FOOD SAFETY SYSTEM CERTIFICATION 22000

FSSC 22000

Certification scheme for food safety systems
in compliance with
ISO 22000: 2005 and technical specifications for sector PRPs

Features

Foundation for Food Safety Certification

Gorinchem, The Netherlands: 2013

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FOOD SAFETY SYSTEM CERTIFICATION 22000

Certification scheme for food safety systems in compliance with ISO 22000:2005 and technical specifications for sector PRPs

This document contains a complete certification scheme for food safety systems which are in compliance with the publicly available food safety management systems standard ISO 22000: 2005 'Requirements for any organisation in the food chain' and technical specifications for sector PRPs (published as e.g. PASxyz or ISO 22002-x documents)

As of February 2010 it is a Global Food Safety Initiative approved scheme. The scheme was re-benchmarked and recognized by GFSI again in February 2013 against Guidance Document version 6.

The Foundation for Food Safety Certification (here after the Foundation) retains the ownership and the copyright and the license agreements for certification bodies.

Due to the dynamic content of this document the user of this document should always verify if the correct version is held. Future revisions of this document will always be published under the same name.

In all cases the English version of the FSSC 22000 certification scheme is leading.

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CONTENT

INTRODUCTION

Food safety is a global concern, not only because of the importance for public health, but also because of its impact on international trade. Globalisation of food production and procurement makes food chains longer and more complex and increases the risk of food safety incidents. Effective and harmonized food safety systems shall manage and ensure the safety and suitability of food in each link of the supply chain. For this reason ISO developed the standard for food safety management systems ISO 22000, which applies to all organizations in the food chain and thus ensures integrity of the chain.

Parallel to this development there is an increasing need for harmonized certification of the food safety systems in order to create justified confidence that all necessary measures are taken to ensure food safety in previous links of the chain. In this context ISO developed the technical specification ISO/TS 22003 that contains requirements for bodies providing certification of the food safety management systems.

These developments were triggered by the increasing need of organizations in the food chain for a generally accepted food safety certificate that meets the requirements of the customers in the chain and may incorporate the requirements of the different certification schemes of the retail organizations.

As a follow up FoodDrinkEurope took the initiative to develop a technical specification that specifies the requirements for good practices in food manufacturing and that meets customer requirements. Implementation of these good practices is an essential part of the food safety system and creates confidence in trade. The British Standards Institution (BSI) issued these requirements as the publicly available specification BSI-PAS 220

As a next step FoodDrinkEurope initiated the development of a certification scheme for food safety systems of organizations in the food chain that incorporates the standards ISO 22000, BSI-PAS 220 and guidance on the application of ISO 22000, ISO/TS 22004. The aim of this scheme is to harmonize the certification requirements and methods for food safety systems in the food chain and to ensure the issue of trustworthy food safety certificates that are comparable as regards content and scope.

The Foundation was commissioned by FoodDrinkEurope to develop this scheme and retains the legal ownership and the license agreements for the certification bodies. In this text this certification scheme is referred to as the scheme. The scheme meets

the requirements of the guidance document of the Global Food Safety Initiative (GFSI).

In addition to the developments described above stakeholder organizations from other parts of the food supply chain have developed technical specifications covering requirements for PRPs for other parts of the supply chain. These technical specifications can be used in addition to ISO 22000 to provide further detail for chapter 7.2 of ISO 22000.

FSSC 22000 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 realized. FSSC 22000 follows the supply chain category description as defined in ISO/TS 22003. As the development of new technical specifications for sector PRPs is on going the actual scope of FSSC 22000 and the applicable technical specifications for sector PRPs are described in Part I, chapter 2: Scope.

Note: PAS 220, referred to in this introduction, has been replaced by ISO TS 22002-1: 2009. The PAS was withdrawn at the end of 2012. Requirements are consistent across the old and new documents, so certifications using the PAS remain valid until their scheduled recertification audit date, when they must be revised to quote the ISO document.

FEATURES OF THE SCHEME

Objective

This certification scheme outlines the requirements for certification bodies (CBs) to develop, implement and operate a system for the assessment and certification of food safety systems of organizations in the food chain and to guarantee its impartiality and competence. The certificate indicates that the organizations food safety system is in conformance with the requirements which are given in this scheme and that the organization is able to maintain conformance with these requirements. It is however not a guarantee of the organization continuous food safety performance. The value added to an organization with a certified food safety system lies in the efforts made by the organization to maintain that system and its commitment to continuously improve its performance.

Scope

This scheme is intended for the audit and certification of food safety systems, which ensure the safety of products during manufacturing of:

- perishable animal products (i.e. meat, poultry, eggs, dairy and fish products)
- perishable vegetal products (i.e. packaged fresh fruits and fresh juices, preserved fruits, packaged fresh vegetables, preserved vegetables)
- products with long shelf life at ambient temperature (i.e. canned products, biscuits, snacks, oil, drinking water, beverages, pasta, flour, sugar, salt)
- (bio)chemical manufacturing (food ingredients i.e. vitamins, additives and bio-cultures) but excluding technical and technological aids
- food packaging manufacturing (i.e direct, indirect contact with the food)

Note: transport and storage on site and as part of the operation are included (e.g. cheese ripening). It is applicable to all organizations in the food chain in these categories, regardless of size and complexity, whether profit-making or not and whether public or private.

Content and plan

The scheme consists of an introductory part and four separate parts in which requirements and/or regulations for the actors in the process of certification have been laid down. These actors are: the organization in the food chain, the certification body (CB), the accreditation body (AB) and the Board of Stakeholders (Board).

The introductory part contains a description of the scheme and information on the background, definitions and reference documents.

The three following main sections contain the normative documents for:

- the organization in the food chain (Part I),
- the CB (Part II) and
- the AB (Part III).

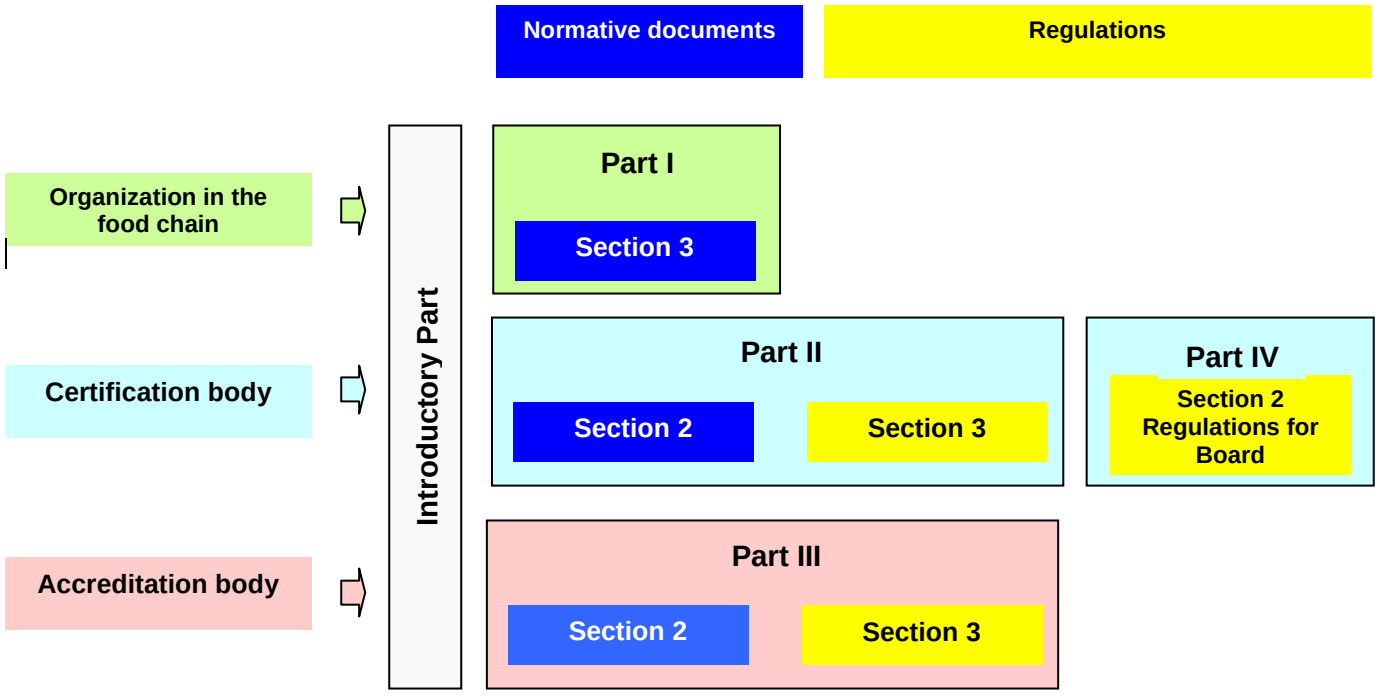
These normative documents are indicated in the scheme as "Requirements". Guidance on the application of these requirements is included if deemed necessary. Apart from this the main sections contain:

- guidance for the organization in the food chain to obtain and maintain a FSSC 22000 certificate (Part I),
- regulations of the Foundation concerning the conditions for the use of the scheme and for providing certification and accreditation by the CB and AB (Parts II and III)

Finally, Part IV contains the regulations for the Board which deals with the requirements and regulations of this scheme.

In figure 1 an outline of scheme is presented

Figure 1 - Plan of certification scheme FSSC 22000
NOTE: the figure does not show the guidance which is included in the normative documents



Development

This certification scheme has been developed by project teams and steering committees comprising of food safety experts of representative international organizations in the food chain, experts of a number of international certification bodies, a representative of the confederation of the food and drink industry of the EU and sector experts. The scheme is approved by and will be maintained by the Board of Stakeholders. Within the board the interests of all involved parties are represented.
As of February 2010 it is a Global Food Safety Initiative approved scheme. The scheme was re-benchmarked and recognized by GFSI again in February 2013 against Guidance Document version 6.

Board of Stakeholders

The Foundation aims to prepare a certification scheme, with a broad acceptance adding particular value to the relationship between the certified organization in the food chain and those around it (the government, customers). In order to achieve this, the Board of the Foundation consists of representatives of trade and industry, authorities and other parties concerned.

Maintenance and review

The Board has at least three meetings per year to maintain the certification scheme. During every meeting major and/or minor changes are decided on. These decisions will be directly published in a current list on the Foundation website. Revisions of all relevant documents of the scheme are published annually on the Foundation website and communicated with the licensed CBs and ABs. If the Board considers it necessary that requirements or regulations should be amended or added on shorter notice than one year, the Board can issue a directive that will be effective from a given date. These directives will be communicated with the licensed CBs and ABs and will be published on the Foundation website. The Board will have an overall review of the certification scheme at intervals not exceeding three years and any amendments arising from the review will be published by the Foundation and made available to all stakeholders.

Operation

By entering into an agreement with the Foundation accredited CBs are authorized to provide certification in accordance with this scheme. Accreditation shall be gained in conformance with this scheme by an associated AB that complies with the regulation for ABs (Part III). Licensed CBs are obliged to adhere strictly to this scheme.

