

PP1268 FSSC 22000 V5 Certification Requirements Revision 12 (October 2020)

BSI Certification Requirements

BSI Standard Terms and Conditions Addendum

FSSC 22000 v5

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Revision History

Rev No	Revision Date	Author	Approved by	Page No	Sec. No	Brief Description of Change
1	February 2018	Gaynor Clow/ Luanshya Naidoo	Todd Redwood			New document
2	July 2018	Gaynor Clow	Todd Redwood	10	3.12	Changed word from three to six.
3	January 2019	Gaynor Clow	Todd Redwood	15		Contact details
4	May 2019	Ana Cicolin	Todd Redwood	11	5	Various updates
5	May 2019	Ana Cicolin	Todd Redwood	10	3.10	RAM for certification and audit cycles
6	July 2019	Ana Cicolin	Todd Redwood	docum	entire nent was iewed	Various updates to be in accordance with FSSC V5
7	November 2019	Ana Cicolin	Todd Redwood	Cover page 3.7 / page 10 3.13.2.1/ page 17		Correction in audit duration comments Correction in audit duration comments
						Change name from "certification guidebook" to "Certification Requirements"
						Updating audit criteria Timline for Minors NC
8	March 2020	Ana Cicolin	Todd Redwood	11 18 21 23 27	3.7 3.3.2.1 4 5.1.2 5.2 10.5	Inclusion the link for the ISO 22000 Guideline; Inclusion the new timeline nfor minor NC;Inclusion of FSMA; Inclusion of BoS Decision List – February 2020 and Updated on March 2020; Inclusion the new timeline for the FSSC Portal;Inclusion of FSSC Position for management of serious even, Including COVID-19
9	May 2020	Ana Cicolin	Todd Redwood	28 29	10.6	Include update provided by FSSC through BoS decision list, May20

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10	June 2020	Ana Cicolin	Todd Redwood	21 27 30 31 32	3.15.3 11.6 11.8 11.9	Inclusion the FSSC requirements related to the use of ICT
11	August 2020	Ana Cicolin	Todd Redwood	15 17 22 27 28	3.11 3.11.3 3.15.3 7 8 9	FTE Information Update additional minimum time when use translator Inclusion of transition audits Use of Marks
12	October 2020	<mark>Ana</mark> Cicolin	Todd Redwood	21-27 38 39	3.17 11.4	Incoportaion of updates made by FSSC on 05/10/20 related to annexx 09 (ICT Audit Approach) and the publication of the addendum realated to Full remote audits

1 Introduction

This certification requirements document is designed to assist your site with the requirements for certification to the Food Safety Systems Certification (FSSC) standard version 5 throughout the BSI Group. This document is considered an addendum to the BSI Standard Terms and Conditions and therefore forms part of the contract with BSI.

The FSSC 22000 V5 certification scheme was launched on 03 June 2019. The main reasons for publishing a revised version include:

- Publication of the new ISO 22000:2018 standard;
- Inclusion of the board of stakeholders list of decisions;
- Compliance with GFSI requirements;
- Continual improvement process.

1.1 FSSC 22000 V5 – Main Changes

FSSC have published a document with an overview of main changes that can be found at <u>FSSC Website</u>.

2 Accreditation Status and BSI Scope of Accreditation

BSI holds a valid global ISO/IEC 17021-1:2015 accreditation, including ISO/TS 22003:2013. The Accreditation Body is ANAB and the Scheme owner is The FSSC Foundation.

BSI operate in the categories and subcategories covered by the accreditation, being categories C, I and K as per detailed below:

FSSC 22000 Category	FSSC 22000 Sub Category
	CI - Processing of perishable animal products
С	CII - Processing of perishable plant products
Food Manufacturing	CIII - Processing of perishable animal and plant products (mixed products)
	CIV - Processing of ambient stable products
I	
Production of Food Packaging and Packaging Material	I - Production of Food Packaging and Packaging Material
К	K - Production of Biochemicals
Production of	
Biochemicals	

3 The Recognition Process

The following section outlines the steps that apply during the BSI recognition process for FSSC. BSI reserves the right to provide its clients and those that request quotations with marketing and technical information relating to standards, training and compliance services.

3.1 Initial Enquiry

BSI will respond to either verbal or written expressions of interest from sites interested in one or more of our programs. If your site is located near one of BSI's offices, an advisory visit may be arranged to discuss your recognition requirements and how BSI can help your site achieve them.

BSI will also, on request and receipt of a Request for Proposal, prepare a proposal suited to your site's needs.

3.2 Application for Certification and Assessment

Receipt of your site's Application form (or authorized acceptance of a valid BSI proposal), along with the accompanying payment of the non-refundable application fee (or invoicing instructions) together with this document forms the contract between your site and BSI.

Your requirements will be entered into our database and an auditor will be appointed to look after your certification or assessment requirements. The auditor will be your primary point of contact with BSI and is responsible for ensuring that our certification/assessment services are delivered to your site in the most effective manner possible.

3.2.1 Application Form Client Contact

- 1) BSI will require completion of an official application form, signed by an authorized representative of the applicant site
- 2) It is the responsibility of the applicant site to ensure that adequate and accurate information is shared with BSI about the details of the applicant site

3.2.2 Annual Fee

- 1) BSI shall charge an annual fee to all sites certified against the FSSC Scheme. This fee will be paid by BSI to The FSSC Foundation
- 2) The FSSC Foundation shall decide annually on the fee amount

3.3 Certification Contract

As soon as practicable after receipt of your signed application/proposal, a BSI auditor (or nominated representative) will contact your site. Your auditor will seek to establish a working relationship between your site and BSI, and to confirm your recognition requirements in terms of the certification or assessment services, standards or codes of practice, locations, and activities and/or products to be included in the scope of certification.

The auditor will seek to gain an appreciation of the structure of your site and the activities being conducted. In particular the auditor will:

- Seek an appreciation of the nature and scope of your site's activities, structure and location(s), including any activities for which certification is being excluded; and
- Determine the status of system documentation and implementation including organizational policies, objectives and targets.

If your site is working with a consultant it is often useful for that person to be party to the communication process.

3.4 Conduct a Self-Assessment / Pre-assessment Audit (not mandatory)

A self-assessment or pre-assessment audit can assist in identifying gaps in your site's FSSC System so that corrective action can occur before engaging BSI for a full certification audit. It can be conducted using internal resources, an FSSC consultant, or an FSSC auditor.

Once your site has signed a contract with BSI, BSI can provide an assessment checklist free of charge to utilize in a self-assessment / pre-assessment audit.

3.5 Identifying the Scope of Certification

FSSC certification is site and product specific. When activities are carried out in different premises but are overseen by the same senior, operational, and technical management, and are covered by the one FSSC System, the scope can be expanded to include those off-site activities.

The scope of certification forms part of the certificate of registration. It describes the food sector categories (refer to table below) and the products processed and handled on that site. The certificate of registration outlines the location of the site and nature and extent of the FSSC certification.

The audit scope will be agreed between your site and BSI before the certification audit begins. The scope of the audit shall cover the required level of certification, the food sector categories, and the products listed under the scope of certification for a site. The audit scope shall cover all processes under the control of your site from raw material receipt to shipment of finished product.

