



FOOD SAFETY SYSTEM CERTIFICATION 22000

OVERVIEW OF MAIN CHANGES VERSION 5

INTRODUCTION

The lay-out of the Scheme has changed. All scheme requirements are combined into one document. Former annexes II, III and V to part V have been integrated resulting in the following contents:

- Part 1: Scheme overview
- Part 2: Requirements for Organizations to be Audited
- Part 3: Requirements for the Certification Process
- Part 4: Requirements for Certification Bodies
- Part 5: Requirements for Accreditation Bodies
- Part 6: Requirements for Training Organizations
- Appendix 1: Definitions
- Appendix 2: References

The following mandatory annexes are published as separate documents:

- Annex 1 CB Certificate Scope Statements
- Annex 2 CB Audit Report template: FSSC 22000
- Annex 3 CB Audit Report template: FSSC 22000-Quality
- Annex 4 CB Certificate template
- Annex 5 AB Accreditation Certificate scope
- Annex 6 TO Course specifications
- Annex 7 TO Training Certificate templates

OVERVIEW OF CHANGES

This overview contains the main changes. It is not intended to be an exhaustive list of all changes.

PART 1: SCHEME OVERVIEW

Reference V5	Change	Reference V4
Chapter 3	Improved definition of what is in and out of the different categories	Part I chapter 3
3.9	Paragraph on FSSC 22000-Quality added	-

PART 2: REQUIREMENTS ORGANIZATIONS TO BE AUDITED

Reference V5	Change	Reference V4
Part 1	Food category and sectors moved to part 1.	1.1
2.1 and 2.2	Replacement of ISO 22000:2005 by ISO 22000:2018	2.1 and 2.2
2.5.1	Management of services: shortened because this is now part of ISO 22000:2018 clause 7.1.6. Management of laboratory services remains as an additional FSSC 22000 requirement.	2.1.4.1
2.5.6	Management of allergens for C, E, FI, G, I and K (was C, I and K)	2.1.4.6
2.5.7	Environmental monitoring for C, E, FI, I and K (was C, I and K)	2.1.4.7
-	Management of natural resources removed.	2.1.4.9
2.5.9	New requirement Transport and Delivery (category FI)	-

PART 3: REQUIREMENTS FOR THE CERTIFICATION PROCESS

Reference V5	Change	Reference V4
4.3 Audit duration	<p>New</p> <p>b) The audit time calculation for FSSC 22000 shall be documented by the CB, including justifications for reduction or addition of time based on the minimum audit duration;</p> <p>e) The on-site audit time shall only apply to auditors that are fully qualified, registered FSSC 22000 auditors;</p> <p>f) Where the FSSC 22000 audit is undertaken in combination with other food safety audits as a combined audit, the audit time stated in the report shall be of the total combined audit and match the audit plan. Total audit duration is then longer than for FSSC 22000 alone. This is considered as an increase in audit duration and the reason for this shall be justified.</p>	Part IV annex II
4.3.1 Audit time calculation	Introduction of T_{FSSC} and rules for audit time reduction	Part IV annex II
4.3.2 Audit time calculation	<p>New:</p> <ul style="list-style-type: none"> • rules for rounding up or down of audit days • additional special audits 	Part IV annex II
4.3.4 Audit time	Referral to new MD 11:2019 for FSSC 22000-Quality audit duration	Part IV annex II
4.4 Contract	11) communication obligations of certified organizations to the CB within 3 working days (for all communications described in this paragraph)	Part IV 4.1 (3 and 4)
5.3 Multi site certification	New requirement	-
5.4.1 Unannounced audits	<p>New</p> <p>2) The certified organization can voluntary choose to replace all surveillance audits by unannounced annual surveillance audits. Recertification audits may be conducted unannounced at the request of the certified organization.</p>	-

Reference V5	Change	Reference V4
5.4.2 Unannounced audits	New: 1)The CB sets the date of the unannounced audit typically between 8-12 months after the previous audit (but respecting recertification planning). The consequence of this may be that the audit is not conducted annually (as required by §5.1). 6) All Scheme requirements shall be assessed including production or service processes in operation. Where parts of the audit plan cannot be audited, an (announced) follow-up audit shall be scheduled within 4 weeks.	-
5.6 Remote audits	CAAT used as a remote audit tool must meet requirements of IAF MD 4	Part IV 3.1.6
5.7 transfer of certification	IAF MD2 shall be followed	-
5.9 transition audits	Transition audits are the start of a new certification cycle and shall therefore be a stage 2 audit (a stage 1 may be performed at the discretion of the CB).	Part III chapter 4
5.11 serious events	Includes situations where unannounced audits cannot be performed as planned	-
6. 1 Audit report	Corrections, corrective action plans and their approval shall be included in the report. A head office report shall contain as a minimum the NCs found at the HO. This report shall be uploaded. At each site audit the implementation of the corrective actions shall be verified and reported	-
6.2 Nonconformities	In case of non-conformities noticed in a head office audit, these are assumed to have impact on the equivalent procedures applicable to all sites. Corrective actions shall therefore address issues of communication across the certified sites and appropriate actions for impacted sites. Such nonconformities and corrective actions shall be clearly identified in the relevant section of the site audit report and shall be cleared in accordance with the CB procedures before issuing the site certificate.	Part IV Annex III