REQUIREMENTS AND REGULATIONS

The requirements and regulations are included in the following parts and are attached to this document:

Part I – Requirements for organizations that require certification

Part II – Requirements and regulations for certification bodies

Part III – Requirements and regulations for providing accreditation

Part IV – Regulations for the Board of Stakeholders

LIST OF DECISIONS BY THE BOARD OF STAKEHOLDERS

In the list all decisions of the Board of Stakeholders are included. The decisions which affect the associated certification bodies as well as the certificate holders are an integral part of the requirements for certification. After every meeting of the Board an updated list is published on the website www.fssc22000.com.

REFERENCE DOCUMENTS

This scheme is based on the following documents and their future versions:

- GFSI Guidance Document, Sixth Edition, January 2011
- IAF Mandatory Document for duration of QMS and EMS audits; 2009 (Issue 1, IAF MD 5: 2009) and all other relevant IAF Mandatory Documents
- ISO 9001: 2008, Quality management systems – Requirements
- ISO 19011: 2202, Guidelines for quality and/or environmental management systems auditing
- ISO 22000: 2005, Food safety management systems – Requirements for any organisation in the food chain
- ISO/TS 22002-1: 2009, Prerequisite programmes for food safety. Where ISO/TS 22002-1 is stated, BSI-PAS 220 can be read
- ISO/TS 22003: 2007, Food safety management systems – Requirements for bodies providing audit and certification of food safety management systems
- ISO/TS 22004: 2005, Food safety management systems – Guidance on the application of ISO 22000: 2005
- ISO/IEC 17000: 2004, Conformity assessment – Vocabulary and general principles
- ISO/IEC 17011: 2004, Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies
- ISO/IEC 17021: 2011~~06~~, Conformity assessment – Requirements for bodies providing audit and certification of management systems
- ~~BSI-PAS 96: 2008, Defending food and drink – Guidance for the deterrence, detection and defeat of ideologically motivated and other forms of malicious attack on food and drink and their supply arrangements~~
- BSI-PAS 223: 2011, Prerequisite programmes and design requirements for food safety in the manufacture and provision of food packaging

TERMS AND DEFINITIONS

For the purpose of this document the terms and definitions given in the standards and technical specifications which are listed in the reference documents apply.

The following terms and definitions also apply:

- **Audit**: systematic, independent, documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled.

- **Board of Stakeholders or Board**: a group of representatives of key interests within the scope of the certification scheme including experts on food safety.

- **Certification system**: rules of procedure and management for carrying out conformity assessment leading to the issuance of a certification/registration document and its subsequent maintenance.

- **Certification scheme**: a set of requirements for the process of certification to certify conformance with a performance standard which is included or referred to in the scheme. Apart from the performance standard, the scheme may contain normative documents for the certification body and the accreditation body which certifies the certification body.

- **Food**: any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of "food" but does not include cosmetics or tobacco or substances used only as drugs

- **Food manufacturing,** also called food processing: The set of methods and techniques used to make food. Food manufacturing typically takes harvested crops or animal products and uses these to produce food for sale or delivery to the consumer and ingredients for food manufacturing.

- **Food processing**: see definition of food manufacturing.

- **Foundation**: the Foundation for Food Safety Certification.

- **General principles of food hygiene of the Codex Alimentarius**: recommended International code of practice - General principles of food hygiene, CAC/RCP

1-1969, Rev. 4 (2003) of the Joint FAO/WHO Codex Alimentarius Commission.

- **Guidelines for drinking-water quality of the WHO**: guidelines for drinking water quality, Third edition, Volume 1, Recommendations, WHO, Geneva 2008.

- **Major nonconformity**: a nonconformity, as referred to in ISO/IEC 17021 clause 9.1.15b, that:
  1) represents failure to fulfil one or more requirements of the management system standard or
  2) a situation that raises significant doubt about the clients system to achieve its intended outputs.

- **Minor nonconformity**: other nonconformities as indicated in ISO/IEC 17021, clause 9.1.15c.

- **Normative document**: normative documents are indicated in the scheme as 'Requirements'.

- **Organization in the food chain**: the party that is responsible for ensuring that products meet and, if applicable, continue to meet, the requirements on which the certification is based.

- **Periodically reviewed**: periodically reviewed includes minimum annually.

- **Standard**: a document against which something can be measured, judged or evaluated. "Document" is to be understood as any medium with information recorded on or in it.

- **Risk**: the probability of causing an adverse health effect caused by the likelihood of occurrence and by the possible severity of the adverse health effect of a particular hazard in food when prepared and consumed according to its intended use.

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PART I

REQUIREMENTS FOR ORGANIZATIONS THAT REQUIRE CERTIFICATION

Foundation for Food Safety Certification

Gorinchem, The Netherlands: 2013

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CONTENT

1. INTRODUCTION

Purpose

This part of the scheme contains the requirements for organizations in the food chain to gain certification. They shall be used by the organization to assess, develop, implement and improve its food safety system and to apply for certification. The requirements of the food safety system also serve as the normative requirements for certification of the organization. They shall as such be used by the certifying body to assess the continuous compliance of the food safety system that is developed and implemented by the organization. Guidance is also given to the CBs and the organizations on the application process for certification.

Food safety management and HACCP

For the greater part the requirements are based on the standard ISO 22000.
ISO 22000 was developed by the International Organization for Standardization (ISO) and fulfils the need of:

- a worldwide food safety standard that is developed and owned by an independent international organization;
- international harmonization of the requirements of food safety systems;
- integration of the technological (i.e. Good practices, HACCP, traceability) and legal food safety requirements in the quality management system requirements of standard ISO 9001;
- a food safety standard that is applicable to the whole supply chain and that requires any organization in the chain to take into account the hazards of the final product of the chain.

Based on this ISO 22000 is considered the most appropriate standard for the food safety management system to be included in this scheme.

Good manufacturing practices

An important prerequisite for ensuring food safety is that organizations in the food chain maintain the conditions for hygienic environment and production.
ISO 22000 requires in clause 7.2 that organizations shall select and implement specific “Prerequisite programmes” (PRPs) for these basic hygiene conditions and shall consider and utilize appropriate information when selecting the program (e.g. the requirements as prescribed in the General principles of food hygiene of the Codex Alimentarius, specific codes of practices of the Codex Alimentarius, food safety legislation and possible customer requirements). It 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 create explicitness on the requirements for PRPs and to allow for a benchmark of ISO 22000 certification schemes by customers (i.e. Global Food Safety Initiative of the Consumer Goods Forum (GFSI)). Stakeholder organizations have developed detailed technical specifications covering sector PRPs. These technical specifications can be used in addition to ISO 22000 to provide further detail for chapter 7.2 of ISO 22000. FSSC 22000 provides a certification scheme for sectors where such a technical specification for sector PRPs has been realised as described in the scope (see also chapter “Scope of the scheme”).

Additional requirements

To meet the needs of the key stakeholders and to ensure an adequate control of food safety, specific requirements for the food safety system are included in this scheme. These may be elaborations of the clauses in ISO 22000 and technical specifications for sector PRPs or additional requirements and are included in the section “Additional requirements” (Part I, Appendix IA). When it appears from the three year review of the scheme by the Board or when the Board decides in one of its three annual meetings that the requirements given in the standards need to be amended or appended, these changes are also included in this section.

2. SCOPE

The requirements in this document are set out for the assessment of food safety systems (see also chapter "Features of the scheme"):

Category codes ISO/TS 22003	Categories	Examples of sectors	Applicable PRP Technical Specification	Additional requirements
C	perishable animal products	i.e. meat, poultry, eggs, dairy and fish products	ISO/TS 22002-1	Appendix IA
D	perishable vegetal products	i.e. packed fresh fruits and fresh juices, preserved fruits, packaged fresh vegetables, preserved vegetables	ISO/TS 22002-1	Appendix IA
E	products with a long shelf life at ambient temperature	i.e. canned products, biscuits, snacks, oil, drinking water, beverages, pasta, flour, sugar, salt	ISO/TS 22002-1	Appendix IA
L	(bio)chemical manufacturing	food ingredients i.e. vitamins, additives, and bio-cultures but excluding technical and technological aids	ISO/TS 22002-1	Appendix IA
M	food packaging material manufacturing	i.e direct, indirect contact with the food	PAS 223	Appendix IA

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

3. REQUIREMENTS FOR THE FOOD SAFETY SYSTEM

3.1 Food safety management system

The requirements for the development, implementation and maintenance of the food safety management system are laid down in the standard ISO 22000: 2005 "Food Safety management systems – Requirements for any organization in the food chain".

3.2 Prerequisite programmes

When establishing, implementing and maintaining the Prerequisite programmes (PRPs) in accordance with clause 7.2 of ISO 22000, the organization shall in addition to ISO 22000 requirements consider and utilise the requirements of technical specification for sector PRPs. Apart from these requirements, other appropriate information shall be considered and utilised especially:

- regulatory requirements,
- recognized sector or product group codes of practices and guidelines,
- customer requirements.

The conditions of the PRPs shall be specified and documented, fully operational and verified in order to facilitate the successful application and implementation of an effective food safety management system. Exceptions where the requirements are not applicable shall be motivated in writing.

3.3 Additional requirements

Additional requirements for the food safety system are laid down in Part 1, Appendix IA.

3.4 Guidance

1. ISO/TS 22004

Guidance on the application of requirements of the food safety management system is provided for in the Technical Specification ISO/TS 22004.

***Reference**: ISO 22000, various clauses*

2. Definition food safety

In the requirements, food safety is defined as the concept that the food will not harm the consumer when it is prepared and/or eaten according to its intended use. Organizations in the chain are therefore required to take into account the food safety hazards of their operation for the final product in the chain when establishing prerequisite and HACCP programmes.

***Reference**: ISO 22000, clauses 3.1 and 3.3, note 4*

3. Chain approach

As is stated in chapter 2 of ISO/TS 22004, ISO 22000 promotes the adoption of a food chain approach when developing, implementing and improving the effectiveness and efficiency of a food safety management system. In this regard the organization is required to consider the effects of the food chain prior and subsequent to its operations when developing and implementing its food safety management system. However, some food safety hazards which originate in the food chain may not or cannot be controlled by the organization itself. In order to ensure that these hazards are also controlled, the organization shall identify organizations in the chain that may have an impact on the food safety of the products of the organization (upstream), of which the food safety of the operations may be affected by characteristics of the products of the organization (downstream). The organization shall than establish, implement and maintain effective arrangements for communication with these organizations, so that the relevant hazards are known and can be controlled. In section 5.6 of ISO/TS 22004, the requirements for external communication and arrangements with organizations in the chain are elaborated. The requirement for communication on food safety aspects and hazards in the chain is an essential criterion in the evaluation and selection of suppliers and relevant partners.

***Reference**: ISO 22000, clauses 1.d and 4.1.a and b*

4. Inventory of applicable regulations

It is pointed out that the organization in the food chain shall make an inventory of:

- the national, and if applicable foreign, regulatory and statutory requirements on food safety which are applicable to the organization and which should be implemented including the raw materials and services that are provided and products that are manufactured and delivered,
- applicable codes of practice related to food safety, customer requirements related to food safety, any other additional requirements on food safety determined by the organization.

The food safety system of the organization shall ensure and demonstrate conformity with these requirements

***Reference**: ISO 22000, clause 4.2.1, 5.6.1, 7.3.1 and 8.4.2*

5. Application for certification

Guidance on the process of the application for certification is given in Appendix I, B.

