i.e. food and feed additives, vitamins, minerals, bio-cultures, flavourings, enzymes and processing aids) but excluding pesticides, drugs, fertilizers and cleaning agents.
3) Manufacturing of food packaging and packaging material
   (e.g. direct, indirect contact with the food)
4) Manufacturing of food and feed for animals
   (e.g. pet food, pet food for dogs and cats, animal feed, fish feed)
5) Transport and storage services
   (e.g. storage and transport activities across the food supply chain)
6) Catering
   Preparations, storage and, where appropriate, delivery of food for consumption, at the place of preparation or at a satellite unit.
7) Retail/wholesale
   Provision of finished food products to a customer (e.g. retail outlets, shops, wholesalers).

3 Reference documents

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

1) BSI PAS 222:2011, Prerequisite programmes for food safety in the manufacture of food and feed for animals

2) BSI PAS 221:2013, Prerequisite programmes for food safety in food retail

3) GFSI Benchmarking requirements, Seventh Edition, 2016

4) ISO 9001:2015, Quality management systems – Requirements

5) ISO 19011:2011, Guidelines for quality and/or environmental management systems auditing

6) ISO 22000:2005, Food safety management systems – Requirements for any organization in the food chain

7) ISO/TS 22002-1:2009, Prerequisite programmes for food safety – Part 1: Food manufacturing

8) ISO/TS 22002-2:2013, Prerequisite programmes for food safety – Part 2: Catering

9) ISO/TS 22002-3:2011, Prerequisite programmes for food safety – Part 3: Farming

10) ISO/TS 22002-4:2013, Prerequisite programmes for food safety – Part 4: Food packaging manufacturing

11) ISO/TS 22002-6:2016, Prerequisite programmes on food safety – Part 6: Feed and animal food production

12) ISO/TS 22003:2013, Food safety management systems – Requirements for bodies providing audit and certification of food safety management systems

13) ISO 22004:2014, Food safety management systems – Guidance on the application of ISO 22000

14) ISO/IEC 17000:2004, Conformity assessment – Vocabulary and general principles

15) ISO/IEC 17011:2004, Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies

16) ISO/IEC 17021-1:2015, Conformity assessment – Requirements for bodies providing audit and certification of management systems

17) NEN NTA 8059:2016, Prerequisite programs on food safety for transport and storage

4 Ownership, Governance and Integrity Program

4.1 Ownership

The Scheme is owned, governed and managed by the Foundation FSSC 22000, based in Gorinchem, Stephensonweg 14, 4207 HB, the Netherlands, registered with the Chamber of Commerce under the number 64112403.
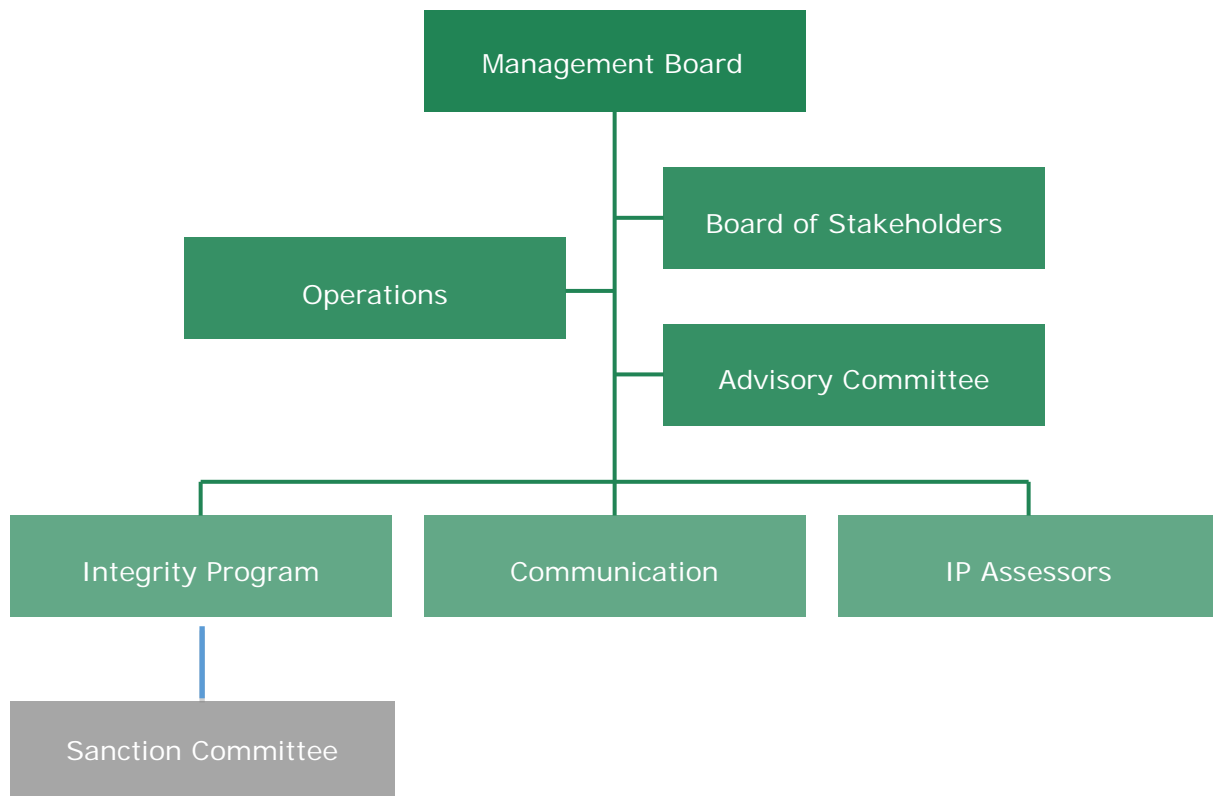
The statutes as deposited with the Chamber of Commerce are outlined below.

4.2 Articles

Article 1: The Foundation

1.1   The Foundation has as its statutory objectives:
  a. Promoting the application of food safety and quality management systems;
  b. Developing, designing, managing and amending food safety certification and inspection systems in the field of food safety and quality;
  c. Promoting national and international recognition and general acceptance of systems it has developed for food safety and quality;
  d. Running information campaigns and providing information on food safety and quality;
  e. Providing support services for certification of food safety systems in the field of food safety and quality;

f. Performing all other actions that are related in the broadest possible sense with the aforementioned or that could in any way be beneficial to it.

1.2   The Foundation endeavours to achieve these objectives by:
   a. Entering into agreements with certification bodies;
   b. Taking appropriate measures in the event of abuse or improper use of the certificates issued by accredited certification bodies;
   c. Taking appropriate measures in the event of abuse or improper use of the Foundation's logo;
   d. Supporting, supervising and financing of other foundations and organizations which strive to achieve similar or partially similar objectives as those mentioned in this Article.

Article 2: The Management Board

2.1   The Foundation's management board, hereinafter referred to as "the Board", consists of at least three members.

2.2   The Board may never consist of a majority of members who represent the interests of one of the stakeholder groups involved. Stakeholder groups in this context being stakeholders or certification bodies or certificate holders or organizations which are intended to be certificate holders.

2.3   The Board shall fill any vacancies that may arise with due observance of the aforementioned. Appointments are made by Board resolution.

2.4   Board members serve 5-year terms. They may be reappointed only twice. Thereof they only become eligible for appointment to the Board at least one year after their last term has expired. The Board shall use the prescribed term to draw up a retirement roster. Furthermore, the Board must ensure that end-of-term departures do not endanger its balanced operation. For that reason the Board shall decide case by case whether or not it can extend a member's term by a period not exceeding one year.

2.5   The Board shall elect a chairman and a treasurer from among its members. The Board shall also appoint a secretary to carry out all necessary administrative activities. The same person may hold the position of secretary and treasurer. The Board can appoint deputies for the chairman, secretary and/or treasurer from among its members. The deputies perform these duties during the officers' absence or incapacity to act. If the secretary is not a member of the Board, he/she shall have only an advisory role.

Article 3: Representation

3.1   The Foundation is represented by the Board or two Board members acting together.

3.2   The Board can grant a Board member or a third party a power of attorney to represent the Foundation within the confines of the power of attorney and the limitations from this Part of the Scheme and/or applicable law.

Article 4: Board meetings

4.1   The Board shall meet at least once each year and, furthermore, as often as the chairman or at least two Board members consider necessary.

4.2   Board members are entitled to have another Board member represent them in a meeting after such written authorisation 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 cognisance of the proceedings of the meeting directly and can participate in all deliberations.

4.4. The Board is authorised to set conditions for the use of electronic means of communication. If the board exercises this authority, the conditions shall be published in the summons.

Article 5: Board decision making

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

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

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

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

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

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

Article 6: Board of Stakeholders

6.1   The Board appoints a Board of Stakeholders, hereinafter referred to as the "BoS", of which it determines the number of members and shall appoint or reappoint its chairman. A Board member cannot be appointed as member of the BoS, but the Foundation secretary can act as Secretary of the BoS, having an advisory role, not having any voting rights. The chairman leads the meetings of the BoS and shall be

independent. The BoS shall consist of representatives of stakeholders in the field of FSSC 22000 certification, accreditation and promotion.

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

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

6.4 With reference to Article 9, paragraph 3 of the Articles of Association of the Foundation the BoS shall from its members appoint a Sanction Committee, existing of at least 3 members and chaired by the independent chairman of the BoS. The Committee has the task to decide on behalf of the BoS on sanctions to be imposed on licensed certification bodies in conformity with the Integrity Program & Sanction Policy as also to be established by the BoS.

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

6.6 The BoS will decide on Terms of Reference for both the Sanction and Advisory Committee(s).

Article 7: FSSC 22000 Integrity Program

7.1 The FSSC 22000 Integrity program consists of the following elements:
   a. Standard contract with certification bodies,
   b. A program of KPI driven desk reviews of full audit reports, as determined by the Board,
   c. A program of KPI driven analysis of audit reports, as determined by the Board,
   d. Registration of all auditors qualified under the Scheme,
   e. A program of office and witness audits as determined by the Board,
   f. A program for obligatory unannounced audits by contracted certification bodies, as determined by the Board,
   g. All further programs, procedures and measures which at any time may be required by the current version of the requirements set by the Global Food Safety Initiative.

7.2 The Foundation shall appoint an independent expert assessing the results of the above mentioned programs, reporting same to the Board.

7.3 The Board shall maintain a sanction policy consisting of a system of written warnings, and yellow and red cards, based on major and minor findings in the programs.

7.4 Directly interested parties may appeal in writing against sanction decisions made by the Board.

7.5 The Board will make public the way on which any interested third party may file complaints against any of the aspects of the Scheme.

7.6 The Foundation shall maintain a public register for all certificates duly issued on basis of the Scheme, safeguarding all information on certified organizations which are to be treated as confidential.

7.7 The Board may, in consultation with the BoS, decide on specific provisions on accreditation of CBs and memoranda of understanding between the Foundation and accreditation bodies, which may go beyond the provisions laid down in the Scheme.

7.8 The standard contract with certification bodies as referred to here above will contain provisions for the use of the FSSC 22000 logo.

Article 8: Further statutory provisions and requirements

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

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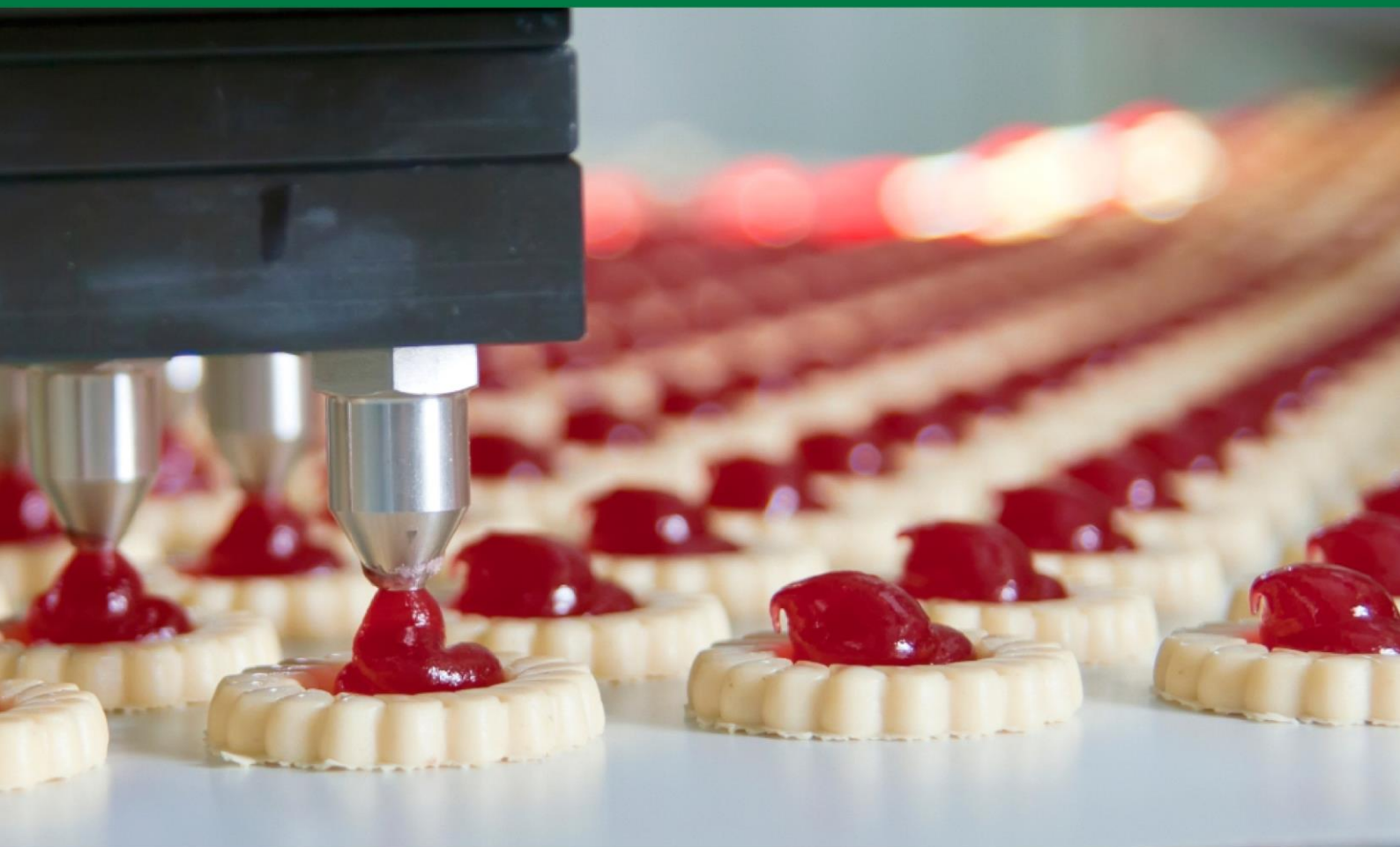
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Part 2: Requirements for Certification

Contents

1 Purpose

This document states 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.