Reference V5	Change	Reference V4
6.2.1 Minor nonconformity	The CB shall review the corrective action plan and the evidence of correction and approve it when acceptable. The CB approval shall be completed within three (3) months after the last day of the audit. Exceeding this timeframe shall result in a suspension of the certificate.	-
6.2.2 Major nonconformity	The CB shall review the corrective action plan and conduct an on-site follow-up audit to verify the implementation of the CA to close the major nonconformity. In cases where documentary evidence is sufficient to close out the major nonconformity, the CB may decide to perform a desk review. This follow-up shall be done within 28 days from the last day of the audit.	-
6.2.3 Critical nonconformity	A separate audit shall be conducted by the CB between 6 weeks to six (6) month after the regular audit to verify the effective implementation of the corrective actions. This audit shall be a full on-site audit (with a minimum on-site duration of one day). After a successful follow-up audit, the certificate and the current audit cycle will be restored and the next audit shall take place as originally planned (the follow-up audit is additional and does not replace an annual audit). This audit shall be documented and the report uploaded.	-
7.3 Certificate suspension, withdrawal or scope reduction	<i>Scope reduction:</i> When the CB has evidence that their client holds a certificate whose scope exceeds their capability or capacity to meet scheme requirements, the CB shall reduce the certification scope accordingly. The CB shall not exclude activities, processes, products or services from the scope of certification when those activities, processes, products or services can have an influence on the food safety of the end products as defined in the scope of certification.	-
8. Portal data and documentation	For all audit types, the required data and documentation shall be entered and kept up-to-date in the Portal at the latest 28 calendar days after the certification decision with a maximum of 4 months after the last day of the audit.	Part IV 2.2.2

PART 4: REQUIREMENTS FOR CERTIFICATION BODIES

Reference V5	Change	Reference V4
2.1 Licensing	The CB may hold more than one accreditation for the main location which shall be covered by a single license. In case the CB has multiple locations holding their own accreditation, a separate license is required for each location.	-
2.1.2.1 Provisional License	The provisional status of the license is valid for twelve (12) months from the date of signature by the Foundation and within this period of time the CB shall: have all required data registered in the Portal for at least two (2) certified organizations;	Part IV 2.1.2.1
2.1.3 license maintenance	In order to maintain its license, the CB shall: Have at least five (5) audited organizations registered in the Portal with a minimum of one for each licensed food chain category. For new CBs this shall be achieved within 12 months after receiving the full license status.	Part IV 2.1.2.2
2.1.4 License extension	At least one certificate shall be listed in the Portal for the new category.	-
3.2 Certification decision maker	Those making the decision to issue, maintain, extend or reduce scope, suspend or withdraw a certificate for registration in the FSSC 22000 Register of Certified Organizations shall have the following demonstrable competencies; <ul style="list-style-type: none"> a) Meet the requirements of Annex C of ISO/TS 22003:2013, b) Knowledge of Scheme requirements, c) Knowledge of food safety management systems and ability to audit them. In case of FSSC 22000-Quality the certification decision maker must have knowledge of ISO 9001.	-

Reference V5	Change	Reference V4
<p>3.3 Technical expert</p>	<p>When deemed necessary a technical expert can be assigned to the audit team.</p> <p>The CB shall have in place a procedure for approval of technical experts who shall have demonstrable experience in the subcategory supporting the scope of the audit. The technical expert shall operate always under the direction of a qualified FSSC 22000 auditor.</p> <p>Where a technical expert is used, the CB shall ensure that at least one auditor in the team has a qualification in the category.</p>	<p>-</p>
<p>3.4 Witnessor</p>	<p>Witnessed audits shall be undertaken by an auditor qualified for a GFSI recognized certification program that can demonstrate competence in the FSSC 22000 Scheme requirements, or by a CB FSSC 22000 technical certification person of equivalent competence and experience. Witnessors shall be assessed and qualified by the CB as suitable to undertake witnessed audits.</p> <p>The witnessor has received training in witness audit techniques.</p> <p>The witnessor plays no active part in the audit.</p> <p>Witnessors shall have, as a minimum, the equivalent competency of the function being evaluated (see ISO/TS 22003:2013 Annex C).</p> <p>A witness audit performed by the CB can only be substituted by an Accreditation Body (AB) witnessed audit if it is the first witnessed audit under a provisional license.</p>	<p>-</p>

