

BSI Certification Requirements BSI Standard Terms and Conditions Addendum FSSC 22000 v5.1



Contents

Revi	sion I	History	۲	. 5
1	Intro	oductio	on	7
	1.1	FSSC 2	22000 V5 – Main changes	7
2	Accr	editati	on status and BSI scope of accreditation	7
3	The	recogn	ition process	. 8
	3.1	Initial	enquiry	8
	3.2	Applica	ation for aertification and assessment	8
		3.2.1	Application form client contact	8
		3.2.2	Annual fee	8
	3.3	Certific	ation contract Erro! Indicador não definic	do.
	3.4	Condu	ct a self-Assessment / pre-assessment audit (not mandatory)	9
	3.5	Identif	ying the scope of certification	9
	3.6	Certific	ation cycle	12
		3.6.1	Planning audits	. 12
	3.7	Audit o	riteria	12
		3.7.1	Legal and regulatory audit requirements	. 14
	3.8	The ce	rtification audit	15
	3.9	Surveil	lance audits	15
	3.10	Recert	ification	15
	3.11	Audit o	luration	15
		3.11.1	Basic guides for audit duration	16
		3.11.2	Audit duration calculation	. 16
		3.11.3	Rounding rule	18
		3.11.4	Minimum audit duration	18
		3.11.5	Reduction in time	18
		3.11.6	Additional time	19
		3.11.7	Multisite sampling methodology	20
		3.11.8	Transition to FSSC 22000	
			FSSC 22000 transfer	
			FSSC 22000 follow up audits	
	3.12		eport	
			Timeline to send the report to the (certified) organization	
	3.13		onformities	
		3.13.1	Nonconformities levels	. 22



FSSC 22000 v5.1 Certification requirements Revision 16 (April 2021)

	3.14	Grantir	ng certification	. 24
	3.15	Mainta	ining certification	. 24
	3.16	ICT au	dit approach and full remote audits	. 24
		3.16.1	Definition	. 25
		3.16.2	ICT audit approach	. 25
		3.16.1	Full remote audit	. 28
4	Man	aging a	audits	30
	4.1	Head of	office functions	. 30
	4.2	Off-site	e activities	. 31
	4.3	Multi-s	ite certification	. 31
		4.3.1	Sampling methodology	. 32
		4.3.2	Requirements for the central function	. 33
		4.3.3	Nonconformity management (for multi-sites)	. 33
	4.4	Unann	ounced audits	. 34
		4.4.1	Frequency	. 34
		4.4.2	Unannounced audit execution	
		4.4.3	Actions if organization refuses to participate in the unannounced audit	. 35
	4.5		onal scheme / combined & integrated audit	
	4.6	Transf	er of certification	. 35
	4.7	Transit	tion audits	. 35
	4.8	Extens	ion and reduction of scope	. 36
	4.9	Follow	up audits	. 36
	4.10	Specia	l audits	. 36
	4.11	Short -	- notice audits	. 37
5	Imp	lement	ation of FSSC 22000	37
	5.1	Learn	about the FSSC 22000 Scheme	. 37
	5.2	FSSC 2	22000 V5 Documents	. 37
	5.3	FSSC [Database	. 38
		5.3.1	Data ownership	. 38
		5.3.2	BSI Portal on FSSC Database	. 38
6	Cert	ificate	Suspension, Withdrawal or Scope Reduction	39
	6.1	Action	Upon Suspension, Withdrawal and Scope Reduction	. 39
7	Use	of Mar	ks (FSSC, ANAB and BSI)	39
	7.1	Use of	the FSSC Logo	. 40
8	Conf	fidentia	ality	40



9	Addi	tional Obligations
	9.1	Complaints
	9.2	Certification Agreement
	9.3	Assessment Scheduling
	9.4	Misleading Statements
	9.5	Communication Obligations
	9.6	Agreement on information sharing 42
	9.7	Management of extraordinary serious event
	9.8	Observers
	9.9	Winessing Assessment by CB 44
	9.10	TE (Technical Expert) use by CB 44
	9.11	FSSC Website
	9.12	Complaints and Appeals 44
10	Imp	artiality
	10.1	In house and open FSSC external trainings 45
	10.2	Consultancy 45
	10.3	Auditor rotation in FSSC 22000 certification audits
11	Ugra	ade timeline from v4.1 to v5
12	Upg	rade Process from FSSC 22000 v5 to v5.145
	12.1	Audit planning and timelines
	12.2	Audits 45
	12.3	Audit duration 47
	12.4	Certificate
		12.4.1 Managing the remaining v5 certificates
	12.5	FSSC Portal 47
	12.6	FSSC v5.1 scheme documents: Erro! Indicador não definido.