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Category	FSSC 22000 Sub Category	Example of included activities and products
		Production of animal products
	CI - Processing of perishable animal	<u>Activities / Processes</u> : Slaughtering, deboning, evisceration, gutting, cutting, sorting, washing, pasteurizing, trimming, curing, fermentation, smoking, freezing, chilling, cooling, scalding.
	products	<u>Final product examples</u> : fish, meat, poultry, eggs, frozen and/or chilled dairy products and fish/seafood products.
		Production of plant products
	CII - Processing of perishable plant	<u>Activities / Processes</u> : De-shelling, drying, packing, sorting, washing, rinsing, fluming, trimming, slicing, pasteurizing, roasting, scalding, peeling, de-husking, cooling, chilling, freezing and final product.
C Food Manufacturing	products	Final product examples: chilled or frozen e.g. fresh fruits, fresh juices, vegetables, grains, nuts and pulses, meat replacers based on plant materials (e.g. soy)
		Production of mixed animal and plant products
	CIII - Processing of perishable animal	Activities / Processes: Mixing, cooking, packing, ensemble cooling, chilling, freezing
	and plant products (mixed products)	Final product examples: mixed products, pizza, lasagna, sandwich, dumplings, ready-to eat meals.
	CIV - Processing of ambient stable products	Production of food products from any source that are stored and sold at ambient temperature.
		<u>Activities / Processes</u> : Mixing, cooking, packing, bottling, brewing, drying, pressing, milling, blending, roasting , refining, ensemble, distilling, drying, canning, pasteurizing, sterilization.
		<u>Final product examples</u> : canned products, biscuits, bread, snacks, oil, drinking water, beverages alcoholic and non-alcoholic, pasta, flour, sugar, food-grade salt, dairy products with long shelf life, margarines.

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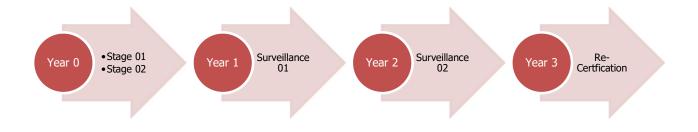
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Category	FSSC 22000 Sub Category	Example of included activities and products
		Packaging that includes the production of food/feed packaging, food/feed packaging materials and intermediate products for:
		- direct food contact surfaces or materials (i.e. physically touching the food or in contact with headspace) that will be in contact with the food during normal use of the food packaging and/or;
I Production of Food Packaging and	I Production of Food Packaging and	- indirect food contact surfaces or materials that are not in direct contact with the food during normal use of the food packaging, but there is the possibility for substances to be transferred into the food.
Packaging Material	Packaging Material	Packaging material used for personal care, pharmacy or other uses are outside the scope of the standard. Disposable tableware can only be certified when it is sold together (and as part of) the food product. Examples are spoons that are packed with yoghurt, forks or chopsticks packed with ready-to-eat food.
		<u>Activities / Processes</u> : All manufacturing activities for plastic, carton, paper, metal, glass, wood and other materials to be used as packaging materials in the food/feed industry.
		<u>Final product examples</u> : bottles, boxes, jars, barrels, cork, cans; devices for closing packaging materials such as tape, plastic strips, or other when the manufacturer can prove that they belong to a food/ feed packaging material; Production of labels with direct food contact.
K Production of Biochemicals	K - Production of Biochemicals	Production of Bio-Chemicals and applies to the production of food and feed additives, vitamins, minerals, bio-cultures, flavorings, enzymes and processing aids but excludes pesticides, drugs, fertilizers and cleaning agents. <u>Activities / Processes</u> : Mixing, cooking, packing, distilling, drying, canning, sterilization for all products at ambient, chilled and frozen temperatures. <u>Final product examples</u> : food and feed additives, vitamins, minerals, bio-cultures, flavorings, enzymes and processing aids, gases as ingredients and/or packaging gas.



3.6 Certification Cycle

A 3-year certification cycle shall be applied to FSSC 22000.



3.6.1 Planning Audits

The basis of timings applied to the certification and audit cycles for FSSC 22000 scheme is that each certificate shall become attached permanently to a month for its CAVs (surveillances) and RAs (Recertifications) audits. This month is defined as a Reoccurring Audit Month (RAM) in which it is expected that these audits shall occur on a regular basis

3.7 Audit Criteria

The audit criteria represent set of requirements used as a reference against which objective evidence is compared. FSSC 22000 audit criteria shall include the requirements as below.

FSSC 22000 Category	FSSC 22000 Sub Category	Requirements of
с	CI - Processing of perishable animal products CII - Processing of perishable plant products	Normative Documents: • ISO 22000:2018 • ISO/TS 22002-1:2009
Food Manufacturing	CIII - Processing of perishable animal and plant products (mixed products)	 FSSC Additional Requirements* (including BoS Decision List as
	CIV - Processing of ambient stable products	applicable)
K Production of Biochemicals	K - Production of Biochemicals	 The defined processes and documentation of the management system developed by the organization Related Statutory/regulatory requirements Related Customer requirements

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FSSC 22000 Category	FSSC 22000 Sub Category	Requirements of
I Production of Food Packaging and Packaging Material	I - Production of Food Packaging and Packaging Material	 Normative Documents: ISO 22000:2018 ISO/TS 22002-4:2013 FSSC Additional Requirements* (including BoS Decision List as applicable) The defined processes and documentation of the management system developed by the organization Related Statutory/regulatory requirements Related Customer requirements

Note: An ISO 22000:2018 was established and is available on the FSSC Website (ISO 22000 Guidance).

3.7.1 Legal and Regulatory Audit Requirements

Legislative and regulatory compliance is a requirement of FSSC 22000. The maintenance and evaluation of legal compliance is the responsibility of the client. BSI's role is to establish confidence that the FSSC 22000 system functions adequately in this regard and to confirm that the FSSC 22000 system is capable of achieving continued compliance.

BSI will verify that the client has included legal and regulatory compliance in their FSSC 22000 system and can show that action has been taken in cases of non-compliance with relevant legislation. BSI will not issue certification to a site where an infringement of food safety related legislation or regulation is discovered. Where an action plan to achieve compliance has been agreed with the appropriate regulator an exception may be requested.

BSI will notify the client if an infringement is discovered. Action will depend upon the nature of the infringement, corrective action proposals and the stance taken by the appropriate enforcement authority but would normally constitute a major non-conformity followed up with a re-audit visit.

Similarly, action will be taken where a post certification infringement is discovered. The conditions of contract require the client to notify BSI of post certification breaches. De-registration is an option for persistent failure to comply.