Reference V5	Change	Reference V4
<p>3.5.3 Assignment of subcategories (initial and extension)</p>	<p>After the initial approval auditors shall be approved/qualified per subcategory (see Part I table 1). In order to assign subcategories to an auditor, the CB shall demonstrate that the auditor complies with the following requirements:</p> <p>Six (6) months' work experience in the subcategory OR five (5) audits against a GFSI recognized scheme in the new sub category (post-farm gate only except for food chain category A) as a trainee or co-auditor under the supervision of an auditor qualified for the subcategory. At least one (1) of these 5 audits shall be an FSSC 22000 audit (stage 2, surveillance or re-certification audits). Where consultancy work is used to demonstrate work experience, the amount of consultancy days shall add up to six (6) months. Demonstrated specific competence in the subcategory;</p> <p>Meeting the CB's own competency criteria for the subcategory</p> <p>The CB shall have defined competency criteria for each subcategory to ensure knowledge of products, processes, practices and applicable laws and regulations of the relevant subcategory. Competence across the whole subcategory shall be demonstrated. Where the CB further split up subcategories, it shall be clear for which parts of the subcategory the auditor is qualified.</p>	<p>-</p>
<p>3.5.4 Maintenance of auditor qualification</p>	<p>Each auditor shall perform at least five (5) on-site FSSC 22000 audits at different organizations each calendar year, either as a lead or co-auditor. In this context, stand-alone stage 1 audits and special audits do not count. Maximum 2 of the 5 can be FSSC 22000 audits as a witnessor.</p> <p>In case an auditor has demonstrated he/she performed FSSC 22000 audits for another CB, these are also allowed to be included. In the event of point 2 or 3 above, the CB shall upload evidence of the audits in the Portal.</p>	<p>Part IV Annex V</p>

PART 5: REQUIREMENTS FOR ACCREDITATION BODIES

Reference V5	Change	Reference V4
3.2.3	The AB shall conduct witnessed assessments covering all categories included in the CB accreditation scope during the AB accreditation cycle.	Part V 2.2.3

PART 6: REQUIREMENTS FOR TRAINING ORGANIZATIONS

Part 6 is entirely new.

APPENDIX 1 DEFINITIONS

Reference V5	Change	Reference V4
Appendix 1 - Definitions	Removal of superfluous definitions	Part 0
	Changed definitions: <ul style="list-style-type: none"> • Black out days • Complaint • Feed • Food 	
	New definitions: <ul style="list-style-type: none"> • Certification decision date • Certificate suspension • Certificate withdrawal • Computer Aided Audit Techniques (CAAT) • Environmental monitoring • Follow-up audit • FSSC logo • Organization in the food chain • Quality Management system • Serious event • Special audits 	

APPENDIX 2 REFERENCES

This part is new.

ANNEX 1 CB CERTIFICATE SCOPE STATEMENTS

A more comprehensive description is provided what should be in which (sub)scope. Generic rules for scope statements are given (valid for all categories). Per category specific rules are added. Examples are provided.

ANNEX 2 CB AUDIT REPORT TEMPLATE: FSSC 22000

This annex consists of a) FSSC 22000 report template and b) FSSC 22000-Quality template. Templates have been redesigned to avoid duplications. A separate stage 1 template is provided.

ANNEX 3 CB AUDIT REPORT TEMPLATE: FSSC 22000-QUALITY

New

ANNEX 4 CB CERTIFICATE TEMPLATES

Templates are provided for:

1. FSSC 22000
2. FSSC 22000 with head office (refer Part III, section 5.2.1)
3. FSSC 22000 with off-site activities (refer Part III, section 5.2.2)
4. FSSC 22000 with multi-site activities (refer Part III, section 5.3)
5. FSSC 22000-Quality
6. FSSC 22000-Quality with head office
7. FSSC 22000-Quality with off-site activities
8. FSSC 22000-Quality with multi-site activities

ANNEX 5 AB ACCREDITATION CERTIFICATE SCOPE

Split of category DII into DIIa Production of pet food (for dogs and cats only) and DIIb Production of pet food (other than cats and dogs) has been made clearer.

ANNEX 6 TO COURSE SPECIFICATIONS

New

ANNEX 7 TO TRAINING CERTIFICATE TEMPLATES

New