***Reference**: ISO/TS 22003, clause 9.2.1(information to be provided by the applicant organisation). ISO/IEC 17021, clause 5.1.2 (certification agreement), clause 8.6.1 (information to be provided by the CB), clause 8.6.1.d. (conditions to be included in the agreement), clause 9.2.1 (information to be provided by the applicant organisation,) clause 9.2.2.1 (review of application) and clause 9.5.1*

Note 1: the guidance in this section is a clarification of the requirements for the food safety system and of the application of these requirements and is informative.
Note 2: if the guidance refers to a subject that is addressed in one or more of the standards mentioned in the sections 3.1 and 3.2 of this part, the applicable clause(s) of these standard(s) is/are indicated in the reference at the end of the section with the guidance.

Appendix I A

ADDITIONAL REQUIREMENTS

1. Specifications for services

The organization in the food chain shall ensure that all services (including utilities, transport and maintenance) which are provided and may have an impact on food safety:

- shall have specified requirements,
- shall be described in documents to the extent needed to conduct hazard analysis,
- shall be managed in conformance with the requirements of technical specification for sector PRPs.

***Reference**: ISO 22000, clauses 7.2.3.f and 7.3.3*

2. Supervision of personnel in application of food safety principles

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.

***Reference**: ISO 22000, clause 6.2.2*

3. Specific regulatory requirements

Organizations seeking certification shall assure that specifications for ingredients and materials take account of any applicable regulatory requirements [e.g. control of prohibited substances].

4. Announced, but unscheduled audits of certified organisations

The certification body will participate in a risk based programme of office audits and announced, but unscheduled, audits of certified organisations. These audits shall be carried out in accordance to the GFSI requirements.

5. Management of Inputs

The organization shall implement a system to assure that analysis of inputs critical to the confirmation of product safety is undertaken. The analyses shall be performed to standards equivalent to those described in ISO 17025.

Note: If an additional requirement refers to a subject that also is addressed in one or more of the standards mentioned in the sections 3.1 and 3.2 of Part I, the applicable clause(s) of these standard(s) is/are indicated in the reference at the end of the section with the additional requirement.

Appendix I B

HOW TO APPLY FOR CERTIFICATION

Introduction

According to this scheme, organizations are certified upon completion of a satisfactory audit and a positive certification decision from a CB. The CB in turn shall have been assessed and judged as competent by an accreditation body. The process for accreditation of CBs and certification of organizations is outlined in Figure 1.

In order to receive a valid certificate, the organization shall select a CB which is approved and licensed by the Foundation. The Foundation stipulates detailed requirements that a CB shall meet in order to gain approval. As a minimum, the CB shall be accredited in accordance with the requirements and regulations in Part II of this scheme.

The certification process

Selection of certification body

It is essential that the organization is assessed against the current issue of the scheme and that the scheme is available throughout the certification process. The current issue of the scheme is available from www.fssc22000.com. The scheme should be read and understood and a preliminary self assessment shall be conducted by the organization against the requirements and guidance in the section 3 of Part I of this scheme. Any areas of nonconformities shall be addressed by the organization. Once the self-assessment has been completed and nonconformities addressed, the organization must select a CB. The Foundation cannot advise on the selection of a specific CB, but the Foundation lists FSSC 22000 approved certification bodies on www.fssc22000.com.

Certification agreement

A contract shall exist between the organization and the CB, detailing the agreed scope of the audit including reference to the FSSC 22000 scheme requirements. This contract shall be formulated by the CB. It is the responsibility of the organization to ensure that adequate and accurate information is given to the CB to enable the CB to select (an) auditor(s) with the required skills to undertake the audit (see Part II). The CB shall require completion of an official application form, signed by a duly authorized representative of the applicant.

Audit program, duration and costs

For the initial audit, the organization shall agree a mutually convenient date or dates, with due consideration given to the amount of work required to meet the requirements of the scheme. The organization shall provide the CB with appropriate information to allow them to review the application and to assess the duration and the costs of the audit. There is a requirement on the organization to plan 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. The initial certification is carried out at the premises of the organization and is conducted in two stages. In the first stage the documentation of the food safety system is evaluated which includes among others the scope of the food safety system, the food safety hazard analyses, the PRP programme, the managements structure, the policy of the organization etc. An important objective of this audit is to assess the preparedness of the organization for the audit. Any areas of concern that could be classified as nonconformity shall be resolved before the stage 2 audit.
In the stage 2 audit the implementation and effectiveness of the food safety system is evaluated.

Certification granted

The audit team of the CB shall analyse and review the findings of the stage 1 and stage 2 audit and report on the assessment. Nonconformities are pointed out and, where applicable, the effectiveness of the corrections and corrective action taken or planned by the organization. On the basis of this audit report and any other relevant information (e.g. comments of the organization on the audit report) the CB shall make a certification decision (see flow diagram).

A certificate shall only be granted if all nonconformities are resolved. In case of minor nonconformities the CB may grant certification if the organization has a plan for correction and corrective action. The certificate shall be issued by the CB typically within 30 calendar days after the CB has reviewed, accepted and verified the effectiveness of the corrections and corrective actions and the plans of the corrections and corrective actions for the revealed nonconformities. The users of the certificates are advised to verify that the scope of the certificate is clearly stated and this information is consistent with their own requirements. Whilst the certificate is issued to the organization, it remains the property of the CB which controls its ownership, use and display. The organization has the right to appeal the certification decision made by the CB in accordance with the documented appeal handling process of the CB.

Changes, scope extension

Once certification has been granted, any changes that may affect the fulfilment of the requirements for the certification shall immediately be communicated to the CB. This may be changes in the products or manufacturing processes that may require extension of the scope of the certification, in the management and ownership of the organization, the location etc. The CB will then conduct a site visit to examine the consequences and determine any audit activities necessary. The CB decides whether or not extension may be granted. If extension is granted the current certificate will be superseded by a new certificate using the same expiry dates as detailed in the original certificate.

Surveillance

The certificate expires three years after the date of issuance. In the intermediate period surveillance audits shall be conducted at least once a year. These audits shall address all scheme requirements from ISO 22000, relevant PRP documents and FSSC 22000 plus ~~including evaluation of internal audits and management review, review of actions taken on nonconformities identified in the previous audit, treatment of complaints, effectiveness of the management system, progress on continual improvement, operational control, review of changes and~~ use of marks and references to certification. Surveillance audits shall be carried out and reported as described in the scheme document "Guidance Notes on Surveillance Audits" which is available on the website.

In case a nonconformity is identified by the audit team, the CB shall take a decision continuation, suspension or withdrawal of the certificate depending on the corrections and corrective actions of the organization (see flow diagram).

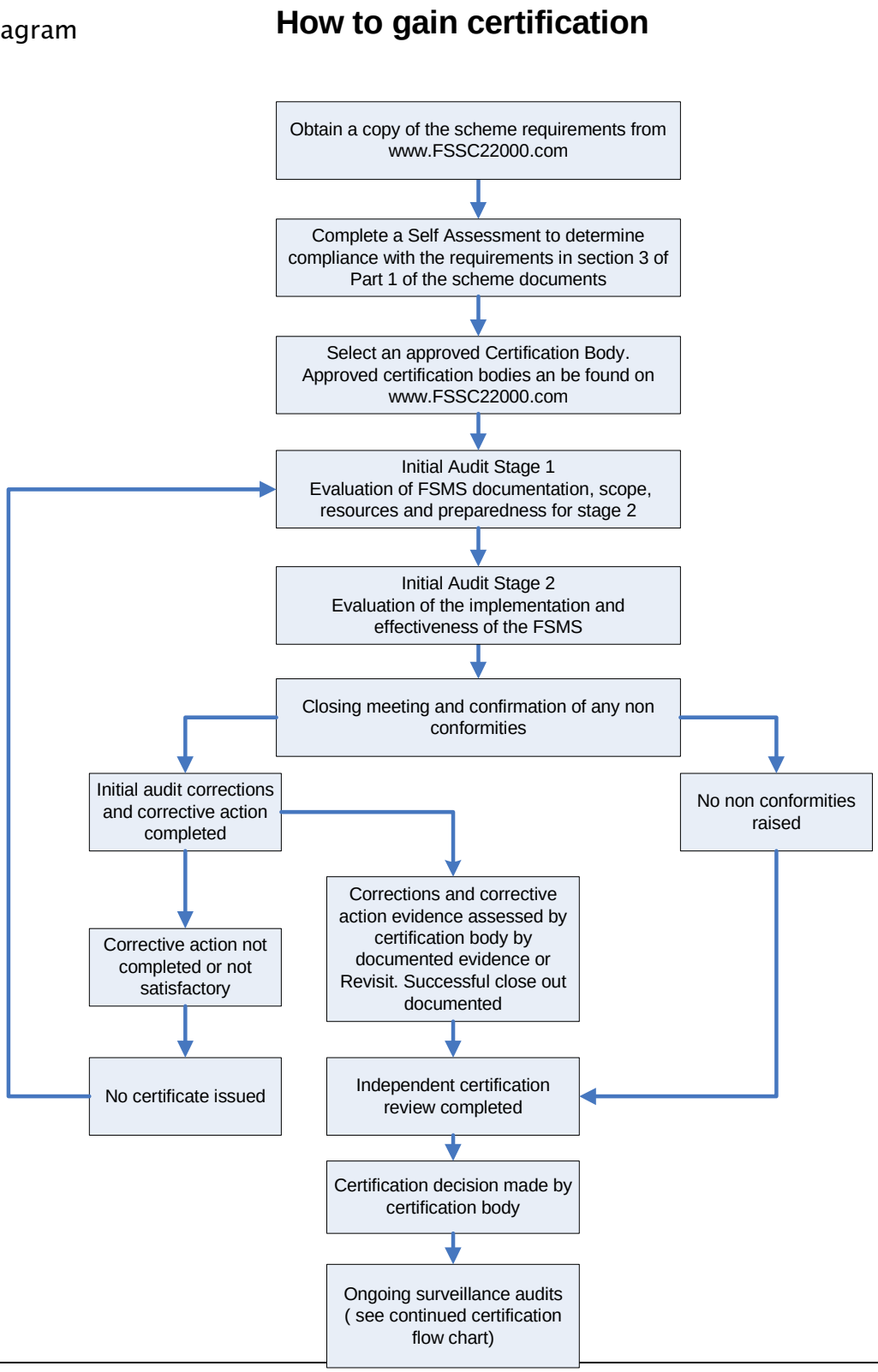
Recertification

Before the date of expiration of the certificate a recertification audit shall be conducted. The purpose of this audit is to confirm the continued conformity and effectiveness of the food safety system as a whole. The fulfilment of all requirements is evaluated. The audit also includes a review of the system over the whole period of certification, including previous surveillance audit reports. Identified nonconformities are dealt with as described in the surveillance audits. The CB makes a decision on renewing of the certification on the basis of the recertification audit, the review of the system over the whole period and complaints received from users of the certification.