Where licenses/consents/permits have not been issued by appropriate authorities, including incomplete document submissions, and steps are being taken to achieve compliance in agreement with the regulator a non-conformity should be raised



3.8 The Certification Audit

The FSSC certification audit consists of two stages:

- 1) The initial auditing for certification is always carried out at the production site of the applicant site and is conducted in two separate stages:
 - a) The stage 1 audit verifies that the system has been designed and developed in accordance with your site's top management commitment to conform with FSSC scheme requirements. The objective of this audit is to assess the preparedness of your site to proceed to the stage 2 audit
 - b) The stage 2 audit substantiates top management's claim by auditing implementation of the food safety management system
 - c) The activities subject to the proposed certification scopes shall be assessed during the initial certification audit

3.9 Surveillance Audits

- 1) Surveillance audits shall assess and report on conformity with all Scheme requirements including the use of marks and references to certification
- 2) At least one of the two annual surveillance audits shall be unannounced
- 3) The audit program shall also consider the results of any previous audits including the unannounced audit(s)
- 4) If not, all audit objectives are fulfilled during an unannounced audit, an additional audit shall be performed of which the nature shall be determined by BSI

3.10 Recertification

- 1) The recertification audit must be planned and conducted in due time to enable timely renewal of the certificate before the expiry date
- 2) The purpose of this audit is to confirm the continuing conformity of the food safety management system as a whole with all FSSC scheme requirements
- 3) The recertification activity also includes a review of the food safety management system over the whole period of certification, including previous surveillance audit reports and complaints received
- 4) BSI decides on renewal of the certification cycle on the basis of the recertification audit which must meet the same requirements as an initial audit

3.11 Audit Duration

The FSSC 22000 audit duration is determined by using the following factors:

- Product Category;
- Number of HACCP plan/study;
- Relevant management system in place
- Number of Employees
 - Number of Employees: The number of employees involved in any aspect of food safety shall be expressed as the number of Full Time **Equivalent** (FTE) Employee. When an organization deploys workers in shifts and the products and/or processes are similar, the FTE number will be calculated based <u>on employees on the main shift.</u>
 - FTE shall include: Production/ manufacturing/ supporting activities/ wholesale/ transport/ quality assurance/ research and development/ office based, full time, part time and seasonal workers.
 - When filled out the application (Service Requet Form), it is the responsibility of the applicant site to ensure that adequate and accurate information is shared with BSI about the details of the applicant site.

3.11.1 Basic Rules for Audit Duration

Audit duration will be based on the information gathered from the organization's application and following the requirements of ISO/IEC 17021-1, ISO/TS 22003 and FSSC 22000 as follows:

- the duration of an audit day normally is eight (8) hours;
- the effective on-site audit duration **does not include a lunch break** (unless in contradiction with local legislation)
- the audit duration calculation for FSSC 22000 shall be documented at the contract review form, including justifications for reduction or addition of time based on the minimum audit duration;
- the on-site audit time does not include planning, reporting or travel activities, only actual on-site auditing time;
- where the FSSC 22000 audit is undertaken in combination or integration 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.



3.11.2 Audit Duration Calculation

The total on-site audit time (for a single site) is defined as $T_s + T_{FSSC}$. In additional to that, BSI shall include appropriate time for preparation and audit report.

The T_S is calculated as follow: $T_S = (T_D + T_H + T_{MS} + T_{FTE})$, each parameter can be obtained thru the table below, being:

- T_s = the minimum audit time for a single site;
- T_D = is the basic on-site audit time, in days;
- T_H = is the number of audit days for additional HACCP studies
- T_{MS} = is the number of audit days for absence of relevant management system
- T_{FTE} = is the number of audit days per number of employees

Category	Basic, on-site audit time, in audit days T _D	Number of audit days for each additional HACCP study	Number of audit days for absence of certified relevant management system	Number of audit days per number of employees (FTE on the man shift)
	-	Тн	T _{MS}	T _{FTE}
С	1.5	0.50		1 to 19 = 0 20 to 49 = 0.5 50 to 79 = 1.0
I	1.0	0.25	0.25	80 to 199 = 1.5 200 to 499 = 2.0 500 to 899 = 2.5 900 to 1299 = 3.0
К	1.5	0.50		$\begin{array}{l} 1300 \text{ to } 1299 = 3.0 \\ 1300 \text{ to } 1699 = 3.5 \\ 1700 \text{ to } 2999 = 4.0 \\ 3000 \text{ to } 5000 = 4.5 \\ >5000 = 5.0 \end{array}$

T_{FSSC} shall be calculated as follows:

Number of Employees (FTE on the main shift)	Number of HACCP studies	T _{FSSC}
< 250 ar	1 or 2 HACCP studies	0.5 auditor day



Number of Employees (FTE on the main shift)	Number of HACCP studies	T _{FSSC}	
≥ 250	or 3 HACCP studies or more	1.0 auditor day	

<u>Preparation and Report Time</u>: Preparation and reporting time shall be in addition to the on-site audit time:

- At least 0.25 auditor day (2 working hours) shall be added to the FSSC 22000 on-site audit time for audit preparation.
- At least 0.5 auditor day (4 working hours) additional shall be added to the FSSC 22000 onsite audit time for audit reporting.

3.11.3 Additional Time

3.11.3.1 Use of translator:

Additional time shall be considered in case an interpreter is required. For translation the minimum time to be added is 0.25 auditor day.

3.11.3.2 Separate Head Office

For organizations where some functions pertinent to the certification are controlled by a Head Office <u>separate to the manufacturing site(s)</u>, the minimum time shall be 0.5 auditor day (4 working hours) onsite to audit the functions pertinent to the certification at the Head Office.

A maximum of 20% audit time reduction can be allowed for each of the single manufacturing sites belonging to the group where the shared functions are controlled by the (off-site) Head Office. The 20% audit time reduction is applied to the minimum audit time (T_s) only.

3.11.3.3 Off-site Activities

For offsite manufacturing or service activities: a 50% audit time reduction of T_s may be applied for each additional site.

<u>For off-site storage</u>: at least 0.25 auditor day (2 working hours) additional on-site audit time shall be added to the FSSC 22000 audit time for each off-site storage facility.



3.11.3.4 Additional Scheme

Where the FSSC 22000 audit is undertaken in combination or integration with other food safety audits as a combined audit, the duration shall be increase on the top of FSSC 22000. The minimum FSSC audit duration shall always be respected. 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.

3.11.4 Reduction Time

Reduction cannot be applied at T_{FSSC} . When properly documented and justified, a reduction of the Ts audit time can be made in accordance with ISO/TS 22003:2013, Annex B. The reduction in Ts audit time can never be more than 0,25 auditor day (2 working hours). The reduction cannot be applied on T_{FSSC} .

<u>Exemption</u>: Further reduction is only allowed for sites with simple processes, having 5 FTE or less and maximum 1 HACCP study. For such sites, a reduction in on-site audit time (T_{FSSC}) can be made but the total time $T_s + T_{FSSC}$ shall be minimum one day. This reduction shall be approved in the contract review.

3.11.5 Rounding Down and Up

If after the calculation the result is a decimal number, the number of days should be adjusted to the nearest half day following mathematic rule/ concept. The rounding is done over the total of $(T_s + T_{FSSC})$.

3.11.6 Audit Duration Confirmation – On Site

For every audit, the auditor has the responsibility to check if the factors that affect the duration has not been changed and if the audit duration allocated is correct. If auditor realized that the audit duration that was allocated to the activity is not corrected, he/she shall immediately contact the BSI office that will provide instruction on how to proceed in order to ensure that the correct duration will be delivered.

In additional to that when this situation occurs the contract review shall be reviewed and re-approved in order to ensure the following audits of the cycle will be delivered in accordance with FSSC 22000 audit duration rules. As per FSSC 22000 Guidebook client is requested to send us the APCF507 when significant changes occur.

3.12 Audit Report

At the conclusion of the audit, the audit team will prepare a written report on the audit findings and the audit team leader will present these findings to your site's senior management at the exit meeting.



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Non-conformities will be discussed with your team during the auditor's visit and outlined at the exit meeting. Non-Conformities are categorized as Critical, Major and Minor.

These Non-Conformities and their categorization at the exit meeting are preliminary and are subject to a technical review by BSI.