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	3.7 / 3.13.2	er page page 10 .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



PP1268

<mark>16</mark>	April 2021	<mark>Ana</mark> Cicolin	Todd Redwood	<mark>5.2</mark>	<mark>37</mark>	section Correction on the version of the version of the scheme
15	March 2021	Ana Cicolin	Todd Redwood	4.3.1	32 33	Inclusion of OFI from internal audit part 01 as highlighted on indicated
14	March 2021	Ana Cicolin	Todd Redwood	37 3.16.1 5.3.1 12.2	12 13 29 38 46 47	Inclusion of FSSC updates published in February 2021 through the BoS decision list
13	February 2021	Ana Cicolin	Todd Redwood	9, 10,11, 12,13, 15,16, 17- 21,22, 23,30, 31,33, 34,36- 39,42, 45 and 46	3.6,3.6, 3.7,3.11 ,3.12,3. 13,3.16, 4.2,4.3, 4.4,4.6, 4.10,5.2 ,5.3,6.1 ,9.6,10 and 12	Inclusion of v5.1 upgrade and clarification of some sections
12	October 2020	Ana 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
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
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



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 5.1 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 v5.1 certification scheme was launched in November 2020. The main reasons for publishing a revised version include:

- Incorporating the GFSI benchmarking requirements version 2020.1
- Strengthening the licensing process and the integrity program

Minor editorial changes or amendments

1.1 FSSC 22000 V5 – Main changes

FSSC have published a document with an overview of main changes that can be found on the <u>FSSC</u> <u>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, G, I and K as per detailed below:

FSSC 22000 Category	FSSC 22000 Subcategory
	CI - Processing of perishable animal products
C - Food Manufacturing	CII - Processing of perishable plant products
	CIII - Processing of perishable animal and plant products (mixed products)
	CIV - Processing of ambient stable products
	GI - Provision of transport and storage services for perishable food and feed
G - Transport and Storage	GII - Provision of transport and storage services for ambient stable food, feed and packaging materials
I - Production of Food Packaging and Packaging Materials	I - Production of Food Packaging and Packaging Material



FSSC 22000 Category	FSSC 22000 Subcategory
K - Production of Biochemicals	K - 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 Initial contact

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/ process 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.

BSI shall define the relevant scope for the organization applying for FSSC 22000 certification. The audit scope shall describe the extent and boundaries of the audit and shall be in accordance with the FSSC rules. BSI shall not exclude activities, processes, products or services 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. Where permitted exclusions apply, this shall be motivated in the report and the certificate shall reference the exclusion as part of the scope statement.

Category	FSSC 22000 subcategory	Example of included activities and products
		Production of animal products



PP1268

Category	FSSC 22000 subcategory	Example of included activities and products
C Food Manufacturing	CI - Processing of perishable animal products	<u>Activities / Processes</u> : Slaughtering, deboning, evisceration, gutting, cutting, sorting, washing, pasteurizing, trimming, curing, fermentation, smoking, freezing, chilling, cooling, scalding.
		<u>Final product examples</u> : fish, meat, poultry, eggs, frozen and/or chilled dairy products and fish/seafood products.
		Production of plant products
		<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.
с	CII - Processing of perishable plant products	<u>Final product examples</u> : chilled or frozen e.g. fresh fruits, fresh juices, vegetables, grains, nuts and pulses, meat replacers based on plant materials (e.g. soy), frozen water-based products.
Food Manufacturing		
		Production of mixed animal and plant products
	CIII - Processing of	<u>Activities / Processes</u> : Mixing, cooking, packing, ensemble cooling, chilling, freezing
	perishable animal and plant products (mixed products)	<u>Final product examples</u> : mixed products, pizza, lasagna, sandwich, dumplings, ready-to eat meals.
		Production of food products from any source that are stored and sold at ambient temperature.
	CIV - Processing of ambient stable products	<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.
		Production of food/feed packaging, food/feed packaging materials and intermediate products for:
I Production of Food Packaging and Packaging Material	I Production of Food Packaging and Packaging Material	- 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;