1.1 Food categories and sectors

The following food chain categories fall within the Scheme scope of certification.

Table 1: Food chain categories, ISO 22000 and PRP standards. Additional requirements apply to all categories.

Category	Sub-category	Description	ISO 22000/ISO 9001	PRP	Additional requirements
A	AI	Farming of animals for meat/milk/eggs/honey	Applicable	ISO/TS 22002-3	Applicable
	AII	Farming of fish and seafood	Applicable	ISO/TS 22002-3	Applicable
C	CI	Processing of perishable animal products	Applicable	ISO/TS 22002- 1	Applicable
	CII	Processing of perishable plant products	Applicable	ISO/TS 22002- 1	Applicable
	CIII	Processing of perishable animal and plant products (mixed products)	Applicable	ISO/TS 22002- 1	Applicable
	CIV	Processing of ambient stable products	Applicable	ISO/TS 22002- 1	Applicable
D	DI	Production of animal feed	Applicable	PAS 222	Applicable
				ISO/TS 22002-6	Applicable
	DII	Production of pet food for other pets than dogs and cats	Applicable	PAS 222	Applicable
				ISO/TS 22002-6	Applicable
	DII	Production of pet food for dogs and cats	Applicable	ISO/TS 22002- 1	Applicable
E	Catering		Applicable	ISO/TS 22002-2	Applicable
FI	Retail		Applicable	PAS 221	Applicable
G	GI	Provision of Transport and Storage Services for Perishable Food and feed	Applicable	NTA 8059	Applicable
	GII	Provision of Transport and Storage Services for Ambient Food and feed	Applicable	NTA 8059	Applicable
I		Production of food packaging and packaging material	Applicable	ISO/TS 22002-4	Applicable
K		Production of (bio)chemicals	Applicable	ISO/TS 22002-1	Applicable

1.2 Field of application

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

2 Outline of Scheme requirements

This section provides an outline of the Scheme requirements to be met in order to achieve certification.

2.1 Main components

The Scheme requirements consist of separate components that shall be audited as a single system.

1) ISO 22000 food safety management system requirements.
2) ISO 9001 quality management systems requirements – when selected (FSSC Quality).
3) Sector specific pre-requisite programs (PRPs) requirements.
4) Additional Scheme requirements.

The following clauses provide a brief commentary on each component and state the high level requirements to be met for each.

2.1.1 ISO 22000

The requirements for the development, implementation and maintenance of the food safety management system are laid down in the standard ISO 22000 "Food safety management systems - Requirements for any organization in the food chain".

In order to facilitate the successful implementation of a food safety management system, the operational conditions of the food safety management system shall be specified, documented and verified.

2.1.2 ISO 9001

For FSSC 22000-Q certification, ISO 9001 is needed in addition to the ISO 22000 management system requirements.

2.1.3 Prerequisite Programs (PRP)

ISO 22000 requires in clause 7.2 that organizations shall select and implement specific PRPs for basic hygiene conditions.

Organizations establishing, implementing and maintaining these PRPs shall consider other appropriate information and utilize it accordingly. Such information shall include:

a) regulatory requirements;
b) recognized sector or product group codes of practices and guidelines;
c) customer requirements.

In order to facilitate the successful implementation of the food safety management system, the conditions of the PRPs shall be;

a) specified,
b) documented,
c) validated and
d) verified.

ISO 22000 does not specify these requirements as the standard is applicable to the whole food chain and the basic hygiene requirements may vary considerably between sectors.

In order to clarify the requirements for PRPs and to allow for a benchmark of ISO 22000 based certification schemes by the Global Food Safety Initiative (GFSI) of the Consumer

Goods Forum, industry stakeholders have developed detailed technical specifications covering sector pre-requisite programs (PRPs).

These technical specifications are used in addition to ISO 22000 to provide an agreed interpretation. Exceptions shall be justified and documented where PRP requirements are deemed not to be applicable and verified during an audit.

FSSC 22000 provides a certification Scheme for sectors where such a technical specification for sector PRPs has been integrated as described in the scope (see table 1 above).

2.1.4   Additional requirements

To meet the needs of the key stakeholders and to ensure an adequate control of food safety, specific additional FSSC requirements for the food safety management system are included in the Scheme.

These may be elaborations of the clauses in ISO 22000 and technical specifications for sector PRPs or additional requirements as outlined below.

The additional Scheme requirements are:

1) Management of services
2) Supervision of personnel
3) Management of supplied materials
4) Management of natural resources (for animal production only)
5) Food defense
6) Food fraud prevention
7) Formulation of products (only for pet food for dogs and cats)
8) Management of allergens
9) Product labelling
10) Environmental monitoring
11) Logo use.

2.1.4.1 Management of services

The organization in the food chain shall ensure that all services that are provided and may have an impact on food safety:

    a) have specified requirements,
    b) are described in documents to the extent needed to conduct hazard analysis,
    c) are managed in conformance with the requirements of technical specification for sector PRPs,
    d) are monitored.

The services referred to in 1) above shall include at least:

    a) utilities,
    b) transport,
    c) maintenance, and
    d) outsourced activities.

2.1.4.2 Supervision of personnel

The organization in the food chain shall ensure the effective supervision of the personnel in the correct application of the food safety principles and practices commensurate with their activity.

2.1.4.3   Management of supplied materials

The organization shall ensure that all inputs (supplied materials) that may have an impact on food safety:

  a)   have specified requirements,

  b)   are described in documents to the extent needed to conduct hazard analysis.

  c)   comply with any applicable regulatory requirements (e.g. control of prohibited substances).

The organization shall implement a system to assure that analysis of all inputs critical to the verification of product safety is undertaken. The analyses shall be performed according to ISO 17025 or equivalent. Equivalent systems shall include at least participation to proficiency testing).

2.1.4.4   Management of natural resources (for animal production only)

1)   The organization (animal farm) shall:

  a)   Identify the risks it exposes from animal production to both,

    i)   animal health, and

    ii)   public health.

  b)   Assess the hazards that expose these risks derived from on-farm used natural resources (e.g. water and soil, to include water for animals, water for irrigation, on farm feed production for own animals).

Put in place appropriate protective and control measures to protect public and animal health.

2.1.4.5   Food defense

2.1.4.5.1   Threat assessment

1)   The organization shall document, establish and maintain a documented procedure for food defense threat assessment that:

  a)   identifies potential threats,

  b)   develops preventive measures, and

  c)   prioritises them against the threats.

2)   In order to identify the threats, the organization shall assess the susceptibility of its products to potential acts of:

  a)   sabotage,

  b)   vandalism, and/or

  c)   terrorism.

2.1.4.5.2   Preventive measures

The organization shall put in place appropriate preventive measures to protect consumer health impacts. These processes shall;

  a)   be controlled within the scope of the food safety management system;

  b)   be in compliance with applicable legislation.

2.1.4.5.3   Annual review

1)   The food defense procedure shall be reviewed:

  a)   after each actual or potential failure of a preventive measure, and

  b)   at least annually.

2.1.4.6   Food Fraud prevention

2.1.4.6.1   Vulnerability assessment

1) The organization shall document, establish and maintain a documented procedure for food fraud vulnerability assessment that:
    a) identifies potential vulnerabilities,
    b) develops preventive measures, and
    c) prioritises them against the vulnerabilities.
2) In order to identify the vulnerabilities, the organization shall assess the susceptibility of its products to potential acts of food fraud.

2.1.4.6.2   Preventive measures

1) The organization shall put in place appropriate preventive measures to protect consumer health. These processes shall;
    a) be controlled within the scope of the food safety management system;
    b) be in compliance with applicable legislation.

2.1.4.6.3   Annual review

2) The food fraud prevention procedure shall be reviewed;
    a) after each actual or potential failure of a preventive measure, and
    b) at least annually.

2.1.4.7   Formulation of products (only for pet food for dogs and cats)

Compounded pet food for dogs and cats shall be formulated in a manner that is consistent with the intended use of the product.

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

2.1.4.8   Management of allergens

1) A documented allergen management procedure shall be in place that includes:
    a) risk assessment identifying potential allergen cross contamination;
    b) controls to reduce or eliminate the risk of cross contact;
    c) validation and verification of effective implementation.

2) All finished products intentionally or potentially containing allergenic materials are labeled according to the allergen labelling regulations in the country of destination.

2.1.4.9   Product labelling

The standard shall ensure that the finished product is labelled according to the applicable food regulations in the country of intended sale.

2.1.4.10 Environmental monitoring

The standard shall ensure that an environmental monitoring program is in place validating and verifying the microbiological hygiene of the site demonstrating the effectiveness of cleaning and sanitation programs.

2.1.4.11 Logo use

Certified organizations are entitled to use the FSSC 22000 logo. The FSSC 22000 logo may be used on the organization's printed matter, website and other promotional material subject to the following design specifications:

Colour	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 imagines are in black and white.

In order to avoid any suggestion that the CB has certified or approved any product, process or service supplied by the certified organization the FSSC 22000 logo is not allowed to be used on:

- a product,
- its labelling,
- its packaging,
- in any other manner that implies FSSC 22000 approves a product, process or service.

2.1.4.11 Logo use

FOOD SAFETY SYSTEM CERTIFICATION 22000

Part 3: Requirements for Certification Process

Version 4: January 2017

Part 3: Requirements for Certification Process

Contents

1 Purpose

This document states the certification process requirements relevant to an organization applying for or maintaining certification to be included in the FSSC 22000 Register of Certified Organizations.

2 Application process

2.1 Certification body selection

In order to receive a valid certificate, the applicant organization shall select a CB that is licensed by the Foundation.

The list containing FSSC 22000-licensed CBs is available on www.fssc22000.com.

2.2 Self-assessment

It is essential that the applicant organization conducts a self-assessment against the current version of the Scheme available from the FSSC 22000 website. The Scheme documents may be used for a preliminary self-assessment.

Once the self-assessment has been completed, and potential gaps are addressed, the applicant organization should contact their selected CB in order to receive an application form and afterwards agree on a certification contract.

2.3 Application form

The CB 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 CB about the details of the applicant organization.

The details shall include at least the following:

a) The proposed certification scope
b) The number of workers in management and production
c) Details of shifts
d) Number of production lines
e) Number of HACCP studies
f) Details of other certified management systems or GFSI recognized schemes
g) When applicable: information regarding head office and (central) functions controlled by the head office
h) When applicable: details related to a request for a transfer audit from the CB currently awarding the certification
i) When applicable: details related to a request for a transition audit from ISO 22000 or another GFSI recognized scheme to FSSC 22000.

2.4 Certification contract

A certification contract shall exist between the organization and the CB, detailing the scope of the certification process including the audit and reporting requirements.

2.5 Annual fee

1) The CB shall charge organizations certified against the Scheme an annual fee payable to the Foundation.
2) The Foundation shall decide annually on the fee amount.

3 Certification process

3.1 Preparation

For the initial certification audit, the applicant organization shall agree mutually convenient date(s) with due consideration given to the preparatory work by the applicant organization required to meet the requirements of the Scheme.

The applicant organization must prepare carefully for the audit, to have appropriate documentation for the auditor to assess and to have appropriate staff available at all times during the on-site audit.

3.2 Two stage audit process

The initial auditing for certification is always carried out at the production site of the applicant organization and is conducted in two separate stages:

a) The Stage 1 audit, verifies that the system has been designed and developed in accordance with the organization's top management commitment to conform with Scheme requirements. The objective of this audit is to assess the preparedness of the applicant organization to proceed to the stage 2 audit.

b) The Stage 2 audit substantiates top management's claim by auditing implementation of the food safety management system.

The activities subject to the proposed certification scopes shall be assessed during the initial certification audit.

3.2.1 Certificate issue

The CB will issue the certificate within 30 calendar days from the date of the certification decision. The certificate expires three years after the date of the initial certification decision. However, whilst the certificate is issued to the applicant organization, it remains the property of the CB under the conditions outlined in the contract.

3.2.2 Surveillance audits

Surveillance audits will assess and report on conformity with all Scheme requirements including the use of marks and references to certification.

At least one of the two annual surveillance audits shall be unannounced.

3.2.3   Recertification

The recertification audit must be planned and conducted in due time to enable timely renewal of the certificate before the expiry date.

The purpose of this audit is to confirm the continuing conformity of the food safety management system as a whole with all Scheme requirements.

The audit also includes a review of the food safety management system over the whole period of certification, including previous surveillance audit reports and complaints received.

The CB decides on renewal of the certification cycle on the basis of the recertification audit which must meet the same requirements as an initial audit.

3.2.4   FSSC 22000 Scheme logo use

1. The use of the FSSC 22000 logo represents achievement of certification against the highest management system standard for food safety.

2. To maintain its integrity, use of the logo and protection of its copyright is controlled by the Foundation FSSC 22000.

3. Mentioning possession of a FSSC 22000 certificate or making any reference such as for example "Produced in a FSSC 22000 certified company" on a product label, packaging, etc. is not allowed.

4. Please note that the CB will audit the use of the FSSC 22000 logo by certified organizations during every initial, surveillance and recertification audit. Any nonconformity associated with the use of the logo will require the organization to take remedial action to restore conformity with the criteria described here.