The audit findings include a summary of the overall compliance of your system with the requirements of the relevant standard(s) or codes of practice.

If you are unclear regarding the meaning of anything in your report, please contact your BSI auditor or local office.

The ownership of the certificate and audit report content is held by BSI. At the request of food safety authorities, information related to the certification and auditing process shall be shared

3.13 Non-conformities

It is your site's responsibility to respond to the non-conformities detailed in your audit report by the designated time frame. Failure to do so may result in suspension or cancellation of your certification.

Close out of non-conformities is via your BSI FSSC auditor. The auditor will review the information provided and will either approve and close out the non-conformance or request further information from your site until such time as the sufficient information has been received. Certain non-conformances require a revisit to the site to confirm satisfactory closure.

3.13.1Nonconformities Levels

BSI shall apply these criteria as a reference against which to determine the level of nonconformities for findings in FSSC audits. There are three nonconformity (NC) grading levels:

Nc Level	Definition		
Minor	A minor nonconformity shall be issued when the finding does not affect the capability of the management system to achieve the intended results.		
Major	A major nonconformity shall be issued when the finding affects the capability of the management system to achieve the intended results.		
Critical	A critical nonconformity is issued when a direct food safety impact without appropriate action by the organization is observed during the audit or when legality and/or certification integrity are at stake.		

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 BSI procedures before issuing the site certificate.

3.13.2Non-Conformity Management

3.13.2.1 Minor Nonconformity

1) the organization shall provide the BSI with objective evidence of the correction, evidence of an investigation into causative factors, exposed risks and the proposed corrective action plan (CAP);

2) BSI shall review the corrective action plan and the evidence of correction and approve it when acceptable. BSI approval shall be completed within 28 days after the last day of the audit. Exceeding this timeframe by the organization shall result in a suspension of the certificate.

3) corrective action(s) (CA) shall be implemented by the organization within the timeframe agreed with BSI;

4) effectiveness of implementation of the corrective action plan shall be reviewed, at the latest, at the next scheduled on-site audit.

3.13.2.2 Major Nonconformity

1) the organization shall provide to BSI with objective evidence of an investigation into causative factors, exposed risks and evidence of effective implementation;

2) BSI 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, BSI may decide to perform a desk review. This follow-up shall be done within 28 days from the last day of the audit;

3) the major nonconformity shall be closed by BSI within 28 calendar days from the last day of the audit. When the major cannot be closed in this timeframe, the certificate shall be suspended;

4) where completion of corrective actions might take more time, the CAP shall include any temporary measures or controls necessary to mitigate the risk until the permanent corrective action is implemented.

3.13.2.3 Critical Nonconformity

1) when a critical nonconformity is issued at a certified site the certificate shall be immediately suspended for a maximum period of six (6) months;

2) when a critical nonconformity is issued during an audit, the organization shall provide to BSI with objective evidence of an investigation into causative factors, exposed risks and the proposed CAP. This shall be provided to BSI within 14 days after the audit;

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3) a separate audit shall be conducted by BSI between six (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;

4) the certificate shall be withdrawn when the critical nonconformity is not effectively resolved within the six (6) month timeframe;

5) in case of a certification audit (initial), the full certification audit shall be repeated.

3.14 Granting Certification

Certification of an FSSC System shall be awarded to an organization with no outstanding nonconformities. BSI will issue the certificate within 30 calendar days from the date of the certification decision. The certificate expires three years after the date of the initial certification decision. However, whilst the certificate is issued to the applicant site, it remains the property of BSI under the conditions outlined in the contract.

3.15 Maintaining Certification

To maintain FSSC certification, your site is required to ensure that surveillance and/or re-certification audits occur within the required timeframe, ensure that no critical non-conformities are raised at surveillance or re-certification audits, and that all major and minor non-conformities are corrected within the time frame specified.

3.16 Multi-site certification

Multisite is not allowed for the categories that BSI is accredited for. Thus, not applicable to FSSC 22000 operation in BSI.

3.17 ICT Audit Approach and Full Remote Audits

The standard method for conducting FSSC 22000 audits is either through full on-site audits as described on this Guidebook or partial on-site audits using the ICT Audit Approach. Both of which are accredited and GFSI recognized options.

The FSSC 22000 full remote option is an **accredited, non-GFSI recognized, voluntary option that** can only be utilized where access to the premises of the certified organization is not possible as a direct result of a serious event, supported by a risk assessment.



3.17.1 Definition

- Full Remote Audit: A full remote audit is defined as an audit that takes place entirely at a location other than that of the certified organization through the use of ICT.
- ICT Audit Approach (Remote + On Site): FSSC 22000 audit as a split process utilizing ICT. The ICT audit approach consists of 2 main steps being the remote audit and the on-site audit.
- ICT: is the use of technology for gathering, storing, retrieving, processing, analyzing and transmitting information. It includes software and hardware such as smartphones, handheld devices, laptop computers, desktop computers, drones, video cameras, wearable technology, artificial intelligence, and others

3.17.2 ICT Audit Approach

The ICT audit approach consists of 2 main steps:

- Remote audit Component consisting of a document review and interviews with key personnel using ICT.
- On-site audit Component focusing on the implementation and verification of the FSMS (including HACCP), PRPs, the physical inspection of the production process and any remaining requirements not covered during the remote audit.

During the **remote audit**, assessment activities are performed from a location other than the physical location of the audited organization. The **on-site audit**, assessment activities are performed at the physical location of the audited organization.

The following criteria will be used for assessing and approving the Use of ICT Audit Approach:

- Maturity of the certified organization's FSMS and performance history;
- Whether the certified organization permits and accommodates remote audit activity (i.e. availability of records in electronic format or document reader) including data protection and security measures;
- The ICT tools to be used;
- Whether the certified organization and/or BSI have the ability to provide representatives capable of communicating in the same language;
- Whether BSI and the certified organization have the capability and ability to conduct the remote audit in the chosen medium/forum of the remote audit;
- Impact on audit duration and audit planning e.g. where more time might be required due to the use of ICT;
- The type of the related FSSC audit

When agreeing to utilize remote auditing techniques with a client it is important to consider both general and specific information security considerations to ensure the security of client information and to manage expectations. As part of the preparation for the use of ICT, all certification legal and customer requirements related to confidentiality, security and data protection shall be identified and actions taken by both client and BSI country to ensure their effective implementation. This implies that both the

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auditor/BSI and the auditee agree to the use of ICT and with the measures taken to fulfil these requirements.

The following points must be considered as a minimum:

- All certification personnel are required to discard all information (excepted those that constitute certification records) collected during the planning and execution of the remote audit, once it has been completed;
- During the remote audit, no unauthorized recording (voice and /or video) is allowed;
- If recording is authorized, all recorded information (voice and /or video) shall only be used as evidence for supporting the raising of certification findings and conclusions.

The ICT means to be used shall be tested with the certified organization before the planned remote audit to confirm that the ICT is appropriate, suitable and effective. Feasibility also depends on the online connection quality. In all instances where ICT utilized is not functioning properly or preventing/hampering a robust audit, the audit shall be aborted, and suitable follow-up actions determined along with the FSSC Global Scheme Manager.