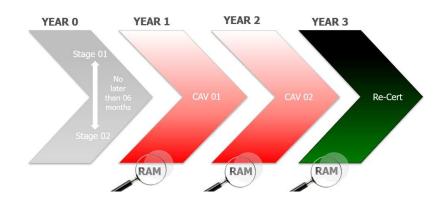
FSSC 22000 v5.1 Certification requirements Revision 16 (April 2021)

Category	FSSC 22000 subcategory	Example of included activities and products
		- 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.
I Production of Food	I	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. The intended use, including that it is sold together (and as part of) the food product, shall be clearly specified in the scope statement.
Packaging and Packaging Material	Production of Food Packaging and Packaging Material	<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, flavourings, 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.
G Transport and	GI - Provision of transport and storage services for perishable food and feed.	Transport and storage with cooling, chilling, or frozen temperatures. Additional activities such as re-packing of packed product, freezing and thawing.
storage	GII - Provision of transport and storage services for ambient stable food, feed and packaging materials.	Transport and storage. Additional activities such as re- packing of packed product.



3.6 Certification cycle

The 3-year certification cycle shall be applied to FSSC 22000 and shall be respected at all times. The first three-year certification cycle begins with the certification decision. Subsequent cycles begin with the recertification decision. Surveillance and re-certification audits shall be scheduled in accordance with the reoccurring audit month, (RAM). The interval between stage 1 and stage 2 audits shall not be longer than 6 months. The Stage 1 shall be repeated if a longer interval is needed.



If BSI has not completed the recertification audit or if is unable to verify the management of nonconformity in accordance with FSSC 22000 requirements prior to the expiry date of the certification, the recertification shall not be recommended, and the validity of the certification shall not be extended. The client shall be informed, and the consequences shall be explained.

Following expiration of certification, BSI can restore the certification within 6 months provided that the outstanding recertification activities are completed (in this case expire date will be based on prior certification cycle), otherwise at least a stage 2 shall be conducted.

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	Audit Criteria
C Food Manufacturing	 ISO 22000:2018 ISO/TS 22002-1:2009 FSSC Additional Requirements* BoS decision list**



FSSC 22000 v5.1 Certification requirements

Revision 16 (April 2021)

FSSC 22000 Category	Audit Criteria
K Production of Biochemicals	 The defined processes and documentation of the management system developed by the organization Related Statutory/regulatory requirements** Related Customer requirements
	ISO 22000:2018ISO/TS 22002-5:2019
G - Transport and Storage	 FSSC Additional Requirements* BoS decision list**
	 The defined processes and documentation of the management system developed by the organization
	Related Statutory/regulatory requirements**
I	 Related Customer requirements ISO 22000:2018 ISO/TS 22002-4:2013
Production of Food Packaging and Packaging Material	 FSSC Additional Requirements* BoS decision list**
	 The defined processes and documentation of the management system developed by the organization
	 Related Statutory/regulatory requirements** Related Customer requirements

Notes:

The Board of Stakeholders (BoS) Decision list is a document which contains decisions applicable to the FSSC 22000 Scheme. The decisions overrule or provide further clarification on existing Scheme rules and have to be implemented and applied within the defined transition period. The decision list is dynamic and can be adjusted by the BoS when deemed necessary.

The Board of Stakeholders is composed of representatives of the food sectors covered by the FSSC 22000 Scheme. The BoS is responsible for approval of the content and functioning of the FSSC 22000 scheme. The Board has the ability to provide binding decisions and voluntary recommendations for the associated Certification Bodies, Accreditation Bodies and Training Organizations with respect to the FSSC 22000 Scheme.

** The BoS decision list can be found <u>here</u> and shall be considered as part of the audit criteria when there are decisions which relates to an audit requirement.