4   Transition to FSSC 22000

1. When transitioning from ISO 22000 or a GFSI recognized scheme to FSSC 22000 certification, a full stage 1 and 2 audit is not required to confirm compliance of the food safety management system with all Scheme requirements. The transition audit is based on the recertification Scheme requirements. In this case, the audit report shall:
    a) clearly specify the audit type i.e. "transition audit from ISO 22000 or a GFSI recognized scheme to FSSC 22000",
    b) provide details of the previous audit in particular related to nonconformities,
    c) confirm the validity of the existing certificate,
    d) confirm compliance with all Scheme requirements.

2. The transition audit time calculation is based on the recertification Scheme requirements.

3. The transition audit shall result in a new FSSC 22000 certificate with a regular validity of three years.

5 FSSC 22000–Quality certification

1. FSSC 22000-Quality certification is an addition to the Scheme documents. It integrates the requirements of the Scheme with ISO 9001 resulting in a combined FSSC 22000-Q certificate.
2. The requirements for the development, implementation and maintenance of the food quality management system are laid down in the standard ISO 9001 "Quality management systems - Requirements".
3. The normative requirements for organizations to gain food safety and quality management system certification (named FSSC 22000-Q) through an integrated audit are the following:
    a) the food safety management system requirements of ISO 22000;
    b) the quality management system requirements of ISO 9001;
    c) the detailed requirements of technical specification for sector PRPs and
    d) additional FSSC 22000 requirements.

6 Significant changes

Once certification has been granted, any significant changes that affect the fulfilment of the requirements for the certification must be communicated to the CB as stipulated in the certification contract.

6.1 Notification

a) The organization shall report significant changes to the CB within three working days as stipulated in the certification contract.
b) Significant changes that could require extension or changes to the scope statement and details on the certificate, and thereby in the FSSC 22000 Register of Certified Organizations, include:
    i)   legal, commercial, organizational status or ownership,
    ii)   organization and management (e.g. key managerial, decision-making or technical staff),
    iii)   organization name, contact address and site details,
    iv)   scope of operations and product categories covered by the certified management system,
    v)   management system and/or processes,
    vi)   any other change that renders the information on the certificate inaccurate.
c) The organization shall seek the advice of the CB in cases where there is doubt over the significance of a change.

6.1.1   CB review

The CB reviews the reported changes, decides upon the significance and consequences for conformity with the Scheme requirements, and comes to a conclusion whether or not additional verification activities are necessary.

The CB decides also whether or not certification changes of scope shall be granted.

If granted, the current certificate will be superseeded by a new certificate using the same expiry date as detailed in the original certificate.

The organization's entry in the FSSC 22000 Register of Certified Organizations will be updated accordingly.

7 Serious events

The organization shall inform the CB about serious events that impact the integrity of the certification and the organization's entry in the FSSC 22000 Register of Certified organizations.

7.1 Reporting

a) The organization shall report serious events to the CB within three working days of occurrence.

b) Serious events include;

    i)   legal proceedings with respect to product safety or legality,

    ii)   product withdrawal or recall related to food safety and/or legality,

    iii)   major threats to business continuity such as an earthquake, fire, flood, tsunami, force majeure etc.

7.1.1 CB review

The CB in turn will take appropriate steps to assess the situation and will take any appropriate action including additional verification activities.

These activities may have implications for the status of the certified organization.

7.2 Public recalls

An organization is always responsible for failures of its management system that could lead to public recalls of products available on the market.

7.2.1 Immediate action

Immediate action is required if there is evidence that the organization's management system has failed to detect and control the compromised product,

a) this product shall be recalled from the market by the organization and

b) the organization shall inform the CB immediately.

7.2.2 Consequences

The CB will assess the organization's corrective actions following the recall and determine any consequences or any actions necessary to maintain the certification.

7.2.3 Reporting

The Foundation will be informed by the CB as soon as possible in case of recalls that seriously affect the integrity of the Scheme and be kept updated of progress at regular intervals.

8 Transition period
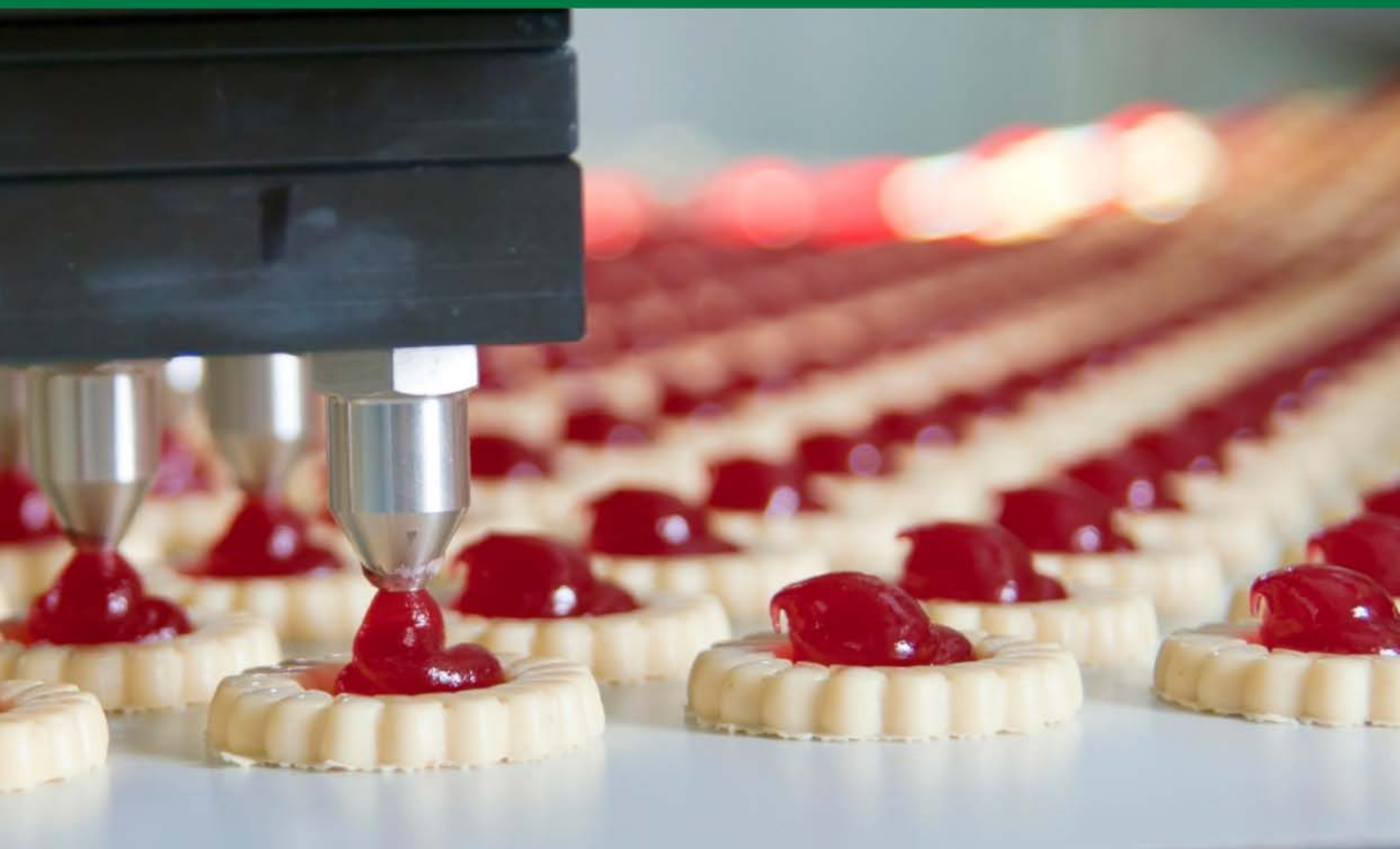
In the event of new Scheme documents, the Board shall give an appropriate transition period for certified organizations to adapt to the implementation of the new requirements, unless legal regulations stipulate a different transition period.

FOOD SAFETY SYSTEM CERTIFICATION 22000

Part 4: Requirements for Certification Bodies

Part 4: Requirements for Certification Bodies

Contents

1   Purpose

This document states the requirements for certification bodies (CB) seeking approval from the Foundation to award FSSC 22000 or FSSC 22000 Quality certificates to their clients.

2   Supplying FSSC 22000 services to clients

2.1   Licensing

2.1.1   Guiding principles

There are four guiding principles that underpin CB responsibilities in supplying FSSC 22000 services to its clients.

These are:

1.   Conformity;
2.   Valid license;
3.   Accreditation;
4.   Communication.

2.1.1.1 Conformity

The CB is responsible for the full application of the Scheme requirements for CBs at all times and the CB has to be able and prepared to demonstrate compliance at any time with all Scheme requirements.

2.1.1.2 Valid license

The CB shall supply its FSSC 22000 services only whilst it holds a valid license from the Foundation to do so.

2.1.1.3 Accreditation

The CB shall hold an accreditation against ISO IEC 17021 including ISO/TS 22003 and all scheme requirements for the food chain categories and subcategories in which it supplies its FSSC 22000 certification services.

2.1.1.4 Communication

The CB shall cooperate with all requests from the Foundation to provide information regarding all aspects in the performance of the Scheme.

2.1.2   Application process

There are three steps in obtaining a license from the Foundation to issue FSSC 22000 and FSSC 22000 Quality certificates.

2.1.2.1 Step 1 – Provisional license

1)   The CB applies for a provisional license.
2)   When applying for a license with the Foundation, the CB shall specify the food chain category or subcategories that it intends to work within when supplying its FSSC 22000 certification services.
3)   The applicant CB shall be requested to commit to meeting all applicable requirements of the Scheme.
4)   The applicant CB shall conduct and complete a self-assessment against the Scheme requirements and submit the self-assessment report to the Foundation for review.

a) Upon successful review of the completed self-assessment, the CB shall be provided with a provisional license agreement allowing it to use the Scheme for unaccredited certification to enable CB accreditation in due course.

b) CB shall have at least two sites listed in the FSSC 22000 Register of Certified Organizations for the first year and retain at least five sites for the following years after.

c) This provisional license shall remain valid for 12 months from the date of signature by the Foundation.

d) Before the end of this 12 month period, the CB shall achieve accreditation from a by the Foundation approved AB that provides its ISO 17021 accreditation scoped for the Scheme requirements.

5) An application fee has to be paid by the CB to the Foundation before its provisional license is granted.

2.1.2.2 Step 2 – Full license

The provisional license with the Foundation shall be converted in a full license when:

1) achieved accreditation by an Accreditation Body approved by the Foundation,

2) forwarded a copy of the accreditation certificate and report to the Foundation for review and retention,

and to maintain its full license the CB shall

3) have at least five sites listed in the FSSC 22000 Register of Certified Organizations for the following years after the provisional license has ended.

Notes

1) The CB shall be requested to supply details of the CB location(s) covered under its accreditation.

2) In case outsourcing of any certification related activities takes place (such as sales, auditing, etc.) this shall be shared with the Foundation.

3) The application for accreditation or extension of scope of accreditation shall be accompanied by written confirmation from the AB shared by the CB with the Foundation.

2.1.2.3 Step 3 – Scope extension

CBs may extend their scope of accreditation under the Scheme and may certify within the scope applied for, without being accredited under the following conditions:

1) The CB applies for a scope extension of the existing license with the Foundation.

2) This concession has maximum duration of one year.

3) If accreditation is not achieved within one year, the CB shall withdraw all the FSSC 22000 certificates it has issued under this concession and remove them from the FSSC Register of Certified Organizations.

2.2 Communication

2.2.1 CB representation

1) The CB shall appoint a FSSC contact person who has technical knowledge and understanding of the Scheme and the IT platform used by the Scheme.
2) This person shall;
   a) be the responsible officer representing the CB,
   b) be the key-user of the Scheme IT platform,
   c) maintain the contacts with the Foundation,
   d) be involved in the Scheme report verification and auditing,
   e) attend Harmonization Meetings annually.

2.2.2 Accreditation status

The CB shall inform the Foundation immediately about (changes in) its accreditation status and always share a copy of the AB assessment report as soon as it becomes available.

2.2.3 Certified organizations

The CB shall inform the Foundation immediately about any changes relevant to its food safety management system certification services when:

1) it suspends or withdraws a certification held by an organization included in the FSSC Register of Certified Organizations covered under its relevant ISO 17021 food safety management system accreditation,
2) it restores a suspended or withdrawn certification.

2.2.4 Register of Certified Organizations

The Foundation maintains a Register of Certified Organizations with the names and information of all certified sites. This register is publicly available on the website of the Foundation.

2.2.5 Database upload

1) Within four (4) weeks after the certification decision, the CB shall upload the certificate in the FSSC 22000 database for the purpose of the public list.
2) Within four (4) weeks after finalizing the audit report, the CB shall upload the audit report in the FSSC 22000 database (see Annex 4 of this part).
3) The CB shall upload the data with respect to auditor competence of FSSC 22000 qualified auditors in the FSSC 22000 database and keep this information up to date at all times.
4) The CB shall on request of the Foundation upload additional documents in the FSSC 22000 database.

2.3 Harmonization process

2.3.1 Annual meetings

Each CB is obliged to participate in consultations on the interpretation of the Scheme.

At least once every year the Foundation will convene at least one Harmonization Meeting where FSSC 22000 staff and assessors will be available to discuss matters of common interest with licensed CBs for the Scheme and other stakeholders.

2.3.2 Designated person

The designated FSSC contact person shall represent the CB during the Harmonization Meeting. Each CB shall discuss the presented material and the results of this meeting in their own operations afterwards and keep records of attendance to these meetings. The FSSC contact person shall facilitate these meetings.

2.4 Participation in the Integrity Program

The CB shall participate in Integrity Program which is the Foundation's system of ongoing monitoring that covers all activities of its licensed CBs to ensure compliance with all Scheme requirements.

The Integrity Program Sanction Committee may issue sanctions against non-compliant CBs that could include:
   a) Nonconformity reports to be acted upon within time limits,
   b) Suspension from the Scheme until discrepancies have been satisfactorily corrected,
   c) Cancellation of the license to issue certifications under the Scheme.

2.4.1 Monitoring activities

The Foundation undertakes monitoring activities which the CB is required to participate that could include:
1. Desk reviews of audit reports and additional information on the audit process,
2. Auditor assessment and registration,
3. Office assessments and witnessed audits,
4. Monitoring of agreed key performance indicators.

