

## **FSSC 22000**

**Certification scheme for food safety systems  
in compliance with  
ISO 22000: 2005 and BSI-PAS 220: 2008**

# **PART I**

# **REQUIREMENTS TO OBTAIN CERTIFICATION**

**Foundation for Food Safety Certification**

Gorinchem, the Netherlands: January 2010

## CONTENT

1. INTRODUCTION .....	3
2. SCOPE .....	4
3. REQUIREMENTS FOR THE FOOD SAFETY SYSTEM .....	5
3.1 Food safety management system .....	5
3.2 Prerequisite programmes .....	5
3.3 Additional requirements .....	5
3.4 Guidance .....	5
Appendix I A: Additional requirements .....	8
Appendix I B: How to apply for certification .....	9

## 1. INTRODUCTION

### Purpose

This part of the scheme contains the requirements for food manufacturing organizations 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 CB's 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.

As such it 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 food manufacturing organizations maintain the conditions for hygienic environment and production. ISO 22000 requires in clause 7.2 that organizations shall select and implement specific "Prerequisite programmes" (PRP's) 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 PRP's and to allow for a benchmark of ISO 22000 certification schemes by customers (i.e. Global Food Safety Initiative of Foundation of CIES (GFSI)), the British Standards Institution (BSI) developed in close cooperation with the Confederation of the food and drink industries of the EU (CIAA), a specification of these requirements for food manufacturers (BSI-PAS 220). This specification is developed in compliance with the General principles of food hygiene of the Codex Alimentarius, the Guidelines for drinking-water quality of the WHO, the specification BSI-PAS 96 and the Key element Good manufacturing practices of the GFSI guidance document (fifth edition; section 6.2).

The BSI-PAS 220 is therefore considered most suitable to be included in this scheme in conjunction with the requirements of clause 7.2 of ISO 22000.

### Additional requirements

To meet the needs of the key stakeholders and/or 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 BSI-PAS 220 or additional requirements and are included in the section "Additional requirements". 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, which ensure the safety of foodstuffs during manufacturing of (see also chapter "Features of the scheme"):

- perishable animal products<sup>1</sup>, excluding slaughtering and pre-slaughtering (i.e. packaged meat, poultry, eggs, dairy and fish products),
- perishable vegetal products<sup>2</sup> (i.e. packed fresh fruits and fresh juices, preserved fruits, packaged fresh vegetables, preserved vegetables),
- products with a long shelf life<sup>3</sup> (i.e. canned products, biscuits, snacks, oil, drinking water, beverages, pasta, flour, sugar, salt),

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See ISO 22003, Annex A:

<sup>1</sup> Category C

<sup>2</sup> Category D

<sup>3</sup> Category E

- food ingredients<sup>4</sup>, excluding technical and technological aids (i.e. additives, vitamins and bio-cultures but).

The requirements are applicable to all of these food manufacturing 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 (PRP’s) in accordance with clause 7.2 of ISO 22000, the organization shall consider and utilise the requirements on PRP’s for food manufacturing which are laid down in the technical specification BSI-PAS 220: 2008.

Apart from these requirements, other appropriate information shall be considered and utilised especially:

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

The conditions of the PRP’s 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 Appendix I, A.

#### 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*

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<sup>4</sup> Category L

### 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 then 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.

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

### 4. Inventory of applicable regulations

It is pointed out that the food manufacturing organization 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 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 food manufacturing organization 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 BSI-PAS 220, clause 9,

**Reference:** ISO 22000, clauses 7.2.3.f and 7.3.3 and BSI-PAS 220, clause 9

#### 2. Supervision of personnel in application of food safety principles

The organization 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

*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 by the auditor(s) of a CB. The CB in turn shall have been assessed and judged as competent by an accreditation body. The process for accreditation of CB's 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 III 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](http://www.fssc22000.com). The scheme should be read and understood and a preliminary self assessment should be conducted by the organization against the requirements and guidance in the section 3 of Part I of this scheme. Any areas of nonconformities should 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 <http://www.fssc22000.com>.

#### Certification agreement

A contract shall exist between the organization and the CB, detailing the agreed scope of the audit and the reporting 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.

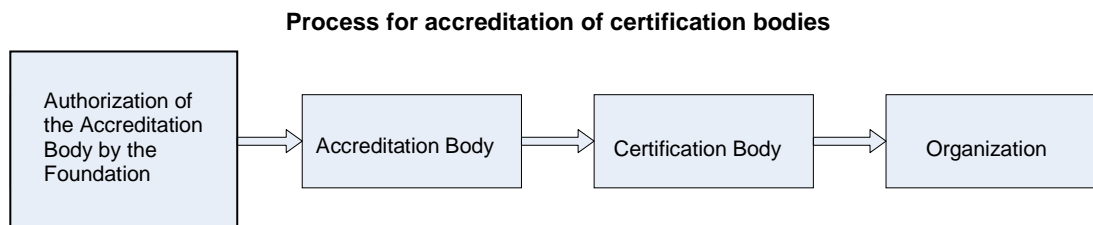
In the stage 2 audit the implementation and effectiveness of the food safety system is evaluated.