* FSSC 22000 Additional requirements applicable to the categories C, G, I and K include:

- $_{\odot}$ $\,$ Management of Service and purchased materials (C, G, I & K) $\,$
- Product Labelling (C, G, I & K)
- Food Defense (C, G, I & K)
- Food Fraud Mitigation (C, G, I & K)
- Logo Use (C, G, I & K)
- Management of Allergens (C, G, I & K)
- Environmental Monitoring (C, I & K)
- Storage and warehousing (C, G, I & K)



PP1268

- Hazard control and measures for preventing cross-contamination (C & I)
- PRP verification (C, G, I & K)
- Product development (C, I & K)
- Requirements for organizations with multi-site certification (G)
- FSSC 22000 also have additional requirements for "Formulation of Products", "Health Status" and "Transport and delivery", however they are not applicable to the categories that BSI is accredited for and so does not form part of the audit criteria related to audits performed by BSI.

The complete guide for FSSC additional requirements can be found on the PP1441 (FSSC v5.1 Additional requirements guidebook).

** BSI certifies conformance to a management system standard (FSSC 22000) which includes requirements for compliance with legislation and regulatory requirements, however BSI is not conducting a compliance audit and, therefore, cannot certify legal compliance.

FSSC has published some guidance to ensure interpretation alignment related the below:

- Guidance: ISO 22000 interpretation, available here.
- Guidance: Food defense, available here.
- Guidance: Food fraud mitigation, available here.
- Guidance: Food safety culture, available here.
- Guidance: Transport tank cleaning, available <u>here</u>.

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



PP1268

- 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 guides for audit duration

BSI shall calculate the audit duration 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 is eight (8) hours (unless otherwise stated in local legislation);
- The effective audit duration **does not include a lunch break** (unless otherwise stated in local legislation);
- The audit duration calculation for FSSC 22000 shall be documented in the contract review form, including justifications for reduction or addition of time based on the minimum audit duration;
- The audit duration does not include planning, reporting or travel activities, only actual auditing time;
- The audit time shall only apply to auditors that are fully qualified, registered FSSC 22000 auditors. Trainee auditors do not contribute to audit duration;
- 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 time 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 in the contract review form.

3.11.2 Audit duration calculation

The total audit duration/site audit time (for a single site) is defined as $T_s + T_{FSSC}$.

<u>**1**</u>st **Calculate the T**_S. The minimum audit time for a single site, T_{S} , expressed in days, is calculated as follows:

 $T_S = (T_D + T_H + T_{MS} + T_{FTE})$, where:

- T_s = the minimum audit time for a single site;
- T_D = is the basic 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

bsi.

FSSC 22000 v5.1 Certification requirements Revision 16 (April 2021)

PP1268

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)		
		Т _н	T _{MS}	T _{FTE}		
С	1.5	0.50		1 to 19 = 0 20 to 49 = 0.5		
I	1.0	0.25 50 to 79 80 to 199				
К	1.5	0.50	0.25	200 to 499 = 2.0 500 to 899 = 2.5 900 to 1299 =3.0		
G	1,0	0,25		$\begin{array}{l} 900 \text{ to } 1299 = 3.0 \\ 1300 \text{ to } 1699 = 3.5 \\ 1700 \text{ to } 2999 = 4.0 \\ 3000 \text{ to } 5000 = 4.5 \\ >5000 = 5.0 \end{array}$		

<u>**2**nd Calculate the T_{FSSC}</u>: T_{FSSC} shall be calculated as follows:

Number of Employees (FTE)	Number of HACCP studies	T _{FSSC}
< 250 ar	1 or 2 HACCP studies	0.5 auditor day
<u>≥ 250</u>	3 HACCP studies or more	1.0 auditor day

<u>**3**</u>rd **Preparation and Report Time**: 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 site audit time for audit preparation.
- At least 0.5 auditor day (4 working hours) shall be added to the FSSC 22000 site audit time for audit reporting.

In summary the FSSC 22000 calculation shall look as follow:

Audit Type	Calculation						
IA	$ \begin{array}{l} \textbf{IA (Initial Audit)} = T_s + T_{FSSC} + Preparation Time + Report Time \\ \circ & Stage 01: 1/3 of (T_s + T_{FSSC}) \\ \circ & Stage 02: 2/3 of (T_s + T_{FSSC}) + Preparation Time + Report Time +* \\ \circ & Stage 01 + Stage 02 = IA \end{array} $						



Audit Type	Calculation							
CAV	CAV 01 (Surveillance 01) = $(1/3 \times T_s) + T_{FSSC}$ + Preparation Time + Report Time +* CAV 02 (Surveillance 02) = $(1/3 \times T_s) + T_{FSSC}$ + Preparation Time + Report Time +*							
RA	RA (Re-certification) = $(2/3 \times T_s) + T_{FSSC} + Preparation Time + Report Time+*$							

*= any other additional audit time need

3.11.3 Rounding rule

If after the calculation, the result is a decimal number, the exact hours may be used or where rounding is applied to the number of days, this shall be rounded upwards to the nearest half day (e.g. 5.3 audit days becomes 5.5).