2.5 Nonconformity

The CB license agreement for FSSC 22000 certification services is based on their declared commitment to conform to Scheme requirements at all times.

Hence, the Foundation defines a "nonconformity" as any breach of Scheme requirements reported to a CB by Foundation personnel in the course of their duties.

2.5.1 Sources

Areas of nonconformity ("NCs") requiring a response from the CB may be raised by the Foundation in response to;
1) Any discrepancy raised by the Integrity Program,
2) Feedback from users of the Scheme,

3) Feedback from Certified Organizations,

4) Feedback from Accreditation Bodies,

5) Feedback from governmental authorities,

6) Feedback from the media and

7) Any other feedback deemed credible.

2.5.2   Follow-up

1) When a nonconformity report is received a CB shall:
   a) record the nonconformity in its internal system,
   b) respond in the set timeframe and take action to,
      i)   restore conformity,
      ii) investigate to identify the causal factors,
      iii) identify the risks to effective food safety management system (FSMS) certification.

2) Then:
   a) take corrective actions to manage the identified causal factors so that the risks exposed by recurrence are reduced to an acceptable level,
   b) use the opportunity to investigate how else and where else a similar nonconformity could occur,
   c) take preventive action to manage these causal factors so that the risks exposed by occurrence are similarly reduced to an acceptable level.

2.5.3   Sanction Committee

1) Detailed information shall be gathered for potential review by the Integrity Program Sanction Committee in cases where a CB:
   a) persistently fails to conform to the requirements set out in the Scheme documents, or
   b) the integrity of the Scheme is deemed to be at stake.

2) When the nonconformity is of a serious nature, the Board shall request a special meeting with the CB to deal with the matter.

3) The Sanction Committee shall determine measures to be taken by the CB to deal with the nonconformity.

4) Failure to implement these binding measures could lead to the termination of the CB license agreement for the Scheme.

2.5.4   License termination

When a CB's license is terminated by the Foundation, the CB is not allowed to apply for a new license within one year from the date of the decision by the Sanction Committee.

3 Managing the CB

3.1 Provision and management of resources

3.1.1 Commitment

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

3.1.2 Communication

In all cases of emergency the CB is expected to operate with discretion in its dealings with its

a) stakeholders,

b) staff,

c) contractors,

d) suppliers,

e) other CBs,

f) clients,

g) the media,

h) and everyone else with whom it has contact with.

3.1.3 Transition period

In the event of Scheme documents being changed, the Board shall provide an appropriate transition period for the licensed CBs to adapt the implementation of the new requirements, unless legal regulations stipulate a different transition period.

With regard to implementation and informing the parties involved:

1) The CBs shall ensure that the changes, which are decided by the Board, are included in their existing quality management system documentation.

2) New information or changes with regard to the requirements in the Scheme shall be communicated by the CBs to those parties involved, such as certified organizations and auditors (auditors and experts), within a period of 1 month.

3.1.4 Document control

CBs shall control all FSSC 22000 Scheme related documentation and records according to its own documentation and records control procedures.

3.1.5 Management of nonconformity

The CB procedures for dealing with nonconformities, suspension and withdrawal of the certificate shall meet the additional requirements set out in clause 4.3.

3.1.6 Computer Aided Audit Techniques

Computer aided audit techniques (CAAT) may be used during FSSC 22000 audits only under the following conditions:

1) CAAT shall 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 products.

3) The CB shall establish, document and maintain a procedure for the use of CAAT during on site audits.

4) The CB shall:
   a) establish criteria for its use of CAAT,
   b) ensure its auditors are able to apply with these criteria consistently.
5) The CB shall ensure that the functions that have been assessed remotely are effectively implemented at the site.
6) The auditor shall include in the audit report:
   a) which CAAT techniques were used;
   b) the audit report shall clearly show:
      i) which functions were assessed using CAAT and
      ii) their relationships with the related audit findings.

3.2 Issue & control of certificates

3.2.1 Issue of certificate

The CB shall keep documented information of certification decisions to indicate that all the above criteria have been considered and by whom. This information shall include;
   a) the names of those making each certification decision, and
   b) the date the decision was made.

3.2.2 Certificate characteristics

The CB shall issue FSSC 22000 certificates in accordance with the templates set out by the Foundation (see Annex 6).

3.2.3 Certification logo

1) The use of the FSSC 22000 logo by the CB will be monitored through the FSSC 22000 Integrity Program.
2) Any nonconformity associated with the use of the logo will require remedial action to correct the use of the logo on issued documents as well as corrective action for future use.

3.2.3.1 Conditions on the CBs entitlement to use the logo

1) A CB is entitled to use the FSSC 22000 logo after they have entered into a license agreement with the Foundation.
2) The FSSC 22000 logo shall be used by a CB on its certificates.
3) Subject to the design specifications below, the FSSC 22000 logo may be used by a CB on its
   a) printed matter,
   b) website and
   c) other promotional material associated with its FSSC 22000 certification activities.
4) The CB shall explain the correct use of the certification logo to the applicant organization and
5) include verifying and validating its correct use during audits.

3.3 Annual fee for certified organizations

1) Organizations certified against the Scheme shall be charged an annual fee by the CB, payable to the Foundation.
2) The CB shall ensure collection of this fee from the certified organization and pay this to the Foundation.
3) The Foundation shall decide annually before October 1th on the fee amount.
4) The CBs shall be charged at least annually by the Foundation for the total amount of fees for all issued FSSC certificates they have under contract per 31 December each year.

4 Communicating with clients

4.1 Introduction

1) The CB shall have a certification agreement with each organization it certifies against the Scheme.
2) This certification agreement sets out the requirements for communications between the CB and its client.

4.2 Certification contract

A certification contract shall exist between the organization and the CB, detailing the scope of the certification process including audit and the reporting requirements.

4.2.1 Contents of the certification contract

The CB shall refer to the relevant Scheme requirements in the certification contract for the following issues:

1) The scope of the certificate and the audit.
2) Reference to all relevant Scheme requirements including the provision for unannounced audits and accepting the audit team.
3) A detailed description of the following processes:
      i) Application,
      ii) Initial and surveillance certification activities (including unannounced audits),
      iii) Granting, refusing, maintaining certification,
      iv) Expanding or reducing the scope of certification,
      v) Renewing, suspending or withdrawal of certification,
      vi) Fees by the Foundation.
4) The requirements for the use of the FSSC 22000 logo.
5) The certified organization shall inform the CB, within three working days, of matters that affect the capability of the management system to continue to fulfil the requirements of the standard used for certification. These include changes relating, but not limited, to:
      i) Legal, commercial, organizational status or ownership,
      ii) Organization and management (e.g. key managerial, decision-making or technical staff),
      iii) Organization name, contact address and site details,

      iv)   Scope of operations and product categories covered by the certified management system,

      v)   Management system and/or processes,

      vi)   Any other change that renders the information on the certificate inaccurate.

6) The certified organization shall inform the CB, within three (3) working days, of product recalls and calamities that affect the capability of the management system to continue to fulfil the requirements of the Scheme used for certification.

7) The certified organization shall inform the CB, within three (3) working days, of any legal proceedings with governmental authorities and the outcomes of these related to food safety and/or quality that affect the capability of the management system to continue to fulfil the requirements of the Scheme used for certification.

8) The certified organization shall inform the CB, as soon as possible, of major threats to business continuity such as an earthquake, fire, flood, tsunami, force majeure etc. related to food safety and/or quality that affect the capability of the management system to continue to fulfil the requirements of the Scheme used for certification.

9) Procedures for nonconformity grading by the CB and timeframe to close nonconformities by the certified organization including the consequences of open nonconformities on any decision by the CB to issue certification or to leave it in place.

10) Procedures for complaints and appeals submitted by the applicant organization to the CB in compliance with ISO 17021.

11) Terms of confidentiality in relation to information gathered by the CB during the certification process.

12) Acceptance of the Foundation's requirements to;

      i)   Share information concerning the certified organization within the Foundation and with governmental authorities when appropriate.

      ii)   Display information with regard to the certification status on the website of the CB and the Foundation, to include display in the FSSC 22000 Register of Certified Organizations.

      iii)   For the purposes of the FSSC 22000 Integrity Program, to allow assessors from the Foundation on their premises to witness the CBs auditors during FSSC 22000 or FSSC 22000-Q audits.

13) Conditions under which the certification contract can be terminated.

14) Ownership of the certificate and the audit report content is held by the CB.

15) The conditions under which the certificate can be used by the certified organization.

4.3 Certificate suspension, withdrawal or scope reduction

1) The following three (3) criteria apply;

   a) The CB shall suspend a certification when there is evidence that their client is either unable or unwilling to establish and maintain conformity with Scheme requirements within the time frames applicable to the clearance of major nonconformities (see Annex 3 for applicable timeframes).

   b) The CB shall withdraw a certification when there is evidence that their client is either unable or unwilling to establish and maintain conformity with Scheme requirements, within the timeframes applicable to the clearance of critical nonconformities (see Annex 3 for applicable timeframes).

   c) When the CB has evidence that their client holds a certificate whose scope exceeds their capability or capacity to meet, the CB shall reduce the certification scope accordingly.

2) Examples include:
   a) The organization's certified management system has persistently or seriously failed to meet the Scheme requirements, including requirements for the effectiveness of the management system.
   b) Immediate risk to the safety of the product impacting consumer health.
   c) The certified organization does not allow surveillance or recertification audits to be conducted at the required frequencies.
   d) The certified organization has voluntarily requested a suspension.

4.3.1 Action upon suspension, withdrawal and scope reduction

1) In case of withdrawal or suspension, the organizations' management system certification is invalid. The CB shall:
   a) Immediately change the status 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 withdrawal or suspension decision within three (3) days after the last day of the audit or any other intervention and confirm the decision.
   c) Ensure the organization takes steps to inform clients accordingly and to also include advertising and product labelling of applicable.

2) In case of scope reduction the organizations' management system certification is invalid beyond the revised certification scope statement. The CB shall:
   a) Immediately change the scope of the certified organization in the FSSC 22000 database and its own Register of Certified Organizations and shall take any other measures it deems appropriate.
   b) Inform the organization in writing of the scope change within three (3) days after the last day of the audit or any other intervention and confirm the decision.
   c) Ensure the organization takes steps to inform clients accordingly to include advertising and product labelling.

3) In the event that that the organization is either unable or unwilling to inform their clients themselves, the CB shall take appropriate steps to protect the integrity of its own Food Safety Management System certification service by using direct mail or advertising for example.

4.4 Delays to audits

4.4.1 Dealing with politically unstable areas and war zones

Sometimes the Foundation is confronted with news about politically unstable regions, natural disasters or regions where a war is going on.

As there may be operational FSSC 22000-certified organizations in those areas, problems can arise with a site such as:

1) natural disasters like earthquakes, flood, etc,.
2) destruction by terrorist acts or acts of war,
3) taken over by soldiers or rebels,
4) shut down of operations by the owner because the region has become unsafe,
5) auditing has become unsafe for CB personnel.

These situations may have a negative impact on the integrity of FSSC 22000 certification and the FSSC 22000 Register of Certified Organizations.

4.4.1.1 The site is destroyed or invaded

1) The CB is informed by the management of the site or receives the information from another source that:
   a) the site has been destroyed, or
   b) has been invaded by military personnel or rebels.
2) When the information is from another source, the CB shall seek confirmation of the fact from reliable source.
3) After confirmation of the facts the CB withdraws the certificate and the Foundation is directly informed in writing, including all relevant details.

4.4.1.2 The head office shuts down the site

The management of the production site or the head office informs the CB that the site has been closed. The CB shall:

1) withdraw the certificate and
2) inform the Foundation in writing, including all relevant details.

4.4.1.3 Contingency arrangements when the FSSC 22000 site cannot be audited

The CB is responsible for the safety and wellbeing of its auditors.

1) On the basis of official travel advice from recognized national or international authorities the CB makes the decision that the region is not safe to be visited by their auditor.
2) The CB shall apply the following contingency arrangements:
   a) The CB may decide to postpone the visit:
      i) a surveillance or recertification audit may be postponed for a maximum 6 months,
      ii) the CB shall decide the length of the deferral period.
   b) The CB shall change the status of the certificate into "postponed".
3) The postponed audit shall be performed within two (2) months from the end of the deferral period.
4) The CB shall withdraw the certificate if the audit cannot take place within the above-described time frame.
5) The CB shall inform the Foundation of their decision immediately, in writing.
6) The information sent to the Foundation shall include:
    a) length of the deferral period, and
    b) evidence that supports the decision.

5 FSSC 22000–Quality certification

1) FSSC-Quality certification is an addition to the Scheme documents. It integrates the requirements of the Scheme with ISO 9001 resulting in a combined FSSC 22000-Q certificate.
2) The requirements for the development, implementation and maintenance of the food quality management system are laid down in the standard ISO 9001 "Quality management systems - Requirements".
3) The CB shall have an accreditation against ISO 9001 according to ISO/IEC 17021.

6 Auditor allocation

6.1 Audit team

1) Auditors in the FSSC 22000 audit team shall meet the competence requirements set out by the Foundation in Annex 5 of this Part.
2) The FSSC 22000-Q audit is a fully integrated audit. The audit team leader shall be qualified for FSSC 22000 and ISO 9001.

6.1.1 Time allowance

The time-allowed calculation for FSSC 22000 audits shall only apply to team members who are current FSSC 22000 auditors registered in the scheme. Other team members may be attending for training and familiarity purposes but their contribution shall not be considered in the time-allowed minima.

6.1.2 Rotation

An auditor is not allowed to perform more than two 3-year certification cycles at the same certified site. If an auditor starts auditing within a certification cycle he/she will be rotated out after six (6) years.

6.1.3 Audit language

1) The audit shall be carried out in a mutually agreed language.
2) An interpreter may be added to the team by the CB to support members of the audit team.