When using the ICT Audit Approach, the related audit duration will be calculated as per FSSC scheme rules, however where rounding is applied, durations shall **ONLY be rounded upwards** to the nearest half day taking into account that additional time might be required to conduct the remote audit. This mandatory requirement to round upwards may result in the ICT Audit approach duration calculation being different from the regular FSSC onsite audit. Total on site audit duration does not include preparation activities or reporting, and additional time is required for these activities as per the FSSC Scheme Rules.

The remote audit component will typically be 0.5 - 1 day and the onsite verification audit the remainder of the total duration of the regular annual audit. The onsite audit component cannot be less than 1 day and shall at least be 50% of the total audit duration. When determining the amount of time spent onsite and remotely, the outcome of the assessment and the historical performance of the organization (including complaints and recalls) shall be taken into consideration. For example, if the assessment demonstrated that a remote audit is possible, but the historical performance of the organization has been of concern, then the proportion of time spent onsite is expected to be increased.

If during the remote audit, time is consumed on issues such as network downtime, unexpected interruptions or delays, accessibility problems or other ICT challenges, this time shall not be counted as audit time and shall be documented on the report as a deviation from audit plan, and the report shall also include the time added to comply with the minimum required audit duration.

It is recommended that the remote and the onsite audit take place as close together as possible, but in all cases the maximum timeline for completion of the audit (remote + onsite) shall not exceed 30 calendar days.

In the case of serious events, the timeline may be extended to a maximum of 90 calendar days, based on a clear and documented concession process and risk assessment by BSI. The risk assessment shall consider the elements of IAF ID3 as a minimum and the extension is only allowed where the efficiency and integrity of the audit will not be compromised. Where concessions are granted by BSI and the 90 days timeline is applied, the risk assessment shall be uploaded to the FSSC portal as part of the audit documentation.

The ICT audit approach can be applied either in extraordinary situations or normal circumstances and may be applied for the following audits:

Stage 01;

- Surveillance;
- Re-certification;
- Head Office (where the corporate functions are controlled separately);

^(Note): In the year where an unannounced audit is due, the ICT audit approach may be used, whilst still applying the requirements of FSSC V5. The prerequisite would be that the onsite part of the shall be conducted **first**, followed directly by the remote audit with a maximum period of 48 hours between the two audit components.

The remote audit includes a document review and interviews with key personnel which includes (**as mandatory**) review at least following key FSMS elements:

- Document/procedure reviews;
- HACCP plans;
- Key changes since the last audit (where applicable);
- Product recalls and significant complaints;
- Status with regard to FSMS objectives and key process performance;
- Management review;
- internal audits;
- Interviews with management and key personnel.

The onsite audit serves as the verification audit for Food Safety Management System (FSMS) implementation with a focus on the production processes and environment as well as the remainder of the clauses not covered as part of the remote audit.

The onsite audit shall include as a minimum inspection/physical verification of PRPs, the traceability test and implementation of the FSMS. The latter includes, but is not limited to, the HACCP system, for example the effective operation of PRPs, verification of the process flow diagram, OPRP and CCP monitoring and verification. It might be necessary to review parts of the remote audit again to ensure implementation of requirements.

All the requirements of the Scheme shall be covered between the remote audit and the onsite audit components and be clearly reflected in the audit plans, audit program and the final audit report.

Any nonconformities identified during the audit (remote and onsite) shall be addressed in line with the Scheme requirements.

- Where the audit (remote + on-site) is completed within 30 calendar days, one nonconformity report is completed and the timeline for nonconformity closure starts at the end of the on-site audit. Any nonconformities identified during the course of the audit shall be communicated to the organization in a timely manner. BSI shall provide a provisional NC BSI Sheet to the organization at the end of the remote audit.
- In the case of a serious event and where the 30 calendar days for audit completion is exceeded (based on a documented concession process and risk assessment by BSI) any nonconformities identified as part of the remote audit shall be recorded and a copy of the nonconformity BSI NC Sheet shall be left with the certified organization at the end of the remote audit. The timeline for closure of these nonconformities starts at the end of the remote audit. The timeline for closure of the on-site audit starts at the end of the on-site audit.



 Where a critical nonconformity is identified at any time during the audit (remote or on-site), the certificate shall be suspended, and a full new on-site audit will be required to lift the suspension within 6 months.

One audit report shall be produced covering both the remote and the onsite audit components.

The audit report shall clearly identify the extent to which any ICT has been used in carrying out the audit and the effectiveness of ICT in achieving the audit objectives. The audit report shall include all summarized information, findings and nonconformity details of both the remote and onsite audit, covering all Scheme normative requirements and meeting the requirements. The report shall also reference the dates and the duration of the onsite and remote audits and the auditor/s involved in both parts. The requirements assessed during the remote audit shall be identified by placing a "**R**" at the beginning of the information.

3.17.1 Full Remote Audit

The FSSC 22000 full remote option is an **accredited**, **non-GFSI recognized**, **voluntary option that can only be utilized where access to the premises of the certified organization is not possible as a direct result of a serious event**, supported by a risk and feasibility assessment. Mutual agreement between BSI and the certified organization is required prior to conducting the full remote audit.

BSI shall conduct an assessment to evaluate the risk of continued certification and review the planned audits when on-site auditing is not possible. A full remote audit may also be considered as an option when planning the audits and where this audit methodology is supported by the feasibility and risk assessments.

In the first instance BSI shall conduct a risk assessment to determine the impact of the serious event on the current certification status of the certified organization. The full remote audit option can only be utilized when the risk of maintaining certification is determined as being low.

Secondly, BSI shall conduct a feasibility assessment to determine, in conjunction with the certified organization, whether a full remote audit is a viable option and to determine if the full audit objectives can be achieved through the use of ICT.

The following is considered when conducting the feasibility assessment through the PF1414, which you will be required to filled:

- Maturity of the certified organization's FSMS and performance history;
- Whether the certified organization permits and can accommodate remote auditing (i.e. availability
 of records in electronic format or document reader) including specific data protection and security
 measures;
- The ICT tools to be utilized;
- Whether the certified organization and/or BSI have the ability to provide representative/s capable of communicating in the same language.
- Whether BSI and the certified organization have the capability and ability to conduct the remote audit in the chosen medium/forum of the remote audit covering all parts of the audit, including the production audit.



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- Impact on audit duration and audit planning e.g. where more time might be required due to the use of ICT
- The feasibility of the audit should be determined to provide confidence that the audit objectives can be achieved. The determination of feasibility should take into consideration factors such as the availability of the following:
 - Sufficient and appropriate information for planning and conducting the audit;
 - Adequate cooperation from the auditee;
 - Adequate time and resources for conducting the audit

For a full remote audit to be conducted, the site needs to be operational with production taking place. In the event that the site has closed and/or no production is taking place, the full remote audit option cannot be applied.

BSI shall ensure that ICT is used to optimize the efficiency and effectiveness of the audit/assessment, while supporting and maintaining the integrity of the audit process.

The use of ICT shall be mutually agreed between the auditee and BSI in accordance with information and data security measures and regulations before ICT is used. Video and/or audio recordings, screenshots, and storage of evidence shall also be mutually agreed and the BSI shall keep record of these agreements.

In all instances where ICT utilized is not functioning properly or preventing/hampering a robust audit, the audit shall be aborted, and suitable follow-up actions determined in line with the audit schedule and Scheme requirements along with the FSSC Global Scheme Manager.