3.11.4 Minimum audit duration

For all audit types (initial, surveillance, recertification), the following minimum audit duration rules apply:

- The minimum Ts is 1 day;
- The minimum basic FSSC 22000 audit duration is then 1.5 2 days depending on the FSSC additional time, however for categories C, I and K the minimum audit duration shall always be 2 days;

The following exemptions apply to the minimum audit durations:

- For organizations with simple processes, having 5 FTE or less and maximum 1 HACCP study, further reductions are allowed, but the total time T_s + T_{FSSC} shall be minimum one day for all audit types.
- For organizations in category C, I or K that have simple processes, less than 20 FTE and maximum 1 HACCP study, further reductions are allowed to a minimum audit duration of 1.5 days for all audit types.

Where any of the exemptions above are applied, BSI shall ensure that the audit duration allows for an effective audit, covering the full FSSC 22000 requirements.

The exemptions mentioned above shall be made manually on the related CRF (contract review form) since one of the condition to apply the exemption is related to the complexity of the processes which shall be analysed case by case by the contract reviewer along with FTE and HACCP to decide if the exemptions can be allowed.

The minimum audit duration for the annual audits shall always be respected.

3.11.5 Reduction in time

When properly documented and justified, a reduction of the T_s audit time can be made in accordance with ISO/TS 2003:2013, Annex B. The reduction in T_s audit time can never be more than 0.25 auditor day (2 working hours) and the Ts cannot be reduced below 1 day. The reduction cannot be applied on T_{FSSC} .



3.11.6 Additional time

3.11.6.1 Use of translator:

Additional audit time shall be added in case a translator is required to support the audit team. The minimum time recommended to be added is from 0.25 - 0.5 auditor day, however the determination of the time to be added will depend on the time/duration that the translator will be used.

3.11.6.2 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 additional time shall be 0.5 auditor day (4 working hours) to audit the functions pertinent to the certification at the head office.

When the responsible person from the head office attends the audit at manufacturing site, no extra audit time is required to be calculated.

If the head office is located at a manufacturing site being audited, no additional time is required.

Note:

• 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.

The same principle indicated above applies to central function/head office of multisite organizations.

3.11.6.3 Off-site activities

<u>For offsite manufacturing or service activities</u>: a 50% audit time reduction of T_s may be applied for each additional site. Travel time between locations shall be included in the audit plan.

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

<u>Cross docking</u>: at least 0.25 auditor day (2 working hours) additional audit time shall be added to the FSSC 22000 audit time for each cross-docking location.

3.11.6.4 Additional scheme / combined audit

Where the FSSC 22000 audit is undertaken in combination or integration with other food safety audits as a combined audit, the duration shall be increased on the top of FSSC 22000 duration. 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 in the contract review form.

3.11.6.5 Extension of scope

If the scope extension audit is combined with one audit belonging to the regular cycle, the total audit duration shall be calculated by including the parameters of the extended scope. If a stand-alone



extension of scope audit is required, the duration may vary depending of the intended scope extension. The duration shall be approved through a contract review process.

Both situations above refer to an extension of scope in a site already FSSC certified. If the site is not FSSC certified yet, it shall be treated as a new certification process based on the initial audit durations.

3.11.6.6 FSSC 22000 special audit

If a separate special audit is required, the duration may vary depending on what will be audited.

If the special audit is combined with one audit belonging to the regular cycle, the audit duration shall be increased on the top of FSSC 22000 regular audit duration.

3.11.6.7 FSMA Addendum

At this stage FSSC 22000 has not published the related FSMA addendum documents against v5.1. Once released this manual will be updated accordingly.

3.11.6.8 Complexity of the process and/or products and/or technologies

In case auditor identifies that, due to the complexity of the process and/or products and/or technologies applied, is necessary add audit time on the top of the regular FSSC audit duration, country is required to submit the CRF (Contract Review Form) to be re-approved.

In this case, the additional time shall be added on the top of FSSC regular audit duration and the related justification shall be made.