### 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. 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 include among others, evaluation of internal audits of the organization, review of actions taken on minor nonconformities which were identified in the previous audit, treatment of complaints, progress on continual improvement, review of changes etc. In case a nonconformity is identified by the audit team, the CB shall take a decision on suspension or withdrawal of the certificate depending on the corrections and corrective actions of the organization (see flow diagram). The decision is (also) based on a review of the effectiveness of the management system by competent personnel of the CB which is different from those who carried out the surveillance audit.

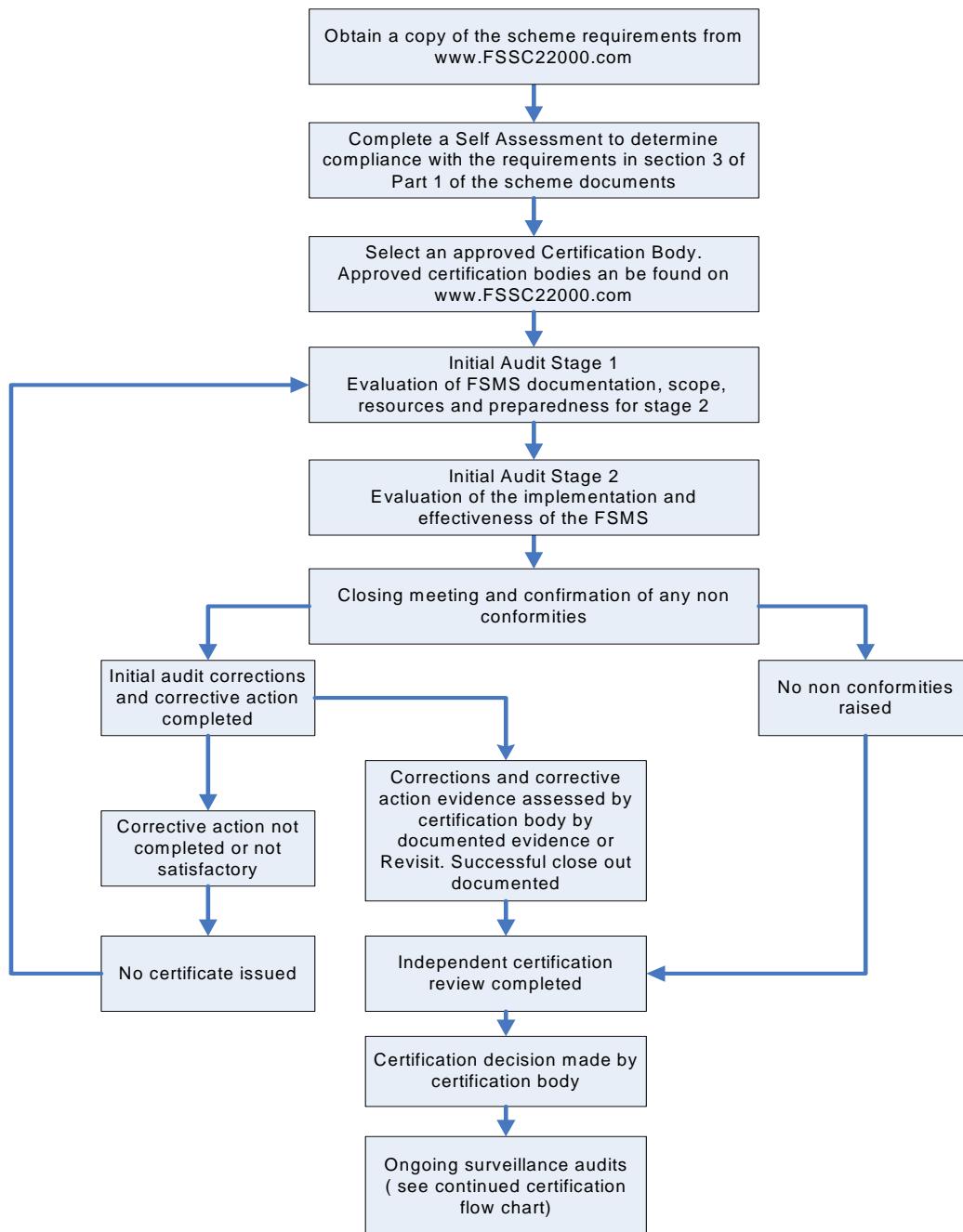
Before the date of expiration of the certificate a recertification audit shall be conducted. The purpose of this audit is to confirm the continued conformity and effectiveness of the food safety system as a whole. The fulfilment of all requirements is evaluated. The audit also includes a review of the 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

**How to gain certification**



### Surveillance Audits