The ICT means to be used shall be tested with the certified organization before the planned remote audit to confirm that the ICT is appropriate, suitable and effective (considering all parts of the audit including but not limited to its use in the production site). Feasibility also depends on the online connection quality.

The total audit duration based on the FSSC scheme rules shall be met. Where rounding is applied, durations shall be rounded upwards to the nearest half day taking into account that additional time might be required to conduct the remote audit. There is a need for effective planning for the remote audit to ensure that it effectively achieves stated objectives and minimum audit time. As a result, more time might be needed for the planning process.

The full remote audit option is only applicable in the following cases when linked to a serious event:

- Where the annual, announced FSSC 22000 surveillance or recertification audits are impacted as a result of a serious event and cannot take place on-site;
- Transition (from another Scheme to FSSC) audits;
- Where follow-up audits to close out nonconformities cannot take place this will be dependent on the nature of the nonconformity, the suitability of the ICT and BSI shall in all instances be able to justify the effectiveness of the methods used. Critical nonconformities require an on-site follow-up audit in all instances;
- Special audit based on the outcome of the serious event risk assessment.

Remote audit activities follow the same principles and format of the on-site audit activities and includes a full audit against the Scheme requirements. Use of remote technology shall ensure that adequate controls are in place to ensure a true representation of the site and a robust audit.

All Full Remote Audits shall include:

- Opening meeting;
- Document review;
- Interviews;
- On Site facilities/infrastructure, manufacturing (and support) processes and storage;
- Intermediate conclusions meeting (between the audit team and/or with client) as appropriate
- Closing meeting

It is therefore likely that different types and combinations of ICT will be used during the same audit, that must be reviewed and agreed on as part of the feasibility and risk assessment and audit planning process.

Remote audit activities follow the same principles of the on-site audit activities and where nonconformities are identified, these are documented, graded and addressed as defined in the Scheme requirements.

The Audit report shall comply with the FSSC Scheme requirements and clearly indicate that the audit was conducted as a full remote audit. An overview shall be included in the executive summary of the report providing details of the serious event and the extent to which ICT was used, including different methodologies applied.

The audit report template to be used when ICT Audit Approach is applied are the same used for the regular on site audit.

As part of the certification decision process, BSI shall review the audit program and take into consideration the need for an on-site special audit and any changes required to the audit program based on risk and the outcome of the audit. It remains the responsibility BSI to ensure a proper and robust audit process and make an informed certification decision.

Where the outcome of the remote audit is to maintain (re-) certification, the certificate shall be updated to reference that a Full Remote Audit was conducted. Following an on-site audit (full on-site or via the ICT Audit approach), the certificate shall be updated and the reference to Full Remote Audit removed.)

3.17.2 Transfer of certification

BSI will follow the requirements of IAF MD 2 for all transfer certification.

3.17.3 Transition Audits

Transition audits are allowed from Dutch HACCP, ISO 22000 and GFSI recognized certification programs with equivalent scopes. Transition audits are only allowed from valid certificated issued by BSI. 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 BSI). The FSSC 22000 certificate issued shall have a validity of 3 years.

<u>Important</u>: Transition CANNOT be performed from a certificate issued by another CB. For this case, clients shall be first transferred and have their BSI certificate issued. Only after that, the transition can be performed (before the expire date of the certificate).

3.17.4 Special Audits

Additional special audits shall be performed on top – but never as a replacement of the annual surveillance/ recertification audits. These special audits shall be documented and upload in the portal.

3.17.4.1 Extension of Scope

BSI shall, in response to an application for expanding the scope of a certification already granted, undertake a review of the application and determine any audit activities necessary to decide whether or not the extension may be granted. This may be conducted in conjunction with a surveillance audit or with a re-certification or separated from the audit cycle being conducted as special audit.

BSI shall be notified at least 90 days in advance to the audit in order to properly update the contract, including all relevant aspects such as audit duration. A new application

3.17.4.2 Short – notice audits

It may be necessary for the BSI to conduct audits of certified clients at short notice or unannounced to investigate complaints, or in response to changes, or as follow up on suspended clients.

In such cases BSI shall describe and make known in advance to the certified clients the conditions under which such audits will be conducted.

3.17.5 FSSC 22000 Follow Up Audits

For follow up audit duration will depend on the number of non-conformities that shall be closed.

3.18 Unannounced Audit

An unannounced audit program is part of the 3-year certification cycle. Participation in the unannounced audit program is mandatory.

1) The program shall ensure that for each certified site, at least one unannounced audit is undertaken after the initial certification audit and within each 3-year period thereafter.

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.

3) The initial certification audit (stage 1 and stage 2) cannot be performed unannounced.



3.18.1 Unannounced Audit Execution

1) Your organization will not be notified in advance of the date of the unannounced audit and the audit plan will not be shared until the opening meeting.

2) The unannounced audit takes place during normal operational working hours including night shifts when required.

3) Blackout days may be agreed in advance.

4) The audit will start with an inspection of the production facilities commencing within 1 hour after the auditor has arrived on site. In case of multiple buildings at the site the auditor shall, based on the risks, decide which buildings/facilities shall be inspected in which order.

5) 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.

6) If the certified organization refuses to participate in the unannounced audit, the certificate shall be suspended immediately, and BSI will withdraw the certificate if the unannounced audit is not conducted within a six-month timeframe from the date refusal.

7) The audit of separate Head offices controlling certain FSMS processes pertinent to certification separate to the site(s) shall be announced . Where Head Office activities are part of a site audit, they shall be unannounced.

8) Secondary sites (off-site activities) and off-site storage, warehouses and distribution facilities shall also be audited during the unannounced audit.

3.19 Auditor Rotation

FSSC has a restriction in place that one auditor may conduct no more than six (6) consecutive audits at the same company. After six (6) audits, another auditor must be assigned to visit your premises. Following this change, the original auditor may return for up to another six (6) consecutive audits after a minimum period of one year.

4 FSMA PCHF Addendum

This is a voluntary addendum that can only be conducted with an FSSC 22000 audit. FSMA addendum as stand-alone audit is not allowed. The scope is limited to the manufacture of human food as regulated by the FSMA PCHF. If applied and additional time will be added (on the top of regular FSSC Audit Duration).

5 Implementation of FSSC 22000

5.1 Learn about the FSSC 22000 Scheme



There are several ways to learn how to implement the FSSC 22000 Scheme within your food business. The following options are available:

- Attend an FSSC 22000 Training course available through the BSI Training Academy (refer to your local BSI office or website)
- Train yourself by downloading the necessary documents from the FSSC website.

5.1.1 FSSC 22000 V5 Documents

FSSC 22000 V5 scheme documents are available at FSSC Website.

The FSSC 22000 scheme version 5 standard is structured in 06 parts compiled in 01 manual, 02 appendices, 07 annexes and guidances that are publicly available in English at FSSC website.

- 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 01: Definitions
- Appendix 2: References
- 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 templates
- Annex 5 AB Accreditation certificate scope
- Annex 6 TO Course specifications
- Annex 7 TO Training certificate templates

5.1.2 Board of Stakeholders List (BoS)

The BoS is composed of representatives of the food categories covered by the FSSC 22000 certification scheme. The Board provides binding decisions and voluntary recommendations for the associated Certification Bodies, Accreditation Bodies and Training Organizations with respect to the FSSC scheme.

