FSSC 22000

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

PART II

REQUIREMENTS AND REGULATIONS FOR CERTIFICATION BODIES

Foundation for Food Safety Certification

Gorinchem, The Netherlands: 2013

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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;
- 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
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 4 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.

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 7.2.4.4, the following is added:

- 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*

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. 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 CCPs and Operational PRPs and shall include a representative sampling of the PRPs. 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 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.

***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.

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 22000 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 (PRPs)*			
7.3	*Preliminary steps to enable hazard analysis*			
7.4	*Hazard analysis*			
7.5	*Establishing the operational PRPs*			
7.6	*Establishing the HACCP plan*			
7.7	*Updating of preliminary information and documents specifying the PRPs 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: 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			
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
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			
5.1General 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			
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	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.			
1.1	Shall have specified requirements.			
1.2	Shall be described in documents to the extent needed to conduct hazard analysis.			
1.3	Shall be managed in conformance with the requirements of technical specification for sector PRPs.			
2	Supervision of personnel in application food safety principles.			
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 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 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