6.2 Competence of CB personnel

6.2.1 Certification Manager

1) Those making the decision to issue a certificate for registration in the FSSC 22000 Register of Certified Organizations shall have the following demonstrable competency;
   a) Annex 3 of ISO/TS 22003,
   b) knowledge of Scheme requirements,
   c) knowledge of food safety management systems and auditing them,
   d) literacy in the terminology and proficiency in the techniques of the food chain category and subcategory under review.
2) Audit team members shall not be involved in the decision to issue or maintain certification.

6.2.2 Auditor

In Annex 5 of this Part, detailed auditor competence requirements are described.

6.2.3 Other personnel

In Annex 3 of ISO/TS 22003, the food safety management system requirements for other CB functions are described.

7 Planning and managing audits

7.1 General

At least annually audits have to take place to ensure that recertification is granted before the expiry date of the certificate.

The audit shall be carried out on-site at the premises of the organization and is a full management system audit.

The on-site audit can include the use of computer aided audit techniques (CAAT) to access information or to interview responsible persons. The CB shall have a process for the use of CAAT during on-site audits.

7.2 Multiple site

1) Certification of multi-site organizations and multi-site sampling (as described in ISO/TS 22003 and ISO/IEC 17021) is not applicable these food chain categories as listed in ISO/TS 22003:

a) CI – IV,

b) DI and DII,

c) I and K.

2) For the food chain categories shown in 1) the Scheme requires that every site shall have:

a) a separate audit,

b) a separate report,

c) a separate certificate, and

d) every site shall be entered separately in the database.

3) Certification of multi-site organizations as shown in ISO 22003, clause 9.1.5 shall be applicable for the following food chain categories as listed in ISO/TS 22003:

a) E,

b) FI,

c) G.

7.2.1 Exceptions – applicable for categories C, D, I and K

The Scheme does offer exceptions for three main categories of organizations shown in section 7.2 clause 1 above, that have multiple sites such as organizations:

a) where some functions pertinent to the certification are controlled by a head office separate to the site(s),

b) with different operations at one site,

c) with off-site activities.

7.2.2 Head office functions

Functions pertinent to the certification but controlled by a head office separate to the site(s) which could include:

a) Procurement,

b) Supplier approval or

c) Quality assurance.

7.2.2.1 Auditing head office functions

1) In all cases where functions pertinent to the certification are controlled by a head office, 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 as per the criteria at 7.2.1 above.

2) The functions at the head office are audited separately and every site belonging to the group shall have:
   a) a separate audit,
   b) a separate report and
   c) a separate certificate.

7.2.2.2 Auditing sites in a multi-site organization

1) An audit at the head office cannot assess the degree of implementation at site level.
   a) This usually means that the auditor shall visit the head office to conduct that part of the audit.
   b) It is strongly recommended that the head office audit is carried out prior to the manufacturing location audit.

2) The subsequent audit at the site(s) shall therefore include a confirmation that the requirements set out by head office are appropriately incorporated into site specific documents and implemented in practice.

3) The site audit report and certificate shall show which functions have been audited at the head office.

4) The report of the head office audit has a validity of 12 months.

5) The head office cannot take responsibility for all functions within the scope of the certification, and can therefore not receive a separate certificate.

6) The head office is mentioned on the site certificate by use of wording such as "An audit was carried out at (name and location of head office) on DDMMYY to assess the following function(s) (describe functions audited at the head office)".

7.2.3 Organizations with different operations at one site

1) In cases where different operations are located on one site, for example where a manufacturing operation is linked to a packing operation, both shall be considered for certification under a single scope based on one audit, report and certificate provided that both are:
   a) subject to one audit appropriate to the combined scope;
   b) part of the same legal entity.

2) The preferred description on the certificate in such cases is to use the name of the legal entity as the primary name. For example: "XYZ company, operating as ABC processing and 123 packaging, (insert address)".

7.2.4 Off-site activities

1) A certified organization has a (single) manufacturing process that is split between different sites that may be part of the same legal entity. The (semi-finished) products are always returned to the primary site for completion.
   a) For example, a semi-finished product is moved to a separate site for a specific process step or steps to be carried out, and is returned to the primary location for completion.
   b) Such processes shall, by exception, be considered for certification under a single scope and one certificate.

2) The preferred description on the certificate in such cases is "An audit was carried out at (name and location of head office) on DDMMYY to assess the following function(s) (describe functions audited at the secondary site), which are integral part of the main production process".

7.2.4.1 Exemption by the Foundation

1) An off-site exemption shall be granted only through application by the CB to the Foundation based on the proposed scope and a detailed justification.

2) No agreement shall be reached or implied with the client prior to approval from the Foundation.

7.2.4.2 Management of off-site activities

3) The off-site activities shall have to meet with the following requirements:
   a) There is a primary manufacturing site and secondary sites for defined process steps.
   b) There is clearly one process involved, resulting in a finished product at the primary site which fits within the scope of the primary manufacturing site.
   c) The scope statement of the primary certified manufacturing site shall clearly show the on-site and off-site activities.
   d) The audit shall clearly include all relevant requirements at both the primary and secondary sites and allow audit and findings to be identified as site specific.
   e) The off-site activities are included in the primary site food safety management system.
   f) The certificate shall show the address of all sites involved, but shall clearly identify which is the primary site.
   g) Full details of the off-site production locations shall be included in the audit reports.
   h) The number of secondary sites shall be limited to a maximum of five.

7.2.5 Dealing with nonconformities

1) Where nonconformities are noted in head office or separate sites, these are assumed to have impact on the equivalent procedures applicable to all sites.
2) Corrective actions shall therefore address issues of communication across the certified sites and appropriate actions for impacted sites.
3) Such nonconformities and corrective actions shall be clearly identified in the relevant section of the audit report.
4) The nonconformities shall be cleared in accordance with the CBs procedures before issuing the site certificate.

7.3 Adding off-site transport and storage to the scope of certification

1) Off-site transport and storage shall only be added to the manufacturing scope in cases when these are:
   a) dedicated to the company's own production and
   b) included within the audited food safety management system
   c) reported as separate locations in the audit report including full details such as address, activities, products, etc.
2) The number of off-site transport and storage sites shall be limited to a maximum of five.

7.4 Unannounced audit program

An unannounced audit program is part of the 3-year certification cycle. Participation in the unannounced audit program is mandatory.

7.4.1.1 At least one in the 3-year cycle

1) The program shall ensure that for each certified organization at least one unannounced audit is undertaken after the initial certification audit and within each 3-year period thereafter.
2) The certified organization can voluntary choose to replace all surveillance audits by unannounced annual surveillance audits.
3) Neither the initial certification audit (stage 1 and stage 2) nor the recertification audit can be replaced by an unannounced audit.

7.4.1.2 Criteria for the execution of the unannounced audit program

1) The CB sets the date of the unannounced audit.
2) The site shall not be notified in advance, by the CB, of the date of the unannounced audit.
3) The unannounced audit takes place during operational working hours including night shifts.
4) When there are legitimate business reasons, blackout days may be agreed in advance between the CB and the certified organization to avoid periods of extreme inconvenience during which the client would find it difficult to participate fully and/or there is no production.
5) The unannounced audit is a full surveillance audit during which the auditor shall spend at least 50% of the time in production area (shop floor) assessing the implementation of the applicable CCPs, PRPs and OPRPs.
6) 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.
7) The auditor shall audit the organization operating on a representative number of product lines covered by the scope of certification.
8) The CB decides which of the scheduled surveillance audits shall be chosen for the unannounced audit.
9) In the event that 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.
10) If access is denied to the auditor the organization will be liable for all costs.
11) Head offices controlling certain functions pertinent to certification are not audited during the unannounced audit.
12) Secondary sites (off-site activities) and off-site storage, warehouses and distribution facilities are also audited during the unannounced audit.

The CB is expected to operate discretion in case of emergencies (e.g. fire, major catastrophic event, another audit on-going).

7.5 Transition to FSSC 22000

1. When transitioning from ISO 22000 or a GFSI recognized scheme to FSSC 22000 certification, a full stage 1 and 2 audit is not required to confirm compliance of the food safety management system with all Scheme requirements. The transition audit is based on the recertification Scheme requirements. In this case, the audit report shall:
    a) clearly specify the audit type i.e. "transition audit from ISO 22000 or a GFSI recognized scheme to FSSC 22000",
    b) provide details of the previous audit in particular related to nonconformities,
    c) confirm the validity of the existing certificate,
    d) confirm compliance with all Scheme requirements.

2. The transition audit time calculation is based on the recertification Scheme requirements.

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

8 Audit reports

8.1 Written report

1) The CB shall provide a written report for each audit.
    a) The content of audit report is to be treated confidentially by the CB.
    b) At discretion of the certified organization, audit reports can be made available to authorized parties.
2) The audit report shall cover all elements in order to confirm that all Scheme requirements are assessed, reported and a statement of conformity given.
    a) Both the procedural and operational conditions of the food safety management system shall be verified in order to assess the effectiveness of the food safety management system meeting the Scheme requirements.
    b) In exceptional cases, the previous requirement can be deemed not applicable but only when the requirements of ISO/TS 22003, clause 9.1.1 are met.
    c) Exclusions shall be assessed and justified in the audit report.
3) The report shall be in conformance with the FSSC 22000 audit report template included in Annex 4A.

8.2 Nonconformity grading

Nonconformities shall be graded and dealt with in accordance with Annex 3.

FOOD SAFETY SYSTEM CERTIFICATION 22000

Part 5: Requirements for Accreditation Bodies
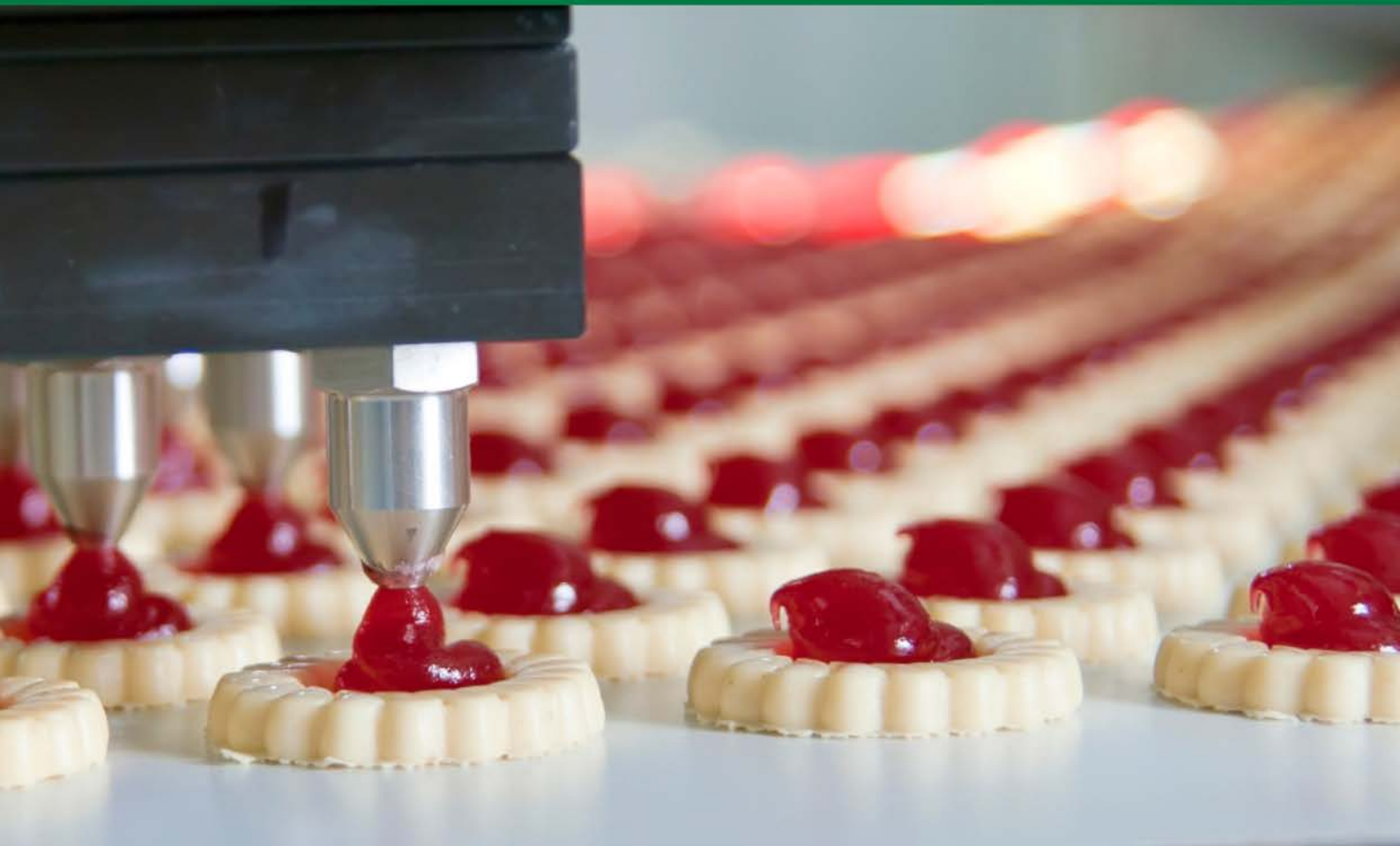
Version 4: January 2017

Part 5: Requirements for Accreditation Bodies

Contents

1 Purpose

This document specifies the criteria against which the Foundation will recognize and register Accreditation Bodies (ABs) on its website providing accreditation to Certification Bodies (CBs) seeking to offer FSSC 22000 certification to their clients in conformity with Scheme requirements.

1.1 Membership of the IAF

1) ABs providing accreditation to CBs seeking to offer FSSC 22000 certification shall:
   a) be a current member of the International Accreditation Forum (IAF) and inform the Foundation in case of changes to its membership status and
   b) be a signatory to the IAF Multilateral Recognition Arrangement (MLA) for Management System certification till 2018 and Food Safety Management System (FSMS) certification from 2018 onwards.

1.2 ISO/IEC 17011

1) ABs shall meet the following requirements for the process of auditing the CB against ISO 17021 having the scope of FSSC 22000 or FSSC Quality:
   a) ISO/IEC 17011 and
   b) all relevant IAF Mandatory Documents (MD) and in particular IAF MD 16 "Application of ISO/IEC 17011 for the Accreditation of Food Safety Management Systems (FSMS) Certification Bodies" and
   c) notify the Foundation in a timely manner of any changes in its ownership, legal status or constitution.

