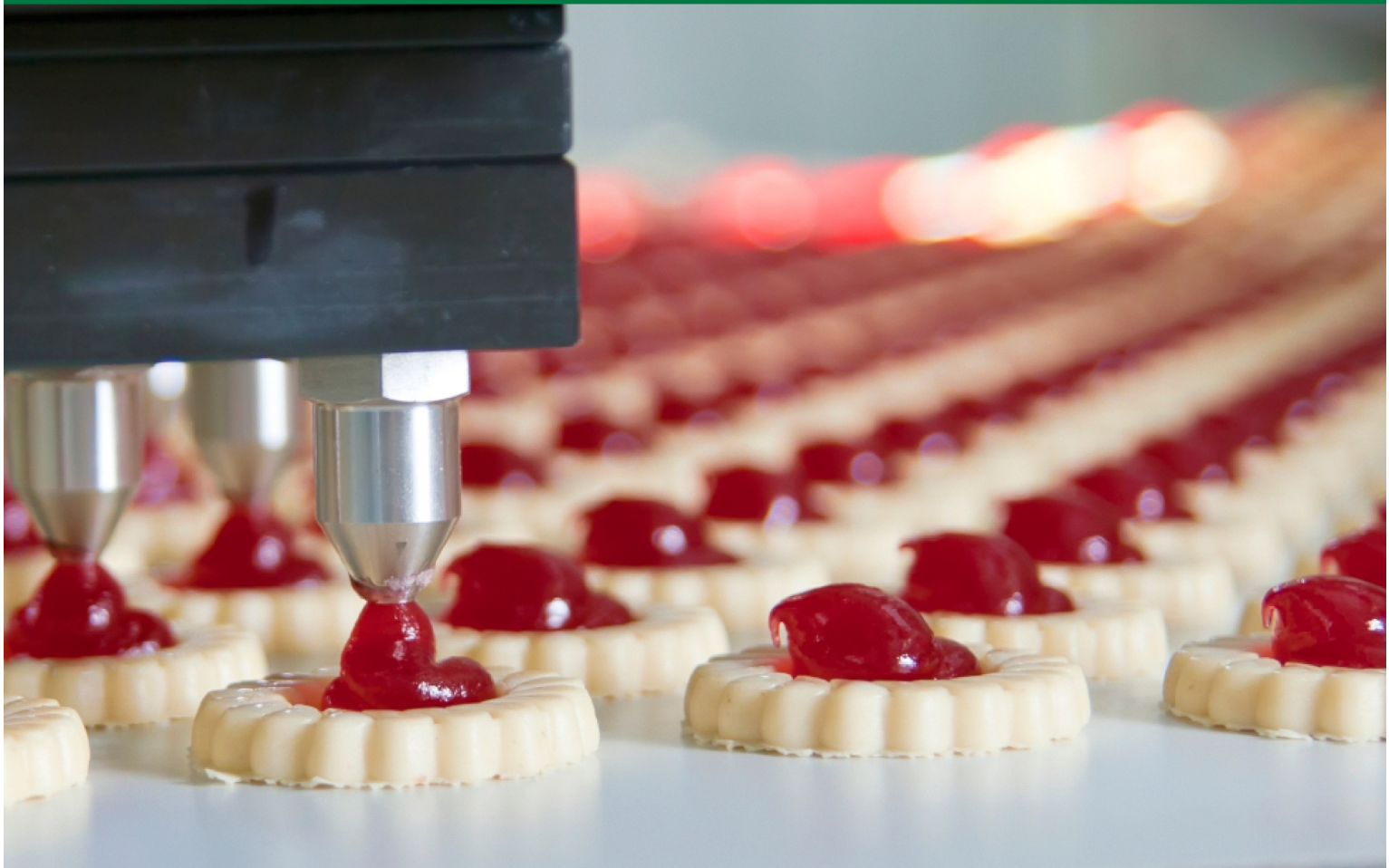




FOOD SAFETY SYSTEM CERTIFICATION 22000

Part III: Requirements for Certification Process



Version 4.1: July 2017

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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 and build on the requirements of ISO/IEC 17021-1 outlining the process requirements for audit and certification of management systems.