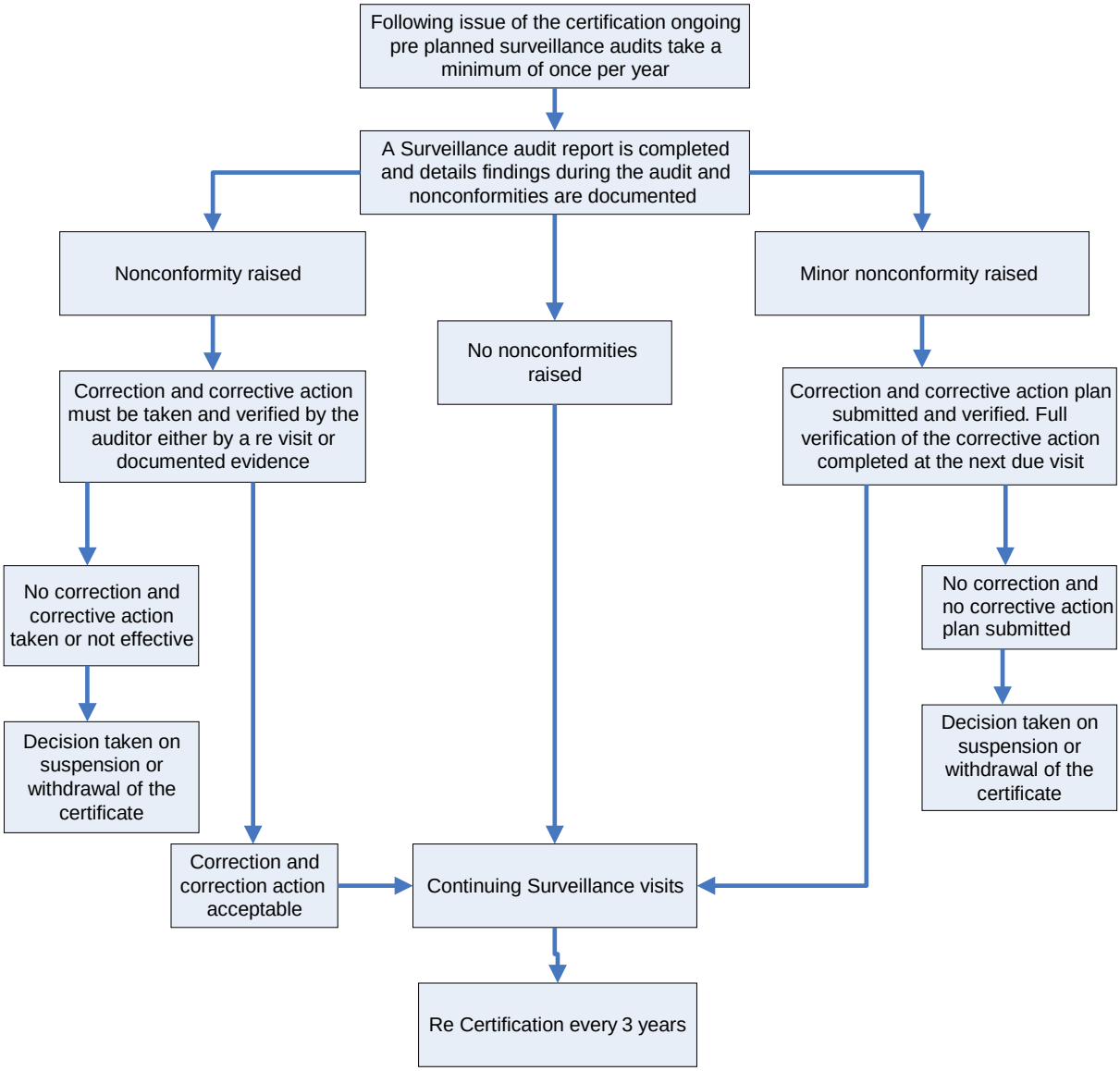
Communication with certification bodies

In the event that the organization becomes aware of legal proceedings with respect to product safety or legality, or in the event of a product recall, the organization shall immediately make the CB aware of the situation. The CB in turn shall take appropriate steps to assess the situation and any implications for the certification, and shall take any appropriate action.

Flow diagram



Surveillance Audits



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PART II

REQUIREMENTS AND REGULATIONS FOR CERTIFICATION BODIES

Foundation for Food Safety Certification

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CONTENT

1. INTRODUCTION

Purpose

This part of the scheme stipulates the requirements for certification bodies (CBs) and their personnel and the way they shall perform assessments and certification. It shall be used by the CB that wishes to grant certificates in conformance with this scheme. It consists of:

- the requirements for the CB and the certification process and
- the regulations and rules for the assignment and authorization of the CB to offer certification against the criteria of this scheme.

Standards and technical specifications

The normative requirements for the organization to gain certification are the food safety management system requirements of ISO 22000, the detailed requirements of technical specification for sector PRPs and a number of additional requirements as specified in section 3 of Part I.
Food safety management systems should, like other quality management systems, be certified by certification bodies that operate management system certification in a competent, consistent and impartial manner in accordance with ISO/IEC 17021 requirements for bodies providing audit and certification of management systems. To promote the harmonized certification of food safety management systems, ISO developed the Technical Specification ISO/TS 22003. This TS elaborates on ISO/IEC 17021 and contains additional requirements to be applied by certification bodies to make the food safety management system certification credible. Therefore, ISO/TS 22003 and ISO/IEC 17021 are considered to be the appropriate standards to apply for certification in accordance with this scheme.
The requirements for assessment and certification according to ISO/TS 22003 also includes the assessment of PRPs.

Additional requirements

To meet the needs of the key stakeholders and/or to ensure an adequate and uniform assessment and certification of the food safety systems, specific requirements for certification are included in this scheme. These may be elaborations of the clauses in ISO/TS 22003 and ISO/IEC 17021 or additional requirements and are included in the section “Additional requirements” (Part I, Appendix IA). When it appears from the review of the scheme by the Board or when the Board decides that the requirements need to be amended or appended, these changes are also included in this section.

2. REQUIREMENTS FOR CERTIFICATION

2.1 Requirements

Evaluation of conformance

The certification body shall take all steps required to evaluate conformance with the standard and fully comply with other associated requirements of the certification scheme.

Criteria for providing certification

The normative requirements for providing certification are specified in Part I, section 3.

2.2 Additional requirements

Additional requirements for the development and implementation of the certification system are specified in Appendix IIA.

The GFSI requirements as indicated in Appendix IIC are explicitly to be met. Future changes to this addendum will be valid. Most requirements in this addendum are in line with ISO/IEC 17021 requirements; others are explicitly included in this scheme. GFSI Requirements that are implicitly met by the scheme and ISO/IEC 17021, however may require attention to guarantee full accordance, are specified in the appendix.

2.3 Accreditation

The CB shall have an accreditation in the applicable Food Chain Category (ref. Part I, chapter 2: scope) according to ISO/IEC 17021 and the additional requirements as specified in the sections 2.1 and 2.2 and ISO/TS 22003.

The certification body shall ensure that accreditation is provided by an accreditation body meeting the requirements specified in Part III.

The CB shall inform the Foundation about the accreditation status and directly communicate suspensions or withdrawals of the relevant accreditations.

3. REGULATIONS FOR CERTIFICATION BODIES

Application

When applying for association with the Foundation, the certification body (CB) must specify the required category or categories and sector(s), related to its competence and experience. The applicant CB will agree to meet all applicable requirements of this scheme. The CB will be given written authorization enabling it to use the scheme for certification.

Accreditation

A contract with the CB will only be signed up after it has been accredited. The CB shall be accredited in accordance with the requirements of the scheme FSSC 22000. CBs which have applied for accreditation or for extension of their scope of accreditation to this scheme may certify within the applied scope for a maximum of one year without being accredited, subject to a provisional contract with the Foundation. The application for accreditation or for extension of their scope of accreditation shall be demonstrated with a written confirmation of the accreditation body (AB).

Application fee

An application fee has to be paid to the Foundation before this authorization will be given.

Design of the certificate

The design of the certificate will be similar to the certificates that are issued by the awarding CB. Notwithstanding this, the certificates shall include the following information:

- name and address of the organization (site) which food safety system is certified;
- period of validity; initial, reissue and valid until
- relevant signatures and positions of signatories;
- scope, expressed in terms of categories, sectors, production processes, products and sites;
- ~~logo of the accreditation body;~~
- date of the certification decision

Furthermore, the certificate shall contain the following standard text:
The food safety management system of (name and place) has been assessed and complies with the requirements of:

FOOD SAFETY SYSTEM CERTIFICATION 22000~~: 2010~~
Certification scheme for food safety systems
including
ISO 22000:2005, "name of applicable technical specification for sector PRPs"
and additional FSSC 22000 requirements

This certificate is applicable for (scope).
This certificate is provided on the base of the FSSC 22000 certification scheme, version 3, published 10 April 2013. The certification system consists of a minimum annual audit of the food safety management systems and a minimum annual verification of the PRP elements and additional requirements as included in the scheme and "name of applicable technical specification for sector PRPs".

Certification logo

Organizations may not display the FSSC 22000 certification logo or mention possession of a FSSC 22000 certificate on their products. The logo (copyright) is allowed to be used on the issued certificates if the certification is conducted in accordance with all requirements of this scheme.
Reference: Conditions for the use of the logo which can be found on the FSSC 22000 website.

Implementation of new requirements

In the event of the relevant documents in the FSSC 22000 scheme being changed, the Board will give an appropriate period of grace for the organizations to adapt to the implementation of the new requirements, unless the legal regulations stipulate a different transition period.

Changes in the certification scheme

New information or changes with regards to the requirements in the FSSC 22000 scheme shall be communicated by the CBs to those parties involved, such as certificate holders and auditors (auditors and experts), within a period of 2 months.

Appeals and complaints

The CB shall have arrangements for appeals and complaints. Clauses 9.7 and 9.8 of ISO/IEC 17021 apply.

Conflicts of interest

The certification body shall require all staff involved in the certification process to sign a contract or agreement which clearly commits them to:

I. Complying with the rules of the organization, with particular reference to confidentiality and independence from commercial or personal interests.

II. Declaring any issues in relation to personal conflicts of interests.

ISO/IEC 17021

The certification body shall clearly document and make known to its employees all requirements in ISO/IEC 17021 related to personnel.

Full application of the FSSC 22000 certification scheme

The certification bodies are responsible for the full application of the certification scheme and have to observe the regulations and directives issued by the Board.

Annual fee for certified organizations

Organizations certified against this scheme will be charged by the CB for an annual fee to the Foundation. The CB will address this obligation in the certification agreement with the organization. The Foundation will decide annually on the amount of this fee. The CBs will be charged at least annually by the Foundation for the total amount of fees of all certificates they have under contract per 31 December of each year.

Duration of certification

The maximum validity of the certificate is three years. Reassessment has to take place in time to ensure that recertification is granted before the expiry date of the certificate (clause 9.4 of ISO/IEC 17021).

Register of certified organizations

The Foundation will keep a register with the names and certification information of the certified organizations. This register will be made publicly available on the website of the Foundation. The CBs will submit the following information to the Foundation in a format as agreed in the contract between the Foundation and the CB:

- name and location of the certified organization
- scope of the certification
- date of the initial certification
- expiry date of the certificate

- in case of suspension or withdrawal; the date of suspension or withdrawal

This information shall be submitted by the CB to the Foundation within 42 ~~2~~ weeks after the delivery of the certificate. The CB shall agree in the certification agreement with the organization that this information will be submitted by the CB to the Foundation and this information will be made public.