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The list of decisions made by the Board of Stakeholders contains an overview of all relevant decisions that are related to the Scheme either as mandatory or voluntary documents. The decision list is dynamic and can be adjusted by the BoS when deemed necessary.

The current decision list is available <u>here</u>.

5.2 FSSC Database

The FSSC Foundation maintains a Register of Certified Sites with the names and information of all certified sites. This register is publicly available on the FSSC website.

For all FSSC 22000 audit types, the required data and documentation shall be entered in the FSSC Portal at the latest 28 calendar days after the certification decision with a maximum of 2 months after the last day of the audit.

6 Certificate Suspension, Withdrawal or Scope Reduction

1) Suspension: BSI shall immediately suspend certification when a critical nonconformity is issued and/or there is evidence that their client is either unable or unwilling to establish and maintain conformity with Scheme requirements

2) Withdrawal: BSI shall withdraw a certificate when:

- the status of suspension cannot be lifted within six (6) months;
- the organization ceases its FSSC 22000 certification activities;
- any other situation where the integrity of the certificate or audit process is severely compromised.

3) Scope reduction: When BSI has evidence that client holds a certificate whose scope exceeds their capability or capacity to meet scheme requirements, BSI shall reduce the certification scope accordingly. BSI 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.

6.1 Action Upon Suspension, Withdrawal and Scope Reduction

1) In case of suspension or withdrawal, the organizations' management system certification is invalid.

The BSI shall:

- immediately change the status of the certified organization in the Portal and its own Register of certified organizations and shall take any other measures it deems appropriate;
- inform the organization in writing of the suspension or withdrawal decision within three (3) days after the decision was made;
- instruct the organization to take appropriate steps in order to inform its interested parties.

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2) In case of scope reduction, the organizations' management system certification is invalid beyond the revised certification scope statement. BSI shall:

- immediately change the scope of the certified organization in the FSSC 22000 database and its own Register of certified organizations and shall take any other measures it deems appropriate;
- inform the organization in writing of the scope change within three (3) days after the decision of change;
- instruct the organization to take appropriate steps in order to inform its interested parties.

7 Use of Marks (FSSC, ANAB and BSI)

To acess FSSC logos, BSI Marks of Trust (assurance marks) and ANAB logo please contact <u>food@bsigroup.com</u>

To access the insructions for use to promote your BSI certification access <u>Guidelines for use</u> related to ANAB and BSI Marks.

For Guidance about FSSC logo use, see section below.

7.1 Use of the FSSC Logo

Certified organizations can use the FSSC 22000 logo only for marketing activities such as organization's printed matter, website and another promotional material.

In case of using the logo, the organization shall comply with the following specifications:

Color	PMS	СМҮК	RGB	#
Green	348 U	82/25/76/7	33/132/85	218455
Grey	60% black	0/0/0/60	135/136/138	87888a

Use of the logo in black and white is permitted when all other text and images are in black and white.

The certified organization is not allowed to use the FSSC 22000 logo, any statement or make reference to its certified status on:

- a product;
- its labelling;
- its packaging (primary, secondary or any other form);
- in any other manner that implies FSSC 22000 approves a product, process or service.

8 Confidentiality

BSI will keep confidential information confidential for a period of 6 years after it has received it and will not use or disclose it except for the purpose of exercising or performing its rights and obligations under the contract, or to the extent required by law, or by any governmental or other regulatory authority, or accreditation authority, or by a court or other authority of competent jurisdiction and/or by the Foundation.

In these cases, BSI will not be required to notify you of such disclosure and will not be required to oppose any demand made by such entities.

The ownership of the certificate and the audit report content of your site is held by BSI. At the request of food safety authorities, information related to the certification and auditing process shall be shared.

9 Additional Obligations

Following certification, there are a number of managerial responsibilities which your site will need to fulfil to maintain BSI's certification. These include:

- Continued compliance with the relevant systems standard(s) or code(s) of practice;
- Compliance with BSI's Standard Commercial Terms and Conditions and obligations as specified in this document as well as other guidance documentation that may be specifically provided from time-to-time;
- Conduct of regular internal reviews of your system, with appropriate documentation of such reviews and of any subsequent corrective actions;
- Notification to BSI of any significant changes in the structure (key responsibilities and management system), ownership and operations of your site to enable the impact of such changes on the certified ownership system to be evaluated; and
- Notification to BSI of any litigation or serious events or matters that relate to the scope of your certification within twenty-four (24) hours of the event.

9.1 Complaints

Your site is required to keep a record of all known complaints. These records must be made available to the audit team and BSI when requested.

Your site is required to demonstrate that you have taken appropriate action to address these complaints through investigation and correct any deficiencies found. These actions must be documented.



9.2 Certification Agreement

Your site is required to meet the requirements of the Certification Agreement. This requires that your site and products remain compliant with the scheme requirements and the conditions of certification at all times.

Your site is required to implement appropriate changes as communicated by BSI in a time appropriate manner.

9.3 Assessment Scheduling

Your site is required to make all necessary arrangements to allow the evaluation and surveillance activities to take place. This includes but is not limited to; Equipment, Product, Locations, Personnel and Sub-contractors.

9.4 Misleading Statements

Your site is not permitted to use its certification in a manner that could bring BSI into disrepute. This includes making misleading or unauthorized statements. If you are unsure if a statement could be misleading you are advised to contact BSI prior to making the statement. Statements include but are not limited to advertising (including your website) and internal communication. The use of the logo on product and product packaging is not permitted.

If your site is required to provide copies of certification documents these must be reproduced in its entirety. Failure to do so may be misleading to the recipient as to the scope of certification.

9.5 Communication Obligations

Your organization has the obligation to communicate with your local BSI office within 3 working days related to the following:

a) any significant changes that affect the compliance with the Scheme requirements and obtain advice of BSI in cases where there is doubt over the significance of a change;

b) changes to organization name, contact address and site details;

c) changes to organization (e.g. legal, commercial, organizational status or ownership) and management (e.g. key managerial, decision-making or technical staff);

d) changes to the management system, scope of operations and product categories covered by the certified management system;

e) an extraordinary event affecting a certified site or BSI may temporarily prevent BSI from carrying out planned audits on-site. When such a situation occurs, BSI in consultation with the certified site will need to determine a reasonable planned course of action;

f) any other change that renders the information on the certificate inaccurate.

9.6 Management of extraordinary serious event

In case your organization is affected by public food safety incidents (such as e.g. public recalls, calamities, food safety outbreaks, etc.) BSI shall be notified within 03 working days through <u>food.recall@bsigroup.com</u>

There is no obligation to communicate product withdrawals to BSI. The definitions of product withdrawal and product recall are listed below for reference:

- <u>Product Recall</u>: The removal by a supplier of a product from the supply chain that has been deemed to be unsafe and has been sold to the end consumer and is available for sale (GFSI v7.2:2018).
- <u>Product Withdrawal</u>: The removal of a product by a supplier from the supply chain that has been deemed to be unsafe and which has not been placed in the market for purchase by the end consumer (GFSI v7.2:2018).

Based on the information provided, the BSI may need to notify Foundation FSSC about some recalls.

In case your organization is affected by serious events that impact the FSMS, legality and/or the integrity of the certification which includes legal proceedings, prosecutions, situations which pose major threats to food safety, quality or certification integrity as a result of natural or man-made disasters (e.g. war, strike, terrorism, crime, flood, earthquake, malicious computer hacking, etc.), BSI shall be contacted within 03 working days through critical.food@bsigroup.com.