1.3 Assessor competence

1) AB assessor teams shall meet the generic competence requirements for AB assessors set out in IAF MD 20 "Generic competence for AB assessors: Application of ISO/IEC 17011".
2) AB assessor teams shall meet the competence requirements for AB assessors set out in section 6.2.1 of IAF MD 16 "Application of ISO/IEC 17011 for the Accreditation of Food Safety Management Systems (FSMS) Certification Bodies''.
3) At least one AB assessor shall attend the annual FSSC 22000 Harmonization Conference and/or FSSC 22000 technical webinars to assure Scheme management updates.

1.4 Contact person

1) The AB shall appoint a contact person for the communication with the Foundation.

2 Accreditation of CBs

2.1 License agreement

The AB shall verify that the CB has signed a license agreement with the Foundation to certify for a predefined ISO 22003 Food Chain Category prior to its accreditation for a maximum of one (1) year.

2.2 Accreditation process

1) The AB shall issue a confirmation of application for accreditation including the detailed scope to the applicant CB.
2) The AB shall issue a confirmation of declining an application for accreditation including the detailed scope to the applicant CB.
3) The accreditation process shall cover all Scheme requirements applicable to the scope of accreditation.
4) CBs undergoing the process of FSSC 22000 accreditation against ISO/IEC 17021 may already carry out FSSC 22000 audits with a qualified FSSC 22000 auditor.
   At least one of these audits shall be witnessed and at least one complete FSSC 22000 certification procedure will be reviewed in course of the initial accreditation process.
5) The accreditation process shall consist of annual on-site assessments with the CB.
6) The AB shall inform the Foundation in case the accreditation status of the CB changes (e.g. granted, extension, suspension or withdrawal).

2.2.1 Accreditation scope

1) The scope of accreditation shall be precisely defined and included on the accreditation documents with reference to the:
   a) FSSC 22000 Certification scheme for food safety management systems.
   b) Normative documents for providing certification:
      i) ISO 22000 requirements,
      ii) Sector specific PRP requirements (e.g. ISO/TS 22002-1),
      iii) Additional FSSC requirements.
   c) Food chain clusters and categories as indicated in Annex A of ISO/TS 22003.
   d) Locations covered under CB accreditation.

2.2.2 Witnessed audits

1) The witnessed audits shall meet the requirements for Witnessing Activities for the Accreditation of Management Systems Certification Bodies, set out in IAF MD 17 with the below Scheme specific requirements:
   a) An initial assessment of a FSSC 22000 cluster shall require at least one (1) witnessed assessment of a category (as defined in ISO/TS 22003) except for the food and feed processing cluster and retail, transport and storage cluster, where the categories shall be assessed separately.
   b) For extensions inside a cluster, a witnessed audit is not mandatory (except for the food and feed processing cluster and retail, transport and storage cluster) however witnessed audits are mandatory for extensions to categories in a new cluster.
   c) The AB shall conduct witnessed audits covering all clusters included in the CB accreditation scope during a period of four (4) years.

2.3 Integrity Program

1) The Foundation provides the AB access to all relevant CB outcomes of its Integrity Program and complaints management system related to ISO/IEC 17021. The AB shall consider the content of this information which could form input for the CBs management system review. ABs are invited to attend the Integrity Program assessments undertaken by the Foundation.

2) Evaluation that an AB meets the requirements of this document shall be monitored by the Foundation and feedback on compliance with these requirements shall be shared directly with the AB for discussion and action when appropriate.

2.3 Integrity Program

Annex 1: Certificate scope statements

The certificate scope statement shall describe the process/activities, products and/or services that are supplied by the certified company and have been audited by the CB.

Table of requirements for certificate scope statements

	Criterion	Specification
1	Language	1. Scope statements shall be in English, but 2. another language may be added (e.g. the native language of the country of the certified organization).
2	Contents of the certificate scope	Certification scope statements shall: 1. Be within the scope of the Scheme. 2. Identify the processes/activities, products and/or services. supplied by the certified organization that have been audited by the CB. 3. Describe briefly main processes/activities belonging to the same legal entity and covered by its Food Safety Management System. 4. Be clear and reflect the intended use. 5. Not include promotional statements or claims.
3	Packaging material	1. The specific type of packaging material shall be identified (e.g. plastics, paper, board, glass, metal, etc.). 2. The intended used shall be specified for the food and/or feed industries. Note: *Packaging for personal care products, pharmaceutical or other uses is not covered by the scope of the Scheme.*
4	By-products	1. By-products from food production intended for use in the feed industry may be included in the food scope statement provided: a. it is stated that these are intended for use in the feed industry.
5	Off-site activities	Off-site activities shall be included in the scope statement.
6	Off-site transport and storage	Off-site transport and storage may be included in the scope statement, only if they are: 1. Dedicated to the certified organizations' own production, 2. Covered by the audited Food Safety Management System, 3. Reported as separate locations in the audit report including full details such as address, activities, products, etc.
7	Gases used as additives	1. Additive gases (to either food or packaging) shall be included in the FAO Codex list of approved additives [refer to URL here]. 2. The intended use of the gas shall be identified e.g. with wording such as "… used as food ingredient or packaging gas".

NOTE

As of 1 January 2017 the scope statement on 'warehousing and distribution' will be replaced by 'transport and storage'.

Annex 2: Audit time calculation

1 Introduction

This Annex deals with the minimum on-site audit time required to cover the Scheme requirements.

1.1 Auditor day

The duration of an audit day normally is eight (8) hours and may or may not include a lunch break depending upon local legislation.

The on-site audit duration shall be stated in auditor working hours giving the time at the production site conducting a FSSC 22000 audit.

1.2 Separate calculation for FSSC 22000 audit duration

Where the FSSC 22000 audit is undertaken with other audits, then a calculation for the time-allowed of the FSSC 22000 audit only shall be stated.

2 Additional time allowances

The following are the additional time allowances to be applied.

2.1 PRPs

1) The Scheme requires that in addition to the preparation, on-site audit and reporting time as stipulated in ISO/TS 22003, clause 9.1.4 and Annex B, the CB shall add 0.5 – 1 auditor day (4-8 working hours, depending on the size of the organization as specified below) for the audit and reporting on the implementation of the relevant PRP(s).

2) This is applicable to initial, surveillance (announced or unannounced) and recertification audits.

2.1.1 Organization size and complexity

The additional FSSC 22000 audit time-allowed shall be calculated as follows:

1) 0.5 auditor day (4 working hours) on-site (including food fraud and food defense assessment) when the company has <u>less</u> than:
   a)   250 FTE and
   b)   3 HACCP studies.

2)   1.0 auditor day (8 working hours) on-site (including food fraud and food defense assessment) when the organization has:
   a)   250 FTE or more; or
   b)   3 HACCP studies or more.

2.2 Reporting time

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

2.3 Use of an interpreter

At least 0.5 auditor day (4 working hours) additional on-site audit time shall be added to the FSSC 22000 audit time when an interpreter is required to support the audit team.

2.4 Off-site storage & warehousing

At least 0.5 auditor day (4 working hours) additional on-site audit time shall be added to the FSSC 22000 audit time for each off site storage or warehousing facility.

2.5 Organizations with a separate head office

1) 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.
2) When the responsible person from the head office attends the audit at manufacturing site, no extra audit time is calculated.
3) 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.
   a) The 20% audit time reduction is applied to the minimum audit time (Ts) as shown in ISO/TS 22003, Annex B.

2.6 Organizations with off-site activities

In organizations with off-site activities where one or more process steps take place at a secondary site, a 50% audit time reduction is applied for the minimum calculated total on-site audit time for each secondary site.

3 FSSC 22000-Quality

1) The audit time for the ISO 9001 part of the audit shall be calculated using IAF MD 5.
2) The audit duration for the integrated FSSC 22000 and ISO 9001 audit shall be based on IAF MD 11, section 2.1.5.1.

4 Transition from GFSI recognized scheme to FSSC 22000

The minimum FSSC 22000 certification on-site audit time shall be two-thirds of the initial ISO 22000 certification audit time, with a minimum of 1 auditor day (8 working hours) on-site plus the FSSC 22000 additional audit time as defined above.

5 Audit time included in the audit report

1) The audit time-allowed calculation shall:
    a) be included in the report or audit time calculation sheet,
    b) match the audit time calculation tool shown in ISO/TS 22003, Annex B
       i.e. (Ts = (D + H + MS + FTE)) plus the additional FSSC 22000 audit time.

2) When properly documented and justified, a reduction of the Ts audit time can be made for a less complex organization measured by number of employees, size of the organization and/or product volume or within number of employees, size of the organization and or product volume or within categories having a Ts time less than 1,5 auditor days, in accordance with ISO 22003.

3) The data to support the calculation shall be included in the report.

5 Audit time included in the audit report

Annex 3: Nonconformity grading

1 Introduction

In accordance with the definitions in the Scheme and as defined below, the CB is required to establish and maintain criteria as a reference against which to determine the level of nonconformities resulting in three grading levels:

a) Minor nonconformity,

b) Major nonconformity,

c) Critical nonconformity.

2 Opportunity for improvement

The use of opportunities for improvement during a FSSC 22000 audit is not allowed by the Scheme.

3 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) When a minor nonconformity is issued during an audit, a proposed corrective action plan is required within three (3) months after the audit.

2) Corrective actions shall be completed within 12 months after the audit.

3) The lead auditor shall review the design of the corrective action plan, challenge it and approve it when acceptable.

4) Implementation of the corrective plan shall be reviewed, at the latest, at the next scheduled on-site audit. The lead auditor shall review the corrective action plan and determine its effectiveness of implementation through recording auditor name and date of review on the CAP.

5) A major NC is raised (on management responsibility and resource allocation) in the event of non-completion of the approved action plan at the next scheduled on-site audit.

4 Major nonconformity

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

1) When a major nonconformity is issued during an audit, the client must provide the CB with objective evidence of an investigation into causal factors and the risks they expose and their proposed corrective action plan (CAP). This shall be provided within 14 days after the audit.

2) The major nonconformity shall be closed within a further 14 days by implementing a corrective action (CA).

3) The lead auditor shall review the corrective action plan, challenge it if necessary and determine its effectiveness and approve the CAP and CA through recording his/her name and date of review on the CAP. The lead auditor can conduct a follow-up audit to verify the implementation of the CA and to close the major nonconformity.

4) A critical NC is raised in the event of non-completion of the approved corrective action.

The completion of corrective 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.

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. A follow-up audit could be conducted to verify the permanent corrective action and to close the major nonconformity.

5 Critical nonconformity

A critical nonconformity is issued when food safety is directly impacted during the audit or when legality and/or certification integrity are at stake:

1) When a critical nonconformity is issued at a certified site the certificate shall be immediately suspended for a maximum period of six (6) months.

2) A follow-up audit shall be conducted by the CB within the six (6) month time frame to verify the closure of the critical nonconformity.

3) The certificate shall be withdrawn when the critical nonconformity is not effectively solved within the six (6) month time frame.

4) In case of a certification audit the full certification audit shall be repeated.

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Annex IVA Audit report template

The content of this report including a summary of the nonconformities shall be uploaded in the English language. The checklists and the completed NC forms can be uploaded in the local language.

Organization profile	
Description of the certified organization.	
Registered legal name	
Trading name(s)	
Registration	Chamber of Commerce and/or governmental registration number
Location	Street address, city, country
Contact person	Name, function, email, phone
General description of audited organisation	

Head Office (where appropriate)	
Description of the role the head office. Does the company belong to al larger group with a central head office? Does the head office control certain functions pertinent to certification? Is the Head Office shown on the certificate.	
Registered legal name	
Trading name(s)	
Registration	Chamber of Commerce and/or governmental registration number
Location	Street address, city, country
Contact person	Name, function, email, phone
Number of sites	Multiple site is possible for food chain categories A, E, FI and G. There are exceptions for food chain categories C, D, I and K namely: • Head office controlling certain function pertinent to certification (20% audit time reduction may be applicable) • Organizations with off-site activities (a maximum of five off-site locations).

Executive summary	
Summary of audit findings	Summarize the ability of the food safety management system to meets its objectives, how it continually improves it effectiveness, strengths and weaknesses of the company's system, etc.

Scope of certification	
Food category	Food chain categories supporting the scope statement (multiple food chain categories may be applicable, see ISO/TS22003, Table A.1)
Scope statement	Specify the products or product categories, processes and production sites that are covered by

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	the food safety management system and mentioned on the certificate.
Exclusions (when appropriate)	Describe the exclusions from the scope (exclusions may not have an (negative) influence on the certified end products).

Summary of audit findings	
Critical nonconformities	Number and short description of critical nonconformities (raised or closed)
Major nonconformities	Number and short description of major non-conformities (raised or closed)
Minor nonconformities	Number and short description of minor nonconformities (raised or closed)
Areas of concern (stage 1 only)	Number and short description a stage 1 finding that may lead to a nonconformity during the stage 2 audit.

General findings	
Legal compliance	Summarize the status, any governmental inspection findings, etc.
Change management	Summarize findings related to changes (e.g. compared to previous audit, to FSMS, etc.) and the effect on the operational FSMS.
Complaints management	Summarize the food safety related complaints (including customer feedback) and the effect on the operational FSMS.
Recalls and withdrawals	Summarize the recalls/withdrawals, actual notification to the CB and the effect on the operational FSMS.

Food Safety Management System (ISO22000) findings	
Food safety management system	Summary of findings related to ISO22K sections 4.1 and 4.2 while highlighting all of the sections shortly and in particular the ones where NC were noted including reference to the checklists with more details.
Management commitment	Summary of findings related to ISO22K sections 5.1 till 5.8 and highlight all of the sections shortly and in particular the ones where NC were noted including reference to the checklists with more details.
Resource management	Summary of findings related to ISO22K sections 6.1 till 6.4 and highlight all of the sections shortly and in particular the ones where NC were noted including reference to the checklists with more details.
Planning and realization of safe products	Summary of findings related to ISO22K sections 7.1 till 7.10 and highlight all of the sections shortly and in particular the ones where NC were noted including reference to the checklists with more details.
Validation, verification and	Summary of findings related to ISO22K sections 8.1

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improvement of the FSMS	till 8.5 and highlight all of the sections shortly and in particular the ones where NC were noted including reference to the checklists with more details.