Auditor registration system

The scheme owner shall have in place an auditor registration system for every scheme specific auditor employed by a certification body. The details of the auditor's qualifications, training, experience and scope of activity in relation to the scheme's product categorization shall be held and maintained within this register. The scheme owner will register approved auditors and shall ensure that the certification body has a system to update the auditors' details, where appropriate. The certification body shall register qualified auditors with the Foundation and update the register at least once per year.

Distribution of audit reports

The certification body shall provide a written report for each audit. The audit team may identify opportunities for improvement but shall not recommend specific solutions. Ownership of the audit report shall be maintained by the certification body. The content of audit reports is to be treated confidentially by the CB. At discretion of the contracted client audit reports may be made available to authorized parties~~, however the ownership of the audit report and determination of details made available and authorization for access remain with the contracted client~~.

Exchange of information

At least once per year, the CBs are obliged to provide the Board with all relevant information relating to the application and the functioning of the FSSC 22000 scheme. This information shall be made anonymous so that confidentiality with respect to organizations is assured.

Harmonization process

The CB is obliged to participate in consultations on the interpretation of the scheme. Once every year there will be a harmonization meeting. In principle a coordinating officer represents the CB during this meeting. Cases will be brought in for discussion. Each CB shall discuss the cases and the results in their own CB with their auditors. A regulation can be set up for the harmonization process.

Implementation of regulations

The CBs are required to ensure that the regulations which are decided by the Board are included in their existing system documentation within a period of two months. Certification bodies are required to control these documents according to their own document control procedures.

Noncompliance with FSSC Scheme Requirements

In cases where a CB fails to comply with the requirements set out in the scheme documents, detailed information will be gathered for review by the Board of Stakeholders. The review will normally take place at the next scheduled BoS meeting. If the nonconformance is of a serious nature, the secretary may request a special meeting to deal with matter. The BoS will determine appropriate measures to be taken to deal with the nonconformity.

The Board of Stakeholders approved these regulations in April 2013.

Appendix II A1

Additional requirements

Note: if an additional requirement refers to a subject that is also addressed in one or more of the standards mentioned in section 2.1 of Part II, the applicable clause(s) of these standard(s) is/are indicated in the reference at the end of the section with the additional requirement.

1. Work experience of auditors

Concerning the requirements on work experience of the auditors in ISO/TS 22003, clause 7.2.~~4~~2.4, the following is added:

- ~~The five years full time work experience in a food chain related industry, shall be in the food related industry in the areas of processing, technology, raw materials and /or products;~~
- ~~The two years of full time work in quality assurance or food safety functions shall be in the food related industry;~~
- The allowance to reduce the required five years of total work experience by one year if the auditor has completed appropriate post secondary education, is not applicable;
- The competence of auditors shall be reestablished every 3 years.

***Reference**: ISO/TS 22003 clause 7.2.4.4 ~~and ISO 19011 clause 7.3.2~~*

2. Auditor training

Training program

A training program for each auditor will incorporate:

- an assessment of knowledge and skills for each field and sub field and assignment of fields of evaluation;
- an assessment of knowledge of food safety, HACCP, PRP's and to have access to, and be able to apply relevant laws, regulations and codes;
- a period of supervised training to cover the assessment of food safety management systems, PRPs and HACCP, specific audit techniques and specific category knowledge;
- for extension of auditor scope for new categories the requirements of ISO/TS 22003, clause 7.2.4.5 apply;
- a documented sign off of the satisfactory completion of the training program by the appointed supervisor;
- a plan for continued training to keep the auditors up to date with the best practices and relevant regulatory and statutory developments in the sector(s) where they perform audits. In order to maintain category and scheme knowledge, auditors shall be required to carry out a minimum of 5 on-site

GFSI Recognized audits at different organizations each year;
- instructions for the auditor to maintain written records of all relevant training undertaken.

***Reference**: ISO/TS 22003, clause 7.2.4.5 and ISO/IEC 17021, clause 7.2.8*

Food safety training

The training in HACCP principles, hazard assessment and hazard analysis shall have a duration of at least 2 days/16 h. The food safety management training shall also include specific elements of the sector(s) in which the auditor conduct audits like raw materials, processes, products, risks and legislation and prevailing code(s) of hygiene.

***Reference**: ISO/TS 22003, clause 7.2.4.2*

Audit training

The training prescribed in section 7.2.4.3 of ISO/TS 22003 shall also cover:

- audit techniques for food safety systems as described in Part I of this scheme;
- the content of this scheme including the standards and technical specification to which is referred.

The training in audit techniques shall have a duration of at least 1 week/40h.

***Reference**: ISO/TS 22003, clauses 7.2.6 and 7.2.4.3*

3. Audit experience

For qualification the requirements of ISO/TS 22003 apply.

In addition to ISO/TS 22003 auditors need to have knowledge of the delivery requirements of FSSC and knowledge of the content of the technical specification for sector PRPs. The certification body shall define how to ensure that this requirement is met.

The total supervised training against this scheme shall include a successful completion of supervised training in practical assessment of this standard through 10 audits or 15 audit days at a number of different organizations.

Previous experience in ISO 22000 and/or GFSI recognized audits is considered to be applicable for meeting the practical assessment training requirements.

Reference: *ISO/TS 22003, clause 7.2.4.5*

4. Defining the scope of the certification

When defining the scope, the CB shall indicate for each location the name of the food chain category and the specific sector as specified in Annex A of ISO/TS 22003 and clause 2 of Part 1.

***Reference**: ISO/TS 22003, clause 9.1.1 and FSSC 22000 guidance document on certification scopes.*

5. Duration of audit and audit reporting

In addition to the onsite audit time and preparation and reporting time as stipulated in ISO/TS 22003, clause 9.1.4. and Annex B, the CB shall depending of the size of the organization add half to one day for the audit and reporting of the establishment and implementation of the PRPs as stipulated in section 6 of this appendix. This additional time is as well required for an initial, surveillance and renewal audit. Details of the duration of the audit shall be incorporated In the audit report.
***Reference**: ISO/TS 22003, clauses 9.1.2 and 9.1.4 and Annex B*

6. Requirements for audit of PRPs

The CB shall assess whether the organization has established and implemented and maintains the necessary PRPs according to the requirements of section 3.2 of Part I. Of all requirements it shall be assessed to what extent the requirements are fulfilled. The specific requirements for which the necessary PRP is not established or is not effective in controlling the introduction of food safety hazards (as specified in clause 7.2.1 of ISO 22000) shall be identified. In order to verify if the PRPs are met a plant tour shall be part of the audit.

***Reference**: ISO/TS 22003 clauses 9.2.3.1.1 and 9.2.3.1.2, 9.2.3.1.4, 9.2.3.1.5 and 9.2.3.2*

7. Requirements for the audit reports

General

Additional to the items for the audit and certification reports as stipulated in ISO/TS 22003, clauses 9.1.7 and ISO/IEC17021, clauses 8.2.3, 9.2.3.1.2, the audit and certification report shall identify the following:

- Name and description of the company to which the organization belongs (name, legal entity and address of headquarters);
- Date of previous audit and name of CB conducting the previous audit
- Details of existing certificates;
- Overview of relevant changes to documentation, requirements, processes and products since the last audit;
- Registered complaints on Food Safety and reports to concerning government;
- List of key personnel present at the audit;
- Evidence that the client representative has seen the report and has accepted any NCs raised and provided an appropriate response;.~~Names and signatures of the audit team members;~~
- ~~Names, function and signatures of the representatives of the auditee;~~
- Description of the assessment of the identification by the organization of the food safety hazards to be controlled and the selection of the appropriate (combinations of) control measures for relevant hazards in the operational

PRPs or in the HACCP plan;

- The audit of the PRP requirements (specified in Part I, section 3.2) shall be reported separately according to the requirements in section 8 "Audit report of PRPs" in this Annex and attached to the audit report;
- Results and the conclusions of the audit per clause of the normative standard or technical specification (specified in Part I, section 3.1) and per additional requirement (specified in Part I, section 3.3);
- Overview of nonconformities and minor nonconformities together with the corresponding clause number of the normative standard or technical specification (specified in Part I, section 3.1 and 3.2) or the number of the additional requirement (specified in Part I, section 3.3);
- Expiry date of the certificate.

The Board may decide on more specific requirements for reporting.

In the result section of the report conformance of compliance or noncompliance shall be indicated. In case of nonconformance details shall be provided. Non applicable clauses shall be motivated. In the summary section positive evidence of confirming compliance shall be provided.

***Reference**: ISO/TS 22003, clauses 8, 9.1.7 and 9.2.3.1.4 and ISO/IEC 17021, clauses 8.2.3, 9.2.3.1.2 and 9.2.5.1*

Audit report format

The audit report shall cover all elements described in the format as indicated in Part II, appendix IIB (ISO 22000, PRPs and additional requirements) in order to confirm that all requirements are assessed and reported.

8. Criteria for nonconformities and certification decision

The CB is required to establish and maintain criteria as a reference against which a nonconformity and minor nonconformity is determined, in accordance with the definitions in this scheme.

Food organizations can only qualify for granting certification on the basis of this scheme if:

- the CB has not revealed any outstanding nonconformities and
- the CB has reviewed and accepted the planned corrections and corrective actions for minor nonconformities.

***Reference**: ISO/IEC17021, clause 9.1.9, 9.1.15 and 9.2.5.2 and ISO 19011, clause 6.2.2.*

9. Requirements for initial certification

Stage 1 includes all requirements of 9.2 of ISO/TS 22003 and shall be performed at the client premises in order to evaluate the preparedness of the organization for stage 2. During the initial certification audit (stage 1 and 2) all requirements of this scheme shall be evaluated. This includes ISO 22000, the applicable technical specification for sector PRPs and additional FSSC requirements (clause 3.3 of Part I). Stage 2 includes a comprehensive site tour and shall cover a representative number of product lines, categories and sectors covered by the scope. The site tour shall include the review of implementation of all CCP's and Operational PRP's and shall include a representative sampling of the PRP's. The tour shall include all areas that might influence food safety. Where comparable activities / processes take place it is allowed to sample.