BSI will manage extraordinary serious event as per <u>IAF ID3:2011</u> as well as per any additional requirement established by FSSC.

For Coronavirus: Based on the FSSC position regarding management of COVID-19, the risk assessment shall be completed for all FSSC certified sites that have been affected by COVID-19 and/or where planned audits have to be postponed or the certificate validity extended as a result of not being able to conduct the onsite audit.

The risk assessment will determine if the certified site has developed/adjusted its procedures and operations to ensure continued compliance to the FSSC Scheme and the supply of safe products.

The documented risk assessment will review:

- The history of the FSSC food safety management system
- Any pending compliance activities or legal proceedings
- Your organization's current and expected future situation as per <u>IAF ID3:2011</u>
 - Emergency preparedness and response including the impact of the COVID-19, including changes to processes or services outsourced following the COVID-19 epidemic
- Key changes since the last audit
- Performance evaluation:
 - Status of your FSMS objectives
 - Status of the key process performance including, but not limited to, the monitoring and corrective actions of OPRPs and CCPs
 - Management review



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- Internal audits: throughout the pandemic it's expected that certified organizations increase the frequency of internal audits in support of the FSMS and to ensure food safety
- Customer complaints as well as product recalls and withdrawals

The outcome of your risk assessment will determine the short-term course of action and establish limitations as below:

- If is identified a high risk for continuing the certification: the certificate will be suspended
- If is identified a <u>low risk</u> for continuing the certification: decision can be as follow as appropriate for each certification cycle
 - Maintain the certification; or
 - Maintain the certification and postpone the surveillance audit by a maximum of 6 months within the calendar year. The timeframe between the 2019 and 2020 audits shall not exceed 18 months. The exception will also apply to the first surveillance audit following an initial certification; or
 - Extend the validity of the certificate up to 6 months. The BSI may issue an extended certificate to the client. The full re-certification on site audit shall be completed within the validity extension window with sufficient time to complete the certification process prior to the expiry of the extended certificate.

9.7 Observers

- From time to time BSI requires an observer to be in attendance at an audit. This may be related to training of new staff and witness assessment of existing staff. It is a requirement of certification that your site allows these activities to occur.
- BSI will, at all times, ensure that the use of observers is kept to a minimum and your site will be advised prior to the assessment activity.
- The observer does not take an active part in an assessment.
- By accepting the FSSC BSI quote your organization accept cooperate with such process

9.8 Witnessing Assessment by CB

From time to time the accreditation body and /or the Foundation FSSC requires a performance of a witnessing process. By accepting the FSSC BSI quote your organization accept cooperate with such process that can be conducted on site or remotely in which the normal confidentially requirement applies.

9.9 TE (Technical Expert) use by CB

BSI may need to use a TE during an FSSC audit. By accepting FSSC proposal presented by BSI your organization accepts to cooperate with such process that can be conducted on site or remotely in which the normal confidentially requirements apply.

9.10 FSSC Website

It is an FSSC scheme requirement for your site's details to be displayed on the FSSC website.

10 Complaints and Appeals

Appeals against certification decisions and/or complaints against service delivery levels may be raised with your auditor. If you remain dissatisfied, contact BSI in writing using the contact details below.

BSI will also investigate legitimate documented complaints, relevant to operation of the system, from clients/customers of certified sites, The FSSC Foundation and the accreditation body (ANAB). Certified sites shall, at all reasonable times, provide representatives of BSI, FSSC or ANAB with access to its premises and records for the purposes of investigating such complaints.

If your site's application for certification has been refused; or your certified site's certification has been suspended, withdrawn, or reduced in scope, you may appeal against the decision. All complaints will be investigated and the originator of a complaint will be advised of the outcomes, as appropriate.

Where necessary a Review Committee will be established and operated as set out below:

- The appellant shall, within 28 days of the disputed advice from BSI, lodge a written notice of appeal with an affidavit as to the grounds of appeal;
- The BSI Global Operations & Compliance Management Group shall be advised within 14 days of receiving the appellant's notice;
- The Global Operations & Compliance Management Group shall then establish a Review Committee;
- The Review Committee shall consist a minimum of three persons considered as experts in the area of technology or business relevant to the appeal. The Review Committee shall be constituted as follows:
 - One-person expert in the relevant area of technology or business
 - Two persons selected by the appellant from a list of four persons
- The appellant shall represent himself and no legal representation will be allowed unless approved by the Review Committee; and
- The Review Committee will carry out investigations as are required, including assessment of information supplied by the appellant and, within a reasonable time, decide by majority vote whether or not to reverse the original decision.



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• The Global Food and Retail Supply Chain Operations and Compliance Director shall give notification of the decision to the appellant within 14 days of the Review Committee decision

To raise a complaint or appeal against the service delivery by BSI or audit outcome please notify:

• Todd Redwood

Global Food and Retail Supply Chain Operations and Compliance Director

Email: todd.redwood@bsigroup.com

11 Upgrade Process from FSSC 22000 V4.1 to V5

11.1 Audit requirements:

Upgrade audits will be performed against FSSC 22000 V5 requirements. These can be found on the FSSC 22000 website under certification scheme documents (FSSC 22000 Scheme Version 5).

11.2 Audit planning

The upgrade audits (surveillance and re-certification) will be conducted as announced audits, unless your organization specifically requests an unannounced upgrade audit.

11.3 Audit duration

The audit time for the upgrade audit will remain the same as for regular planned audit and will be calculated in accordance with certification scheme documents (<u>FSSC 22000 Scheme Version 5 - Part 3</u> <u>Requirements for Certification Process - chapter 4.3</u>).

11.4 Timelines

Audits against FSSC 22000 V4.1 are only allowed until 31 December 2019.

Upgrade audits against FSSC 22000 V5 scheme requirements will be conducted between 1 January .+, 2020 and 31 December 2020.

Under **extraordinary circumstances**, the V5 upgrade audit could take place in 2021, however this process must be completed in accordance with FSSC 22000 V5 scheme requirements and before **31** March 2021. The extraordinary circumstances must be documented, shared with and approved by BSI.

If approved, BSI must communicate the delayed audits by 31 December 2020 at the latest. In order to us comply with this time frame, your organization must make BSI aware of your organization's extraordinary circumstances no later than 29 November 2020. It will also be need plan date for the V5



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upgrade audit as well as the scheduled date for the 2021 annual audit – both of which have to be completed within the calendar year to ensure the Scheme audit program requirements are being met.

11.5 Certificates

All FSSC 22000 V4.1 certificates will become invalid after 29 June 2021 and will be withdrawn by BSI. If your organization doesn't comply with the upgrade process timelines detailed above, the process to regain the certification will require that your organization begins the certification process at stage 1 as per ISO 17021 requirements.

A new V5 certificate will be issued after a successful upgrade audit (maintaining the same certificate expiry date in case of surveillance audit. For re-certification a new certification cycle will be established).

11.6 FSSC portal

The FSSC portal (database) will be updated by BSI when the new V5 certificates are issued. The V4.1 certificate of clients that upgrade during 2020 will be withdrawan in the Portal once the V5 certicate is uploaded.

All remaining V4.1 certificates of clients that do not upgrade, will be automatically set to invalid by the portal after 29 June 2021 and no longer visible on the public list of certified organizations on the FSSC 22000 website.