Prerequisite Program findings	
Summary of PRP implementation	Summary of findings related to PRPs. Highlight all of the sections of the relevant PRP(s) shortly and in particular the ones where NC were noted including reference to the checklists with more details

Additional Requirements findings	
Summary of all additional requirements	Summarize all the sections of the Additional Requirements shortly and in particular the ones where NC were noted including reference to the checklists with more details

Audit recommendation	
Stage 1 audit to be repeated	Specify audit recommendation to the committee that takes the certification decision.
Proceed to stage 2 audit	
Initial certification	
Continue certification	
Re-certification	

Audit details				
Certificate number				
CB Name and office location				
Audit team				
Name 1 (role)	Lead auditor / auditor / technical expert / translator / etc.			
Name 2 (role)	Lead auditor / auditor / technical expert / translator / etc.			
Name 3 (role)	Lead auditor / auditor / technical expert / translator / etc.			
Audit objective	Confirm any special attention areas			
Audit type	Certification (stage 1 or stage 2) / surveillance / recertification / follow-up			
Audit dates and times	Start and finish date including times.			
Audit duration (auditor days)	Also state head office time (without production) – where applicable			
Audit time reduction	See exceptions			
Additional audit time for off-site activities	See exceptions			
On-site audit time calculation				
D	H	MS	FTE	FSSC addition
Other standards	Mention the other standards that are audited together with FSSC 22000. Also show audit type and man-days allocated to these standards.			

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Number of HACCP studies	Describe details and cross check with audit time calculation.
Number of employees (FTEs)	Cross check with audit time calculation.
Number of shifts	Cross check with audit time calculation.
Employees per shift (FTE)	Cross check with audit time calculation.
Off-site activities	
Describe any third-party off-site services hired by auditee such as storage, transportation, production of semi-finished products, etc.	
Registered legal name	
Trading name(s)	
Scope	
Location	

Annexes (in local language)
Annex 1: Audit plan
Annex 2: Attendance sheet
Annex 3: ISO 22000 checklist
Annex 4: PRP standard checklist(s) applicable to scope (not audited during stage 1)
Annex 5: Additional FSSC requirements checklist

Annex 4: Audit reports

1 Introduction

1) For the purpose of the FSSC 22000 audit report the following audit reporting templates shall apply (see Annex 4A).
2) The FSSC report, shall give confidence that the certified organization has all basic Food Safety Management Systems (FSMS) conditions and PRPs well managed and fulfilled.
3) The auditor conducts a plant tour along the CCPs, PRPs and locations where OPRPs are applied.
4) Records of compliance of the CCPs, PRPs and OPRPs shall be inspected wherever they are and shall be checked and examined.

2 Significance of the audit report

1) The audit report is a transparent and concise reflection of the findings of the auditor during the audit.
2) It provides clear evidence that all scheme requirements have been audited for conformity with the Scheme.
3) In the first place, the report:
   a) verifies that the FSMS has been designed and configured to conform with scheme requirements and
   b) validates the organization's claim that their FSMS works in practice.

3 Auditor's responsibility

1) The (lead) auditor shall ensure that the audit report is prepared and shall be responsible for its content.
2) The audit report shall provide an accurate, concise and clear record of the audit to enable an informed certification decision to be taken by the CB certification manager.
3) The report shall include references to:
   a) PRPs used by the organization,
   b) HACCP methodology used,
   c) comments on the HACCP team,
   d) complaints,
   e) changes and other issues relevant to the FSMS.

4 Ownership of the report

The certification body retains ownership of the audit report.

Annex 5: Auditor Competence

Contents

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FSSC 22000 Auditor Competence

1 Purpose

This document states the requirements for certification bodies (CBs) with respect to the auditor competence and qualification process.

2 Scope

These requirements apply to all auditors conducting FSSC 22000 audits – from initial training, through qualification, to requalification and also covers extensions to sector and/or category(ies).

3 Qualification

There are four steps in the qualification process:
1) selection of the auditor;
2) initial training;
3) assessment and
4) registration.

3.1 Selection

The CB shall select auditors on the basis of meeting the education and work experience requirements defined in the sector specific specification.

3.2 Initial Training

The CB shall provide initial training in the following areas if the auditor does not already meet the requirements detailed in the section specific specifications:
1) HACCP training – minimum 16 hours;
2) Food Safety Management Training – minimum 40 hours, as lead auditor in ISO 22000 or in FSSC 22000;
3) Sector specific training in relevant PRPs;
4) FSSC 22000 Scheme requirements, and
5) ISO/TS 22003; ISO 19011 and ISO 17021-1.

Note: Lead auditor qualification in ISO 9001 of 40 hours (five days), along with an ISO 22000 conversion course of 24 hours (three days) is acceptable for the food safety management system training.

3.3 Assessment

The CB shall:
1) provide supervised training in FSSC 22000 audits as per sector specifications;
2) conduct a witnessed audit of the auditor to confirm competence is attained and
3) document the sign-off of the satisfactory completion of the training program and witness audit.

The supervised training and the witnessed audit shall be conducted by a FSSC 22000 qualified auditor for the relevant category/sub-category as defined in section 4.4.

The qualification sign-off shall be performed by the appointed supervisor of the CB.

3.4   Auditor registration system

The Foundation provides an auditor registration system for every Scheme specific auditor employed or contracted by a CB.

The details of the auditor's qualifications, training, experience and scope of activity in relation to the Scheme's product categories are held and maintained within this register and shall be kept up to date by the CB.

The CB shall:

1) Register qualified auditors with the Foundation.
2) On request provide the following documents or evidence related to verified qualification documents in the register:
    a) CV/resume (detailing education, work experience, relevant food safety training, date of joining the CB, date of qualifying as a FSSC 22000 auditor);
    b) Training records (certificates, where available to demonstrate requirements have been met);
    c) Qualification records, per sector/category;
    d) Witnessed audit reports.
3) Indicate the categories the auditor is qualified for, and maintain the dates for the initial and renewal dates in the register.

4   Maintenance of auditor qualification

The CB shall ensure a system is in place to maintain auditor qualification.

4.1 GFSI recognised audits

At least five (5) on-site GFSI recognized scheme audits at different sites each calendar year, of which at least three (3) are FSSC 22000 audits.

Note: A temporary exception to this requirement can be granted by the Foundation in specific cases:

- Long term sickness of the auditor;
- Extended leave (e.g. maternity, paternity, sabbatical);
- Lack of clients in the region/country.

4.2 Continual training

Auditors shall attend any relevant annual training specified by the Foundation (at least one event e.g. training, conference, seminars and/or network meetings) in order to keep up-to-date with Scheme changes, best practices and relevant regulatory and/or statutory developments in the sector(s) where they perform audits.

4.3 Audit and training logs

The audit and training log of the qualified auditor shall be evaluated and updated annually by the competent supervisor of the CB.

4.4 Witnessed audit

1) At least one (1) on-site witnessed audit of a GFSI recognized scheme shall be conducted every three years to confirm acceptable auditor performance.
2) The witnessed audit shall be undertaken by a qualified auditor and shall be assessed and qualified by the CB as suitable to undertake witnessed audits.
3) The witnessed assessor has received training in witness audit techniques.
4) The witnessed assessor who observes the auditor undertaking the audit plays no part in the audit.
5) The witnessed assessor shall provide a witness audit assessment report with recommended conclusion for sign-off of the witnessed auditor.

Note: The witnessed audit shall be performed by the CB and cannot be substituted by an Accreditation Body (AB) witness audit.

5   Auditor requalification

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

Note: Only one witness audit is required, irrespective of the number of categories/sub-categories that the auditor is qualified in.

6   Category extension

For extension of the auditor qualification scope to a new category, the CB shall demonstrate that the auditor possesses the relevant competence as outlined in the sector specifications. The auditor shall have;
   a) six (6) months of audit experience in the new category, or
   b) four (4) FSSC 22000 audits in the new category as a co-auditor under the supervision of a qualified FSSC 22000 auditor.

The CV is to be updated on completion of auditor qualification for additional food chain category(ies).

7   FSSC 22000-Quality auditor qualification

Audit team leaders conducting integrated FSSC 22000 and ISO 9001 audits (FSSC 22000-Quality) shall meet the quality auditor specifications.

FSSC 22000 Auditor Category requirements

Based on ISO/TS 22003

Farming – Category A

Cluster	Category		Sub-category	
	Code	*Name*	*Code*	*Name*
Farming	A	Farming of Animals	AI	Meat/milk/eggs/honey
			AII	Fish & seafood

Item	Topic	Specification
1	Education	1) A degree in a food related or bio-science discipline, OR 2) Successful completion of a food related or bio-science higher education course or equivalent, OR 3) A post-secondary education in agronomy, agriculture or veterinary sciences.
2	Work Experience	1) Minimum five (5) years experience in food related industry. 2) Including minimum two (2) years in relevant specific sectors of animal farming.
3a	HACCP training	HACCP principles, Hazard assessment and hazard analysis: minimum two (2) days/16 hours (note this is in addition to 3b requirements).
3b	Food Safety Audit training	1) Food Safety Management System Lead Auditor training – minimum duration of 40 hours (5 days), or 2) ISO 9001 Lead Auditor training (minimum 40 hours) and ISO 22000 or FSSC 22000 conversion course (minimum 24 hours), 3) Industry relevant training in PRPs (ISO/TS 22002-3), 4) FSSC Scheme requirements, 5) ISO 22003; ISO 19011; ISO 17021 training.
4	Practical Assessment	1) Successful completion of supervised training through 5 audits or 10 audit days at a number of different organizations. 2) Previous ISO 22000 and/or GFSI recognized audits are considered applicable for meeting the practical assessment. 3) Final assessment by a competent assessor/supervisor during FSSC 22000 audit (qualifying witnessed audit)- to cover the following: a) Knowledge of i) Food safety; ii) HACCP; iii) PRPs; iv) Food fraud prevention; v) Food defense, and vi) Applicable laws/regulations/codes. b) Food Safety Management System knowledge; c) Specific audit techniques; d) Specific category knowledge.

Item	Topic	Specification
5	Auditor qualification	1) Documented sign-off of the completed review of work experience, supervised audits, training and witness audit by the appointed supervisor of the CB indicating when the auditor became a qualified FSSC auditor. 2) Register auditor qualification details into the FSSC 22000 Auditor Database in accordance with instructions of the Foundation. 3) A plan for continued training in the sector(s) in which they perform audits in order to keep auditors current with respect to: a) Best practices, and b) Relevant regulatory and statutory developments. 4) Instructions for the auditor to maintain written records of all relevant training undertaken.
6	Extension of scope - new category	1) Demonstrate the required competences through relevant a) Education b) Food safety related training in the new category. 2) AND either: a) Six (6) months experience in the new category, OR b) Four (4) FSSC 22000 audits in the new category under the supervision of a qualified auditor. 3) Registrations to be updated and maintained and in the FSSC 22000 auditor database.
7	Maintenance of qualification	1) Competence and qualification of auditors shall be re-established every three (3) years. 2) The following to be re-evaluated prior to requalification: a) Minimum five (5) GFSI recognized on-site audits conducted at different locations each year including at least three (3) FSSC 22000 audits. Note: this can include GFSI recognized audits conducted on behalf of any CB; b) Attendance of at least one (1) training activity per year (such as training, conference meetings, seminars and/or network meetings) in order to keep up to date with the best practices and relevant regulatory and statutory developments in the sector(s) where audits are performed; c) Annual Scheme updates (based on the Harmonization Conference); d) Annual review of the audits and training logs by a competent supervisor of the CB; e) A minimum of one (1) on-site Witnessed Audit of a GFSI recognized scheme conducted every three (3) years; f) CV to be updated every three (3) years; g) A documented sign-off to re-establish the qualification of the auditor for the next three (3) years, per category; h) Transition training to be completed for ISO 22000, ISO 22002-3 and FSSC 22000 as standards are updated and prior to next FSSC 22000 audit to the new standards.

END

FSSC 22000 Auditor Category requirements

Based on ISO/TS 22003

Food & feed processing – Category C

Cluster	Category		Sub-category	
	Code	*Name*	*Code*	*Name*
Food & feed processing	C	Food manufacturing	CI	Processing perishible animal products
			CII	Processing perishible plant products
			CIII	Processing perishible animal and plant products
			CIV	Processing ambient stable products

Catering – Category E

Cluster	Category		Sub-category	
	Code	*Name*	*Code*	*Name*
Catering	E	Catering	E	Catering

Retail – Category FI

Cluster	Category		Sub-category	
	Code	*Name*	*Code*	*Name*
Retail, Transport and Storage	F	Distribution	FI	Retail/Wholesale

Transport & Storage – Category G

Cluster	Category		Sub-category	
	Code	*Name*	*Code*	*Name*
Retail, Transport and Storage	G	Provision of transport and storage services	GI	Provision of transport and storage services for perishable food and feed
			GII	Provision of transport and storage services for ambient stable food and feed

Biochemicals – Category K

Cluster	Category		Sub-category	
	Code	*Name*	*Code*	*Name*
Biochemical	K	Production of (Bio) Chemicals	NA	NA

Requirements for Categories C, E, FI, G and K

Item	Topic	Specification
1	Education	1) A degree in a food related or bio-science discipline, OR 2) Successful completion of a food related or bio-science higher education course or equivalent.
2	Work experience	1) Minimum five (5) years experience in food related industry, 2) Including minimum two (2) years full-time work in quality assurance or food safety function in the following sectors: a) Manufacturing b) Catering c) Retail d) Transport and storage e) Biochemicals f) or the equivalent (e.g. inspection, enforcement, etc.)
3a	HACCP training	HACCP principles, Hazard assessment and hazard analysis: minimum 2 days/16 hours (note this is in addition to 3b requirements).
3b	Food Safety Audit training	1) Food Safety Management System Lead Auditor Training – minimum duration of 40 hours (5 days); or 2) ISO 9001 Lead Auditor training (minimum 40 hours) and ISO 22000 or FSSC 22000 conversion course (minimum 24 hours), 3) Industry relevant training in PRPs, 4) FSSC Scheme requirements, 5) ISO 22003; ISO 19011; ISO 17021 training.
4	Practical assessment	1) Successful completion of supervised training through five (5) audits or 10 audit days at a number of different organizations. 2) Previous ISO 22000 and/or GFSI recognized audits are considered applicable for meeting the practical assessment. 3) Final assessment by a competent assessor/supervisor during a FSSC 22000 audit (qualifying witness audit)- to cover the following: a) Knowledge of i) Food safety; ii) HACCP; iii) PRPs; iv) Food fraud prevention v) Food defense, and vi) Applicable laws/regulations/codes b) Food Safety Management System knowledge; c) Specific audit techniques; d) Specific category knowledge.