***Reference**: ISO/TS 22003, clause 9.1.2*

10. Requirements of the surveillance audits

During the surveillance activities and surveillance audit all scheme requirements from ISO 22000, relevant PRP documents and FSSC 22000 ~~the effectiveness of the food safety management system and the compliance with the requirements of ISO 22000, technical specification for sector PRPs and the additional requirements of this scheme (section 3.3 of Part 1)~~ will be reviewed. Surveillance audits shall be carried out and reported as described in the scheme document "Guidance Notes on Surveillance Audits" which is available on the website. ~~This shall include an examination of the food safety management system documentation on the registration of changes and of the internal communication of changes in the production process, the (origin of) raw materials, the products and product characteristics or in the context in which the food safety system is operating (e.g. changes in legislation, codes of practices, customer requirements) in the period after the previous audit. If any changes are identified by this examination or otherwise, the surveillance audit shall include a full assessment and reporting of the assessment of:~~

- ~~the documentation requirements, specifically clauses 4.2.1. and 7.3.1 of ISO 22000 and clause 1 of Section 3.3 (Appendix I A) of Part I of this scheme;~~
- ~~the establishment and implementation of the PRPs;~~
- ~~the hazard analysis and the operational PRPs and CCPs.~~

~~During surveillance audits it is allowed to sample activities and a number of product lines, categories and sectors covered by the scope. The sampling shall result in a representative review of the scheme implementation.~~

***Reference**: ISO/IEC 17021, clauses 9.3.*

11. Notification of factors affecting the certification

The CB shall have arrangements in place with certified organizations for the timely notification in the event that the organization becomes aware of legal proceedings with respect to product safety or legality, or in the event of a product recall. The organization shall immediately, at least within 3 working days, make the CB aware of the situation. The CB in turn shall take appropriate steps to assess the situation and any implications for the certification, and shall take any appropriate action. The CB shall have procedures in place to ensure the integrity of certification following such notification.

12. Requirements for additional audits

The CB shall undertake additional surveillance audits in the event that there is evidence or suspicion of nonconformity within the certified organization.

13. Requirements for recertification

All requirements given in ISO/IEC 17021 clause 9.4 apply. The recertification shall include a full assessment and reporting of all requirements ~~(see Part II, chapter 9)~~.

14. Risk based office audits

The CB will participate in a risk based programme of office audits and announced, but unscheduled, audits of certified organisations. These audits shall be carried out in accordance to the GFSI requirements.

Appendix II A2

Additional requirements Packaging

1. Auditor competence

A primary qualification, a degree or higher certificate in packaging technology and a relevant certificate recognised by the scheme owner in food technology, food hygiene or related science subject OR a primary qualification in food technology, food safety/ hygiene or related science subject and a certificate in packaging technology that is recognised by the scheme owner. Experience is required in the specific sectors of packaging manufacture:

- plastics
- paper and board
- metal
- glass.

Food auditor with a packaging certificate
A primary qualification in food technology, food safety/ hygiene or related science subject and a certificate in packaging technology that is recognised by the scheme owner. The training organization needs to demonstrate to the Foundation that the training (live or on-line) is delivered by a WPO recognized training organization (including post-training examination) which include the following minimum requirements which have to be verified by the CBs:

a. Basics of Packaging Principles & Concepts
b. Packaging Legislation, Standards and Regulations
c. Packaging Materials (Plastics, Paper & Board, Metal, Glass) Manufacturing
d. Specifics to Packaging of Food Products – Food related Hazards
e. Quality / Food Safety Control and Testing
f. Printing Processes and Printing Inks
g. Packaging Recycling
h. Design of Packaging Materials

Auditor with packaging certificate and food experience/knowledge
A primary qualification, a degree or higher certificate in packaging technology and a relevant certificate recognised by the scheme owner (the Foundation) in food technology, food hygiene or related science subject.

FSSC Food Packaging auditor

- Meeting requirements for and qualified as FSSC food auditor;
- Meeting requirements for ISO 22000 auditor for food supply chain category M (reference ISO 22003);
- Has a minimum of 30 hours education in Food Packaging Material technology, potentially being part of the primary or secondary Food Technology education.

Records are available showing the training covers for the applicable Packaging Material Type as minimum the knowledge and understanding of:

  - Characteristics of raw materials, intermediate and finished packaging materials;
  - The intended use of Packaging Materials and related hazards and risks;
  - Packaging Material production processes and supporting processes;
  - Applicable potential food safety hazards, PRP's, (see also FSSC Packaging Auditor requirements on PAS 223), CCP's and OPRP's;

- Has worked for a minimum of 4 years in a food company producing also producing packaging material in a food safety related function.

The qualification is allocated per Food Packaging Material type (glass, metal, plastic, wood) and the described training and experience shall be specific for these packaging material types.

2. Design and development processes

If applicable, design and development processes have to be clearly described in the scope and on the issued certificate.

Appendix II B

Format of the audit report

***Reference**: ISO/TS 22003, clauses 8, 9.1.7 and 9.2.3.1.4 and ISO/IEC 17021, clauses 8.2.3, 9.2.3.1.2 and 9.2.5.1*

General information

For the requirements for general information in the audit report see ISO/IEC 17021, clause 8.2.3 and relevant items Appendix II A, section 7 "Requirements for the audit reports" In the audit report of PRPs reference can be made to corresponding information in the main audit report.

Appendix IIB1

ISO 22000 Food Safety Management Systems, requirements for organizations throughout the food chain

Client name:		Client address:		
Date:		Assessor:		
	Reference: ISO 22000	Conformance		Remarks
		Yes	No	
	Provide a summary for each ISO 22000 requirement below			
4	*Food Safety Management System*			
	Summary*:*			
4.1	*General requirements*			
4.2	*Documentation requirements*			
5	*Management responsibility*			
	Summary*:*			
5.1	*Management commitment*			
5.2	*Food safety policy*			

5.3	*Food safety management system planning*			
5.4	*Responsibility and authority*			
5.5	*Food safety team leader*			
5.6	*Communication*			
5.7	*Emergency preparedness and response*			
5.8	*Management review*			
6	*Resource management*			
	Summary*:*			
6.1	*Provision of resources*			
6.2	*Human resources*			
6.3	*Infrastructure*			
6.4	*Work environment*			
7	*Planning and realization of safe products*			
	Summary*:*			
7.1	*General*			
7.2	*Prerequisite programmes (PRP's)*			
7.3	*Preliminary steps to enable hazard analysis*			
7.4	*Hazard analysis*			
7.5	*Establishing the operational PRP's*			
7.6	*Establishing the HACCP plan*			
7.7	*Updating of preliminary information and documents specifying the PRP's and the HACCP Plan*			
7.8	*Verification planning*			
7.9	*Traceability system*			
7.10	*Control of nonconformity*			

8	*Validation, verification and improvement of the FSMS*			
	Summary*:*			
8.1	*General*			
8.2	*Validation of control measure combinations*			
8.3	*Control of monitoring and measuring*			
8.4	*Food safety management system verification*			
8.5	*Improvement*			

Appendix IIB2

Results and conclusion of the audit of PRPs

Information on assessment per item.

The number of the items refer to the sections of the applicable technical specification for sector PRPs. For each item shall be referred to the requirements of technical specification for sector PRPs and to the requirements of applicable legislation, recognized sector codes and customer requirements.

+ = assessed; OK – = assessed; nonconformity or minor nonconformity. Indicate: NC = nonconformity MNC = minor nonconformity NA = not applicable	Result	Identification of specific requirement which is not fulfilled	Details of NC or MNC

Appendix IIB2.1: ~~BSI-PAS 220~~ ISO/TS 22002-1

4. Construction and layout of buildings			
4.1 General requirements			
4.2 Environment			
4.3 Locations of establishments			
Summary Construction and layout of buildings:			

5. Layout of premises workspace			
5.1General requirements			
5.2 Internal design, layout and traffic patterns			
5.3 Internal structures and fittings			
5.4 Location of equipment			
5.5 Laboratory facilities			
5.6 Temporary/mobile premises and vending machines			
5.7 Storage of food, packaging materials, ingredients and non			

food chemicals			
Summary Layout of premises workspace:			

6. Utilities – air, water, energy			
6.1 General requirements			
6.2 Water supply			
6.3 Boiler chemicals			
6.4 Air quality and ventilation			
6.5 Compressed air and other gases			
6.6 Lighting			
Summary Utilities – air, water, energy:			

7. Waste disposal			
7.1 General requirements			
7.2 Containers for waste and inedible or hazardous substances			
7.3 Waste management and removal			
7.4 Drains and drainage			
Summary Waste disposal:			

8. Equipment suitability, cleaning and maintenance			
8.1 General requirements			
8.2 Hygienic design			
8.3 Product contact surfaces			
8.4 Temperature control and monitoring equipment			
8.5 Cleaning plant, utensils and equipment			
8.6 Preventive and corrective maintenance			
Summary Equipment suitability, cleaning and maintenance:			

9. Management of purchased materials			
9.1 General requirements			
9.2 Selection and management of suppliers			
9.3 Incoming material requirements (raw/ingredients/packaging)			
Summary Management of purchased materials:			

10. Measures for prevention of cross contamination			
10.1 General requirements			
10.2 Microbiological cross contamination			
10.3 Allergen management			
10.4 Physical contamination			
Summary Measures for prevention of cross contamination:			

11. Cleaning and sanitizing			
11.1 General requirements			
11.2 Cleaning and sanitizing agents and tools			
11.3 cleaning and sanitizing programmes			
11.4 Cleaning in place (CIP) systems			
11.5 Monitoring sanitation effectiveness			
Summary Cleaning and sanitizing:			

12. Pest control			
12.1 General requirements			
12.2 Pest control programmes			
12.3 Preventing access			
12.4 Harbourage and infestations			
12.5 Monitoring and detection			
12.6 Eradication			
Summary Pest control:			

13. Personnel hygiene and employee facilities			
13.1 General requirements			
13.2 Personnel hygiene facilities and toilets			
13.3 Staff canteens and designated eating areas			
13.4 Workwear and protective clothing			
13.5 Health status			
13.6 Illness and injuries			
13.7 Personal cleanliness			
13.8 Personal behaviour			
~~13.9 Visitors~~			
Summary Personnel hygiene and employee facilities:			

14. Rework			
14.1 General requirements			
14.2 Storage. identification and traceability			
14.3 Rework usage			
Summary Rework:			

15. Product recall procedures			
15.1 General requirements			
15.2 Product recall requirements			
Summary Product recall procedures:			

16. Warehousing			
16.1 General requirements			
16.2 Warehousing requirements			
16.3 Vehicles, conveyances and containers			
Summary Warehousing:			

17. Product information/consumer awareness			
~~17.1 Product information~~			
~~17.2 Labelling of pre-packaged foods~~			
Summary Product information/consumer awareness:			

18. Food defence, biovigilance and bioterrorism			
18.1 General requirements			
18.2 Access controls			
Summary Food defence, biovigilance and bioterrorism:			

Other items required by applicable legislation, recognized sector codes and customer requirements.			