2 Application process

2.1 Certification body selection

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

- 1) It is recommended that the applicant organization conducts a self-assessment against the current version of the Scheme. The relevant ISO standards can be obtained from the ISO Store while the FSSC Additional Requirements are included in Part II and can be downloaded from the FSSC website.
- 2) 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

- 1) The CB will require completion of an official application form, signed by an authorized representative of the applicant organization.
- 2) 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.
- 3) The details shall include at least the following:
 - a) The proposed certification scope
 - b) The number of full-time equivalent (FTE) employees
 - c) Details of shifts
 - d) Number of HACCP studies
 - e) Details of other certified management systems (such as Dutch HACCP, ISO 22000 or ISO 9001) or GFSI recognized certification schemes
 - f) When applicable: information regarding organizations with off-site storage, separate head office and off-site activities (see Annex II of Part IV)
 - g) When applicable: details related to a request for a transfer audit from the CB currently awarding the certification
 - h) When applicable: details related to a request for a transition audit from Dutch HACCP, ISO 22000 or a GFSI recognized certification scheme to FSSC 22000 or FSSC-Quality.

2.4 Certification contract

A certification contract shall exist between the organization and the CB, detailing the scope of the certificate and referring to all relevant Scheme 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

- 1) 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.
- 2) The 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) The organization shall ensure that the relevant products and/or services and related processes for the scope of certification are in place and can be assessed during the audit.

3.2 Two stage audit process

- 1) 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.
- 2) 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

- 1) Surveillance audits shall assess and report on conformity with all Scheme requirements including the use of marks and references to certification.
- 2) At least one of the two annual surveillance audits shall be unannounced.
- 3) The audit program shall also consider the results of any previous audits including the unannounced audit(s).

- 4) If not all audit objectives are fulfilled during an unannounced audit, an additional audit shall be performed of which the nature shall be determined by the CB.

3.2.3 Recertification

- 1) The recertification audit must be planned and conducted in due time to enable timely renewal of the certificate before the expiry date.
- 2) The purpose of this audit is to confirm the continuing conformity of the food safety management system as a whole with all Scheme requirements.
- 3) The recertification activity also includes a review of the food safety management system over the whole period of certification, including previous surveillance audit reports and complaints received.
- 4) 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 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 to ensure compliance with the logo use requirements described in section 2.1.4.5 of Part II. 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 Dutch HACCP, ISO 22000 or a GFSI recognized certification 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 Dutch HACCP, ISO 22000 or a GFSI recognized scheme to FSSC 22000",
 - b) provide details of the previous audit 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, as specified in Part IV, Annex II.
- 3) The transition audit shall result in a new FSSC 22000 certificate with a regular validity of three (3) years.

5 Transition to FSSC 22000–Quality

- 1) When transitioning from ISO 9001 to FSSC 22000–Quality certification, a full stage 1 and 2 audit is not required to confirm compliance of the food quality 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 9001 to FSSC 22000-Quality",
 - b) provide details of the previous audit 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, as specified in Annex II of Part IV.
 - 3) The transition audit shall result in a new FSSC 22000-Quality certificate with a regular validity of three (3) years.

6 FSSC 22000–Quality certification

- 1) FSSC 22000-Quality certification is a voluntary addition to the Scheme documents. It integrates the requirements of the Scheme with ISO 9001 resulting in a combined FSSC 22000-Quality 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-Quality) 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.

7 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.

7.1 Notification

- 1) The organization shall report significant changes to the CB within three (3) working days as stipulated in the certification contract. These include changes relating to:
 - a) legal, commercial, organizational status or ownership,
 - b) organization and management (e.g. key managerial, decision-making or technical staff),
 - c) organization name, contact address and site details,
 - d) scope of operations and product categories covered by the certified management system,
 - e) management system and/or processes,
 - f) any other change that renders the information on the certificate inaccurate.
- 2) The organization shall seek the advice of the CB in cases where there is doubt over the significance of a change.

7.2 CB review

- 1) 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.
- 2) The CB decides also whether or not certification changes of scope shall be granted.
- 3) If granted, the current certificate will be replaced by a new certificate using the same expiry date as detailed in the original certificate.
- 4) The organization's entry in the FSSC 22000 Register of Certified Organizations will be updated accordingly.

8 Serious events

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

8.1 Reporting

- 1) The organization shall report serious events to the CB immediately and these include at a minimum:
 - a) legal proceedings, prosecutions and the outcomes of these related to food safety or legality,
 - b) public food safety events (such as e.g. public recalls, calamities, etc.)
 - c) extraordinary events which pose major threats to food safety or certification integrity such as war, strike, riot, political instability, geopolitical tension, terrorism, crime, pandemic, flood, earthquake, malicious computer hacking, other natural or man-made disasters.
- 2) The CB in turn will take appropriate steps to assess the situation and will take any appropriate action including additional verification activities.
- 3) These activities may have implications for the certified status of the organization.

8.2 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.

8.2.1 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:

- 1) this product shall be recalled from the market by the organization and
- 2) the organization shall inform the CB immediately.

8.2.2 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.

9 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.