Item	Topic	Specification
5	Auditor qualification	1) Documented sign-off of the completed review of work experience, supervised audits, training and witness audit by the appointed supervisor of the CB indicating when the auditor became a qualified FSSC auditor. 2) Register auditor qualification details into the FSSC 22000 Auditor Database in accordance with instructions of the Foundation. 3) A plan for continued training in the sector(s) in which they perform audits in order to keep auditors' current with respect to: a) Industry best practices, and b) Relevant regulatory and statutory developments, c) Food safety and technological developments. 4) Instructions for the auditor to maintain written records of all relevant training undertaken.
6	Extension of scope -new category	1) Demonstrate the required competences through relevant a) Education; b) Food safety related training in the new category. 2) AND either: a) Six (6) months experience in the new category, OR b) Four (4) FSSC 22000 audits in the new category under the supervision of a qualified auditor. 3) Registrations to be updated and maintained and in the FSSC 22000 auditor database.
7	Maintenance of qualification	1) Competence and qualification of auditors shall be re-established every three (3) years. 2) The following to be re-evaluated prior to requalification: a) Minimum five (5) GFSI recognized on-site audits conducted at different locations each year including at least three (3) FSSC 22000 audits. Note: this can include GFSI recognized audits conducted on behalf of any CB; b) Attendance of at least one (1) training activity per year (such as training, conference meetings, seminars and/or network meetings in order to keep up to date with the best practices and relevant regulatory and statutory developments in the sector(s) where audits are performed; c) Annual Scheme updates (based on the Harmonization Conference); d) A minimum of one (1) on-site Witnessed Audit of a GFSI recognized scheme conducted every three (3) years; e) A documented sign-off to re-establish the qualification of the auditor for the next three (3) years, per category; f) Annual review of the audits and training logs by a competent supervisor of the CB; g) Registrations to be updated and maintained into the FSSC 22000 auditor database.

END

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FSSC 22000 Auditor Category requirements

Based on ISO/TS 22003

Food & feed processing – Category D

Cluster	Category		Sub-category	
	Code	*Name*	*Code*	*Name*
Food & feed processing	D	Animal feed production	DI	Production of feed
			DII	Production of pet food

Item	Topic	Specification
1	Education	1) Post-secondary education in related field or equivalent by experience. 2) Trained on the sector specific risk assessments. 3) Work experience or training in the feed and/or food sector, and experience in quality management environment in the feed/food sector.

2	Work experience	1) Minimum five (5) years experience in feed related industry.
		2) Including minimum two (2) years full-time work in quality assurance or feed safety function in the following sectors:
		   a) Animal feed production or
		   b) the equivalent.

3a	HACCP training	HACCP principles, Hazard assessment and hazard analysis: minimum two (2) days/16 hours (note this is in addition to 3b requirements).
3b	Food Safety Audit training	1) Food Safety Management System Lead Auditor Training – minimum duration of 40 hours (5 days); or 2) ISO 9001 Lead Auditor training (minimum 40 hours) and ISO 22000 or FSSC 22000 conversion course (minimum 24 hours), 3) Industry relevant training in PRPs, 4) FSSC Scheme requirements, 5) ISO 22003; ISO 19011; ISO 17021 training.

4	Practical assessment	1) Successful completion of supervised training through five (5) audits or 10 audit days at a number of different organizations.
		2) Previous ISO 22000 and/or GFSI recognized audits are considered applicable for meeting the practical assessment.
		3) Final assessment by a competent assessor/supervisor during FSSC 22000 audit (qualifying witness audit)- to cover the following:
		   a) Knowledge of
		      i) Food safety;
		      ii) HACCP;
		      iii) PRPs;
		      iv) Food fraud prevention;
		      v) Food defense, and
		      vi) Applicable laws/regulations/codes.
		   b) Food Safety Management System knowledge;
		   c) Specific audit techniques;
		   d) Specific category knowledge.

Item	Topic	Specification
5	Auditor qualification	1) Documented sign-off of the completed review of work experience, supervised audits, training and witness audit by the appointed supervisor of the CB indicating when the auditor became a qualified FSSC auditor. 2) Register auditor qualification details into the FSSC 22000 Auditor Database in accordance with instructions of the Foundation. 3) A plan for continued training in the sector(s) in which they perform audits in order to keep auditors current with respect to: a) Industry best practices, and b) Relevant regulatory and statutory developments c) Food safety and technological developments 4) Instructions for the auditor to maintain written records of all relevant training undertaken.
6	Extension of scope -new category	1) Demonstrate the required competences through relevant a) Education; b) Food safety related training in the new category. 2) AND either: a) Six (6) months experience in the new category, OR b) Four (4) FSSC 22000 audits in the new category under the supervision of a qualified auditor. 3) Registrations to be updated and maintained and in the FSSC 22000 auditor database.
7	Maintenance of qualification	1) Competence and qualification of auditors shall be re-established every three (3) years. 2) The following to be re-evaluated prior to requalification: a) Minimum five (5) GFSI recognized on-site audits conducted at different locations each year including at least three (3) FSSC 22000 audits. Note: this can include GFSI recognized audits conducted on behalf of any CB; b) Attendance of at least one (1) training activity per year (such as training, conference meetings, seminars and/or network meetings in order to keep up to date with the best practices and relevant regulatory and statutory developments in the sector(s) where audits are performed; c) Annual Scheme updates (based on the Harmonization Conference); d) A minimum of one (1) on-site Witnessed Audit of a GFSI recognized scheme conducted every three (3) years; e) A documented sign-off to re-establish the qualification of the auditor for the next three (3) years, per category; f) Annual review of the audits and training logs by a competent supervisor of the CB; g) Registrations to be updated and maintained into the FSSC 22000 auditor database.

END

FSSC 22000 Auditor Category requirements

Based on ISO/TS 22003

Auxiliary services – Category I

Cluster	Category		Sub-category	
	Code	*Name*	*Code*	*Name*
Auxiliary services	I	Production of food packaging and packaging material	NA	NA

Item	Topic	Specification
1	Education	1) A degree in packaging technology, food hygiene or related science subject or equivalent OR 2) A higher certificate in packaging technology recognized by the Foundation, such as WPO Packaging training (minimum 30 hours), which covers: 　a) Basics of packaging principles and concepts; 　b) Packaging legislation, standards and regulations; 　c) Packaging materials manufacturing; 　d) Specifics to packaging of food products; 　e) Quality/food safety control and testing; 　f) Printing processes and printing inks; 　g) Packaging recycling and 　h) Design of packaging materials.
2	Work experience	1) Minimum five (5) years experience in food chain related industry. 2) Including two (2) years in quality assurance or food safety function within 　a) Food packaging production (such as the manufacture of plastics, paper and board, metal glass, wood or other materials), or 　b) The equivalent.
3a	HACCP training	HACCP principles, Hazard assessment and hazard analysis: minimum two (2) days/16hrs (note this is in addition to 3b requirements).
3b	Food Safety Audit training	1) Food Safety Management System Lead Auditor Training – minimum duration of 40 hours (5 days); or 2) ISO 9001 Lead Auditor training (minimum 40 hours) and ISO 22000 or FSSC 22000 conversion course (minimum 24 hours), 3) Industry relevant training in PRPs, 4) FSSC 22000 Scheme requirements, 5) ISO/TS 22003; ISO 19011; ISO 17021 training.
4	Practical Assessment	1) Successful completion of supervised training through five (5) audits or 10 audit days at a number of different organizations. 2) Previous ISO 22000 and/or GFSI recognized audits are considered applicable for meeting the practical assessment. 3) Final assessment during FSSC 22000 audit - to cover the following: 　a) Knowledge of 　　i) Food safety; 　　ii) HACCP; 　　iii) PRPs; 　　iv) Food fraud prevention; 　　v) Food defense and 　　vi) Applicable laws/regulations/codes. 　b) Food Safety Management System knowledge; 　c) Specific audit techniques; 　d) Specific category knowledge.

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Item	Topic	Specification
5	Auditor qualification	1) Documented sign-off of the completed review of work experience, supervised audits, training and witness audit by the appointed supervisor of the CB indicating when the auditor became a qualified FSSC auditor. 2) Qualification is allocated per Food Packaging Material type. 3) Register auditor qualification details into the FSSC 22000 Auditor Database in accordance with instructions of the Foundation. 4) A plan for continued training in the sector(s) in which they perform audits in order to keep auditors current with respect to: a) Industry best practices, and b) Relevant regulatory and statutory developments c) Food safety and technological developments. 5) Instructions for the auditor to maintain written records of all relevant training undertaken.
6	Extension to scope - new category	1) Demonstrate the required competences through relevant a) Education b) Food safety related training in the new category. 2) AND either: a) Six (6) months experience in the new category, OR b) Four (4) FSSC 22000 audits in the new category under the supervision of a qualified auditor. 3) Registrations to be updated and maintained and in the FSSC 22000 auditor database.
7	Maintenance of qualification	1) Competence and qualification of auditors shall be re-established every three (3) years. 2) The following to be re-evaluated prior to requalification: a) Minimum five (5) GFSI recognized on-site audits conducted at different locations each year including at least three (3) FSSC 22000 audits. Note: this can include GFSI recognized audits conducted on behalf of any CB; b) Attendance of at least one (1) training activity per year (such as training, conference meetings, seminars and/or network meetings) in order to keep up to date with the best practices and relevant regulatory and statutory developments in the sector(s) where audits are performed; c) Annual Scheme updates (based on the Harmonization Conference); d) A minimum of one (1) on-site Witnessed Audit of a GFSI recognized scheme conducted every three (3) years; e) A documented sign-off to re-establish the qualification of the auditor for the next three years, per category; f) Annual review of the audits and training logs by a competent supervisor of the CB; g) Registrations to be updated and maintained into the FSSC 22000 auditor database.

END

FSSC 22000 Auditor Category requirements

FSSC 22000–Quality

Cluster	Category		Sub-category	
	Code	*Name*	*Code*	*Name*
Quality	All	All FSSC food & feed categories	N/A	N/A

Item	Topic	Specification
1	General	Must meet relevant qualification and competence requirements as a FSSC 22000 auditor in the relevant sector/category (refer to previous Auditor Specifications).
2	Quality Systems Training	For FSSC 22000–Quality: 1) Recognized training in quality management systems: ISO 9001 Lead Auditor (5 days, 40 hours). 2) Approved auditor for ISO 17021 accredited ISO 9001 certification 3) Conduct one (1) witness FSSC 22000-Quality or one (1) FSSC 22000/ISO 9001 audit with a completed witness audit report to demonstrate the ability of the auditor to conduct integrated audits.
3	Auditor qualification	1) Documented sign-off of the completed review of work experience, supervised audits, training and witness audit by the appointed supervisor of the CB indicating when the auditor became a qualified FSSC 22000-Quality auditor 2) Register auditor qualification details into the FSSC 22000 Auditor Database in accordance with instructions of the Foundation. 3) A plan for continued training in the sector(s) in which they perform audits in order to keep auditors current with respect to: a) Industry best practices, and b) Relevant regulatory and statutory developments. 4) Instructions for the auditor to maintain written records of all relevant training undertaken.
4	Maintenance of qualification	3) Competence and qualification of auditors shall be re-established every three (3) years. 4) The following to be re-evaluated prior to requalification: a) Attendance of at least one (1) training activity per year (such as training, conference meetings, seminars and/or network meetings) in order to keep up to date with the best practices and relevant regulatory and statutory developments in the sector(s) where audits are performed; b) Annual FSSC 22000 Scheme updates (based on the Harmonization Conference); c) A documented sign-off to re-establish the qualification of the auditor for the next three (3) years, per category; d) Annual review of the audits and training logs by a competent supervisor of the CB; e) Registrations to be updated and maintained into the FSSC 22000 auditor database.

END

Certificate of registration

The Food Safety Management System of

Name of Company

at
Site Address

has been assessed and determined to comply with
the requirements of

FSSC 22000
(Version 4 – January 2017)

Certification scheme for food safety management systems
consisting of the following elements:
ISO 22000:2005, "name of applicable technical specification for sector PRPs" and
additional FSSC 22000 requirements.

This certificate is applicable for:

Scope Statement
Food Chain Category

Certificate of registration No: *Certificate number*

Date of the certification decision:

Initial certification date:	Authorized by:
Reissuing date:	Position of signatory AB logo
Valid until:	

Issued by:
Name and address of certification body

Validity of this certificate can be verified in the
FSSC 22000 database of certified organizations available on www.fssc22000.com.

FSSC 22000

Certificate of registration

The Food Safety Management System of

Name of Company

at
Site Address

has been assessed and determined to comply with
the requirements of

FSSC 22000-Quality
(Version 4 – January 2017)

Certification scheme for food safety and quality management systems including
ISO 22000:2005, ISO 9001:2015, "name of the applicable technical specification for sector PRPs" and
additional FSSC 22000 requirements

This certificate is applicable for:

Scope statement
Food chain category

Certificate of registration No: *Certificate number*

Date of the certification decision:

Initial certification date: Authorized by:
Reissuing date: Position of signatory   AB logo
Valid until:

Issued by:
Name and address of certification body

Validity of this certificate can be verified in the
FSSC 22000 database of certified organizations available on www.fssc22000.com.