Appendix IIB2.2: BSI-PAS 223

4. Establishments			
4.1 General requirements			
4.2 Environment			
4.3 Locations of establishments			
Summary Establishments:			

5. Layout and workspace			
5.1 General requirements			
5.2 Internal design, layout and traffic patterns			
5.3 Internal structures and fittings			
5.4 Equipment			
5.5 Temporary/mobile structures			
5.6 Storage			
Summary Layout and workspace:			

6. Utilities			
6.1 General requirements			
6.2 Water supply			
6.4 Air quality and ventilation			
6.5 Compressed air and other gases			
6.6 Lighting			
Summary Utilities:			

7. Waste			
7.1 General requirements			
7.2 Containers for waste			
7.3 Waste management and			

removal			
7.4 Drains and drainage			
Summary Waste:			

8. Equipment suitability and maintenance			
8.1 General requirements			
8.2 Hygienic design			
8.3 Food packaging contact surfaces			
8.4 Testing and monitoring			
8.5 Preventive and corrective maintenance			
Summary Equipment suitability and maintenance:			

9. Purchased materials and services			
9.1 General requirements			
9.2 Selection and management of suppliers			
9.3 Incoming raw materials			
Summary Purchased materials and services:			

10. Contamination and migration			
10.1 General requirements			
10.2 Microbiological contamination			
10.3 Physical contamination			
10.4 Chemical contamination			
10.5 Chemical migration			
10.6 Allergen management			
Summary Contamination and migration:			

11. Cleaning			
11.1 General requirements			
11.2 Cleaning agents and tools			
11.3 Cleaning programmes			
11.4 Monitoring cleaning programme effectiveness			
Summary Cleaning:			

12. Pest control			
12.1 General requirements			
12.2 Pest control programmes			
12.3 Preventing access			
12.4 Harbourage and infestations			
12.5 Monitoring and detection			
12.6 Eradication			
Summary Pest control:			

13. Personnel hygiene and facilities			
13.1 General requirements			
13.2 Personnel hygiene facilities and toilets			
13.3 Staff canteens and designated eating areas			
13.4 Workwear and protective clothing			
13.5 Illness and injuries			
13.6 Personal cleanliness			
13.7 Personal behaviour			
~~13.8 Visitors~~			
Summary Personnel hygiene and facilities:			

14. Rework			
14.1 General requirements			
14.2 Storage identification and traceability			
14.3 Rework usage			
Summary Rework:			

15. Withdrawal procedures			
15.1 General requirements			
15.2 Withdrawal requirements			
Summary Withdrawal procedures:			

16. Storage and transport			
16.1 General requirements			
16.2 Warehousing requirements			
16.3 Vehicles, conveyances and containers			
Summary Storage and transport:			

17. Food packaging information and consumer awareness			
17.1 General requirements			
Summary Food packaging information and consumer awareness:			

18. Food defence, biovigilance and bioterrorism			
18.1 General requirements			
18.2 Access controls			
Summary Food defence, biovigilance and bioterrorism:			

19. Food packaging design and development			
19.1 General requirements			
19.2 Communication and change control			
19.3 Design			
19.4 Specifications			
19.5 Process validation			
Summary Food packaging design and development:			

Other items required by applicable legislation, recognized sector codes and customer requirements.			

Appendix IIB3

Additional FSSC 22000 requirements

Section	Reference: FSSC part 1 appendix 1A	Conformance		Remarks
		Yes	No	
~~1~~	~~*Inventory of applicable regulations*~~ ~~*The food manufacturing organisation shall have an inventory of:*~~			
~~1.1~~	~~The national and, if applicable foreign, regulatory and statutory requirements on food safety which are applicable to the organisation and which should be implemented including the raw materials and services that are provided and products that are manufactured and delivered~~			
~~1.2~~	~~Applicable codes of practice related to food safety, customer requirements related to food safety, any other additional requirements on food safety determined by the organisation.~~			
~~1.3~~	~~The food safety system shall ensure and demonstrate conformity with these requirements~~			
~~2~~1	Specifications for services The organization shall ensure that all services (including utilities, transport and maintenance) which are provided and may have an impact on food safety.			
~~2~~1.1	Shall have specified requirements.			
~~2~~1.2	Shall be described in documents to the extent needed to conduct hazard analysis.			
~~2~~1.3	Shall be managed in conformance with the requirements of technical specification for sector PRPs.			

~~3~~2		Supervision of personnel in application food safety principles.			
~~3~~2.1		The organization shall ensure the effective supervision of personnel in the correct application of food safety principles and practices commensurate with their activity.			
3		Specific regulatory requirements[1]			
4		Management of inputs[2]			

[1] See Appendix 1A, item 3
[2] See Appendix 1A, item 5

Appendix II C

Introduction

This appendix shows the additional requirements from the global food safety initiative for Certification bodies and Scheme owners who choose accreditation according to ISO/IEC 17021 and ISO/TS 22003.

Most requirements in this addendum are in line with ISO/IEC 17021 requirements; other issues are explicitly included in this scheme. GFSI Requirements that are implicitly met by the scheme and ISO/IEC 17021, however may require additional explanation to guarantee full accordance, are specified below:

requirement	Explanation
general	Where the term Quality Management System is used this may be read as Management System, as used in ISO/IEC 17021.
4.	A quality manual shall be available. In practice this may be a documented system either on paper or in electronic form.
IX	Records shall be available showing the names of subcontractors who are contracted and qualified for delivering the audits
XII	There shall be policy and procedures for appeals, complaints and disputes. The explicit inclusion of disputes is additional to the wording as used in ISO/IEC 17021.

Additional GFSI requirements

As specified in GFSI Guidance Document – 6th edition – version 6.1, Part ~~I~~II Chapter 3 Annex 1: Additional requirements for Certification Bodies and scheme owners choosing accreditation according to ISO/IEC 17021 and ISO /TS 22003

1. The scheme owner and certification body will recognize the definition of supplier as; 'the party that is responsible for ensuring that products meet and, if applicable, continue to meet, the requirements on which the certification is based.'
2. The certification body shall take all steps required to evaluate conformance with the standard and fully comply with other associated requirements of the of the certification scheme.
3. The certification body shall operate an effective and fully implemented quality system. The quality system shall be fully documented and used by all relevant certification body staff. Within the certification body there shall be a designated member of staff responsible for the quality system's development, implementation

and maintenance. This designated member of staff will have a reporting role to the organization's executive and shall also have the responsibility for reporting on the performance of the quality system for the basis of management review and subsequent system improvement.

4. The required quality system shall be fully documented within a quality manual, which in turn will contain all necessary procedures for compliance. As a minimum, the quality manual shall contain:

I. A quality policy statement

II. A description of the legal status of the organization, including ownership, and an organizational structure including named individuals their job titles and description of responsibilities. The organizational structure shall include a chart listing each job title and how these functions interrelate through a management structure. Changes in the legal status, management personnel or constitution of the CB shall be notified to the Foundation in a timely manner.

III. A list of named individuals employed by the organization which includes their qualifications and full details of their experience. Changes in personnel which may impact the operational effectiveness of the CB shall be notified to the Foundation in a timely manner.

IV. A description of the management of the certification process including its committee structure, terms of reference and procedures.

V. Details of management review policy and procedures.

VI. Procedures in relation to documentation control

VII. Details of operational and functional responsibilities pertaining to quality defining an individual limits of responsibility and accountability

VIII. Recruitment procedures, i.e. selection, initial training, ongoing training and performance assessment for all relevant certification body personnel.

IX. A list of all subcontractors and a detailed procedure for their appointment, assessment and their ongoing management

X. Procedures for actions in response to nonconformities the effectiveness of agreed corrective and preventative actions taken

XI. Procedures in relation to the use of the certificate and in the event of the requirement to withdraw or suspend certification the actions taken by the certification body.

XII. Policy and procedures relating to appeals, complaints and disputes

XIII. Procedures for conducting internal audits and corrective actions arising from internal audits

5. In the event of significant change which could affect the safety of product, changes to the requirement of the certification scheme standard, change of ownership or management of the supplier or the certification has reason to believe there could be compliance issues in relation to certification, the certification body shall re-evaluate the supplier(s) to assess compliance with the certification scheme standard. Such cases shall be notified to the Foundation in a timely manner.

6. The certification body shall make available the following information at all times:
I. Authority under which the organization operates
II. Statement in relation to its certification system, including information on rules and procedures for granting, maintaining, extending, suspending and withdrawing certification of its clients.
III. Evaluation procedures and certification process in relation to the certification scheme
IV. Details of the means of obtaining financial support and fees charged to clients
V. Details of the rights and requirements of applicants and clients such as the use of logo and marks and the way in which a client can use information in relation to certification
VI. Details of complaints, appeals and disputes procedures
VII. A comprehensive list of all certificated clients against the scope of the certification scheme's standard
7. The certification body shall require all staff involved with the certification process to sign a contract or agreement which clearly commits them to
I. Complying with the rules of the organization, with particular reference to confidentiality and independence from commercial or personal interests
II. Declaring any issues in relation to personal conflicts of interest.
The certification body shall clearly document and make known to its employees all requirements in ISO 17021 related to personnel.
8. The certification body shall hold and maintain records regarding qualifications, training and experience of all staff involved in the certification process. All records shall be dated. ~~*The above information regarding auditor qualification shall be made available to the Foundation to facilitate the maintenance of a register of auditors.*~~
The information shall be updated periodically [minimum annually].
The information shall include as a minimum:
I. Name and address
II. Organisation affiliation and position held
III. Educational qualification and professional status
IV. Experience and training in the relevant fields of competence in relation to the certification categories described in the scheme's requirements [ISO 22003 Annex 1, Table 1A]
V. Details of performance appraisal

FSSC 22000

Certification scheme for food safety systems
in compliance with
ISO 22000: 2005 and technical specifications for sector PRPs

Part III

REQUIREMENTS AND REGULATIONS FOR PROVIDING ACCREDITATION

Foundation for Food Safety Certification

Gorinchem, The Netherlands: 2013

Version Control	Version 3 Published on April 10, 2013
Reason for change	All scheme documents updated from 2011 version 2, to include general updating of requirements and edits made during benchmarking for GFSI GD 6

CONTENT

1. INTRODUCTION

Purpose

This part of the scheme contains the requirements for the accreditation process for certification bodies (CBs) that wish to apply for accreditation in conformance with this scheme. It consists of:

- the requirements for accreditation and
- the regulations for the assignment of accreditation bodies.

Standards, guidelines and IAF membership

As indicated in Part II, the CBs shall operate a certification system which is in compliance with the requirements of the standard ISO/IEC 17021 and with the complementary requirements of ISO/TS 22003. The assessment of the CB by the AB shall therefore be conducted against these requirements with reference to the normative requirements for the organizations which are granted certification. The latter are outlined in section 3 of Part I and are in compliance with ISO 22000 and the applicable technical specification for sector PRPs and a number of additional requirements.
In order to ensure that the ABs operate to a high standard of competence and probity and that they apply the standards in a consistent and equivalent manner, they shall be member of the International Accreditation Forum (IAF) and a signatory to the IAF Multilateral Recognition Arrangement.

Additional requirements

To meet the needs of the key stakeholders and/or to ensure adequate control of food safety and certification, specific requirements are included in this scheme. They may be an elaboration of the clauses in the standards and technical specifications of the food safety system and certification system or additional requirements and are included in the sections “Additional requirements” of Part I and II. These requirements shall be included or implemented in the certification system and shall also be assessed in the accreditation process. They are therefore included in the section “Additional requirements” of this Part.
Also it may be necessary to elaborate clauses in the standard for the accreditation system ISO/IEC 17011 or to add requirements to these criteria. When this appears from the three yearly review of the scheme by the Board or when the Board takes decisions in this area in one of its three yearly meetings, these specific requirements are also included in the section “Additional requirements” of this Part.

2. REQUIREMENTS FOR ACCREDITATION

2.1 Requirements

Accreditation system

ABs that provide accreditation to CBs that wish to offer certification in conformance with this scheme shall meet the requirements of ISO/IEC 17011 and shall be a member of the International Accreditation Forum, IAF and a signatory to the IAF ISO/IEC 17021 (QMS/EMS) multilateral recognition arrangement.

Criteria for providing accreditation

The CBs shall be accredited in compliance with:

- ISO/IEC 17021 and ISO/TS 22003
- the additional requirements as specified in the sections 2.1 and 2.2, and specifically the requirements as included in the appendices (IIA, IIB and IIC) these sections refer to.

The CB shall have a provisional contract with the Foundation to certify within the applied scope for a maximum of one year without being accredited. A contract between the CB and the Foundation will only be signed up after it has been accredited.

Scope of accreditation

The scope of accreditation shall be precisely defined and indicated on the certificate of accreditation with reference to:

- this scheme FSSC 22000
- the normative requirements for providing certification in the sections 3.1, 3.2 and 3.3 of Part I
- the category as indicated in Annex A of ISO/TS 22003.

2.2 Additional requirements

Accreditation system

Accreditation bodies shall act conform the requirements of ISO/IEC 17011 and GFSI Requirements on the Application of ISO/IEC 17011:2004.

2.3 Guidance

No guidance as yet.

FSSC 22000

Certification scheme for food safety systems
in compliance with
ISO 22000: 2005 and technical specifications for sector PRPs

Part IV

REGULATIONS FOR THE BOARD OF STAKEHOLDERS

Foundation for Food Safety Certification

Gorinchem, the Netherlands: 2013

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Reason for change	All scheme documents updated from 2011 version 2, to include general updating of requirements and edits made during benchmarking for GFSI GD 6

CONTENT

1. INTRODUCTION

This part of the scheme contains the regulations for the Board of Stakeholders.
The Board has been established to function as an advisory body – with discretionary powers – to the certification bodies (CBs) that have been authorized to offer certification against the criteria of the scheme FSSC 22000. This Board deals with the requirements and regulations of the scheme. The Board does not review the actual impartiality of the CBs which remains the task of Committee of safeguarding impartiality of the CBs. (Ref. ISO/TS 22003, clause 6.2).
The Board offers parties which have an interest in international food safety system certification the possibility to participate in the development of the certification scheme FSSC 22000 as well as in the functioning of the scheme. The Board meets three times a year to discuss all relevant subjects concerning the scheme. The decisions of the Board may affect the associated CBs as well as the certificate holders. The Board is legally represented by the Foundation.

A list of the members of the Board of Stakeholders is published on www.fssc22000.com.

2. REGULATIONS FOR THE BOARD OF STAKEHOLDERS

Composition

The Board consists of representatives of the food categories covered by the FSSC 22000 scope including relevant stakeholders like, trade, retail, CBs, authorities as well as of independent experts. The Board invites the relevant organizations to make binding nominations. The Board appoints its members and ensures that the composition is balanced and manageable in size. The Board may only reject a nominee if this is in the interest of the Board or the functioning of the scheme and in such a case the reasons shall be explained. If the nominee is rejected, the organization involved is given the opportunity to make a new nomination. Members are appointed in consultation with the Foundation. The Foundation may reject a nominee if the rejection is based on interests which the Foundation looks after. Membership is terminated if the member relinquishes the capacity for which he or she was nominated and if the organization concerned indicates a wish to terminate this membership. The Board can appoint independent experts as members, as advisers or as temporary advisers. In doing so, the Board can determine to what extent the adviser has voting powers.

The chairperson is appointed by the Board in his or her capacity and is not an individual appointed from the ranks of the organizations which are represented in the Board. In the absence of the chairperson the Board shall appoint a deputy chairperson. The (re) appointment of the boardmembers, chairperson and the independent experts takes place every ~~three~~ five years. In the event of prolonged absences of a member, the organization concerned shall be asked to make a new appointment.

The Board is composed of representatives of the food categories covered by the FSSC 22000 scope

Tasks and responsibilities

The Board is responsible for the content and functioning of the certification scheme FSSC 22000 within the scope of the scheme. The Board organises co-ordination activities in the field of certification on the basis of the scheme and evaluates these in view of developments desired by interested parties, as well as with respect to other relevant (e.g. technical) developments. The Board has the possibility to provide recommendations – on request or otherwise – to the associated CBs with respect to the FSSC 22000 certification scheme.

In any event, the Board is required to provide advice and to take decisions in the following areas:

- The nature, content and functioning of the FSSC 22000 scheme;
- The establishment and implementation of a procedure to vet and approve personnel employed by the scheme to ensure their professional integrity, competence and impartiality;
- Arrangements to cover any liabilities which may arise from the activities of the scheme owner;
- Establishment and oversight of an internal audit programme to assure continuing compliance of the scheme with GFSI requirements. The review of scheme operation carried out at the Board meeting 3 times per year shall be included in the audit;
- The scope of certification;
- The establishment of requirements and the methods of investigation, which underpin the certification scheme, and establishment of the period of validity for the certification scheme;
- Reviewing cases where CBs have failed to comply with scheme requirements, and determining appropriate measures to address identified noncompliance;
- The establishment of the frequency of surveillance assessments in order to ensure that stipulated requirements are continuously met;
- Overseeing the effective operation of the complaints procedure described in the scheme documents;
- The FSSC 22000 certificate template;
- The competence of auditors; including maintaining a register of approved auditors based upon information provided by the relevant CBs;
- The approval of accreditation bodies in accordance with the Regulations for Accreditation Bodies in section 3 of Part III of this scheme;
- Overseeing the scheme conformity assessment programme “FSSC Integrity Program” described in the scheme documents;
- The full review of the FSSC 22000 certification scheme every 3 years.

Additionally, the Board is authorized to provide recommendations – on request or otherwise – with regards to any aspect related to the management of the FSSC 22000 certification scheme and the co-ordination activities in the field of certification.

With respect to all the aforementioned items, the associated CBs can accept or reject the recommendations of the Board only in their entirety. In the event that (one or more of) the CBs do not accept the recommendations of the Board, this needs to be notified to the Board in writing, stating the reasons for this. The Board shall

reconvene and reach a decision on possible changes of the appealed recommendation. If the CB in question continues to reject the decision with respect to the recommendations, no further appeal procedure is possible and the CB shall be excluded from further use of the services of the Board. The services of the Board can be called upon in the event of disagreements regarding the interpretation of the certification scheme, on the understanding that the Board does not rule on individual differences. The appeal board of the CB is available for this purpose.

Working order

- In order to effectuate the responsibilities specified in section 2, the Board convenes at least three times a year, and whenever the chairperson or three members of the board make a request to do so.
- The secretarial work for the Board is carried out by an agency or company or individual, which is nominated by the CBs and approved by the Board. The secretary or his or her deputy attends the meetings. He or she has an advisory vote in the meeting. The secretary provides the Board with all the information (if required in coded form) which the Board seems necessary for the effectuation of its responsibilities.
- The chairperson can impose confidentiality on the Board if the board receives confidential information necessary for carrying out its responsibilities.
- To accomplish the tasks specified in section 2, the secretary's office (possibly by outsourcing) is responsible for formulating drafts after consultation with the involved parties. Any opinions on the part of the involved parties that differ from the draft shall be submitted to the Board.

Decision making

The Board aims to make decisions on the basis of consensus, including all participants, also those with no voting rights. In any event, two-thirds of the number of those members entitled to vote is required to be present or to have been balloted. Those entitled to vote are the members, with the exception of the representatives of the CBs. Decisions can either be made in the meeting or by written consultation. Written consultation can be carried out by means of correspondence, i.e. by letter, fax or e-mail.

In the case of written consultation, those votes are counted which are received by the secretary's office within two weeks following a request to do so. In the event of the written procedure, all participants in the Board can request verbal consultation in a meeting.

In the event of written consultation, decisions are made by consent: those opposing a motion can indicate whether to accept the majority position or remain opposed in principle. In case half or less vote for the motion, or if at least one person votes against the motion on principle, the proposal is required to be dealt with in a meeting or an amended motion is required to be submitted.
When decisions are made in a meeting, recommendations are accepted by a simple majority of votes. In the event of a tie, the issue is dealt with again and a vote taken. If a new vote is required, the final motion shall be sent to the members entitled to vote within two weeks following the tie, to which a reply must be submitted within two weeks in writing. Split recommendations can be made in the event that the associated CBs are not required to integrally accept or reject the recommendations.

The Board shall validate changes in the scheme preceding the implementation with regards to the following aspects:

- Feasibility,
- Effectiveness (with regards to the intended effect),
- Compliance with the relevant standards which apply to the scheme.

Harmonization process

Once every year the CBs shall participate in a harmonization meeting. Expertise requirements can be stipulated for these representatives. In the harmonization meetings the following topics are addressed:

- co-ordination and harmonization with respect to the delivery process of the audits and the certification of the scheme FSSC 22000;
- proposals for items on the agenda for meetings of the Board;
- preparing recommendations for the Board;
- evaluation of practical cases with respect to FSSC 22000 certification;
- organization of harmonization workshops for auditors.

The minutes of the meetings of the harmonization committee(s) are discussed in the meeting of the Board.

Recording of meetings and resolutions

The secretary is responsible for the minutes of the meetings of the Board. The draft minutes, including a list of draft resolutions, is sent to the members of the Board within three weeks following the meeting. If applicable, members are required to submit their comments with respect to the minutes and the list of resolutions to the secretary in writing within 14 days. If no comments are received, the chairperson authorizes the minutes and list of resolutions to be finalised. The list of resolutions

is sent to the associated CBs. The list is also published on the website. If recommendations or decisions imply alterations of one of the relevant documents of the scheme, the list shall state the alteration and be valid as long as the alteration has not been processed and published. All associated CBs shall be informed of the publication. For the subsequent meeting, the list of resolutions is sent out again as a "document received". In case the secretary receives comments, the draft report shall be dealt with and finalised at the subsequent meeting.

Exchange of Information

The secretary shall draw up reports of the activities of the Board. These reports are made available to the participants and the advisers on the Board and to the associated CBs which are not represented on the Board. In addition, the assigned ABs are entitled to have access to the reports. The Board shall notify all associated CBs with regards to all binding recommendations that have been issued and shall provide the necessary documents. The certification bodies are required to respond to the recommendations issued within two months.

In order to fulfil its responsibilities, the Board is required to receive information at least once a year from the secretary and the associated CBs. This information must relate to the nature, content and functioning of the scheme and shall include at least the following;

- the frequency and the results of the audits (if necessary, in code) conducted by the associated CBs;
- complaints with respect to the FSSC 22000 certification;
- the number and nature of appeal procedures with respect to FSSC 22000 certification with the ABs and the CBs;
- reports on the periodic assessments by the ABs with relevance to those sections which are important for the functioning of the FSSC 22000 scheme;
- applications and agreements for FSSC 22000 certification as well as certificates granted, suspended or withdrawn.

The mentioned information may provide a source of discussion for the Board in respect of possible changes to the FSSC 22000 scheme.

All information made available shall be treated in confidentiality by the Board. The secretary, in order to ascertain that the duties of the Board are conducted correctly, shall be responsible to ensure that the documents and information provided to the Board do not contain any commercially sensitive information.

Ratification and amendments

The Board is entitled to ratify and amend these regulations. This requires the approval of all the members of the Board. Ratification and amendments also require the approval of the associated CBs.

Concluding provision

In cases not covered by these regulations, the Board of Stakeholders shall make the final decision.

The Board of Stakeholders approved these requirements in April 2013.