Both additional time and related justification shall be documented on the related CRF (Contract Review Form).

3.11.7 Multisite sampling methodology

Multi-site certification (including sampling) is only allowed for category G (Transport and storage).

To apply the sampling plan for category G, the related organization shall have more than 20 sites operating similar processes within the category. This applies to the initial certification, to surveillance and to recertification audits. BSI shall justify its decision on sampling for multi-site certification using the related CRF (contract review form).

The basis for determining the sample site shall include the below to ensure an effective audit of the FSMS:

- For organizations with 20 sites or less, all sites shall be audited.
- The sampling for more than 20 sites shall be at the ratio of 1 site per 5 sites as indicated on the table below. All sites shall be randomly selected and, after the audit, no sampled sites may be nonconforming.

Total number of sites								
Number of sites to	21	22	23	24	25	26	27	28

	be audited between 1 and 20								
Number of sites above 20	0	1	2	3	4	5	6	7	8
Additional number of sites to audit	0	1	1	1	1	1	2	2	2
Number of sites to be audited	х	21	21	21	21	21	22	22	22

- At least annually, an audit of the central office for the FSMS shall be performed by the certification • body;
- At least annually, surveillance audits shall be performed by the certification body on the required • number of sampled sites.
- Audit findings of the sampled sites shall be considered indicative of the entire system and ٠ correction shall be implemented accordingly.
- The risk categories and performance of the sites shall be considered and might result in an ٠ increase in the sample size.
- Where sites are added to the group, an audit is required before adding them to the certificate • either as a special audit or as part of the annual audit.
- Once every 3 years, the annual audit shall be conducted fully unannounced as set out in, including • the central function and the site audits.

3.11.8 Transition to FSSC 22000

When transitioning from ISO 22000 or an equivalent GFSI recognized certification to FSSC 22000 certification, the minimum FSSC 22000 certification audit duration shall be two-thirds (2/3) of the initial certification audit time, with a minimum of 1 auditor day (8 working hours plus TFSSC). Requirement related to minimum duration, as stated on this manual, applies.

3.11.9 FSSC 22000 transfer

The minimum time required will depend of the scope being transferred as well as the outcomes from previous CB audit. FCoE recommend from 0.25 (2 hours) to 0.5 (4 hours). Duration shall be documented on the related CRF (contract review form).

3.11.10FSSC 22000 follow up audits

In the case where a follow up audit is required, duration will depend on the number of non-conformities that need to be closed. It is up to the auditor decide the time needed to conduct the follow up related to NC close out based on the quantity of NC as well as on its categorization and associated risks. Duration for follow up audits does not need to be approved by FCoE nor be registered on the CRF (contract review form).



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.

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 (governmental), the Foundation and GFSI information related to the certification and auditing process shall be shared

3.12.1 Timeline to send the report to the (certified) organization

The full audit report shall be sent to the (certified) organization, by the relevant BSI country (auditor), within 2 weeks of the certification decision for all audits conducted.

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.

3.13.1.1 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 calendar 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. Failure to address a minor nonconformity from the previous audit <u>could</u> lead to a major nonconformity being raised at the next scheduled audit

3.13.1.2 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 calendar 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.



3.13.1.3 Critical nonconformity

1) When a critical nonconformity is issued at a certified site the certificate shall be **suspended** (within 3 working days of being issued) for a maximum period of six (6) months. The certificate shall be withdrawn when the critical nonconformity is not effectively resolved within the six (6) months timeframe.

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 calendar days after the audit;

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 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 global scheme manual or partial on-site audits using the ICT Audit Approach. Both of which are accredited and GFSI recognized options.

Information and communication technology (ICT) may be used as a remote auditing tool during FSSC 22000 audits with the following applications and meeting the applicable requirements of IAF MD4:

- For conducting interviews with people and review of policies, procedures or records as part of the on-site audit;
- When utilizing the ICT Audit Approach



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.

3.16.1 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

3.16.2 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 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 NCs identified at 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 " \mathbf{R} " at the beginning of the information.

3.16.1 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.
- 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.)

4 Managing audits

4.1 Head office functions

In all cases where functions pertinent to the certification are controlled by a head office (such as procurement, supplier approval, quality assurance etc.), those functions shall be audited, interviewing the personnel described in the food safety management system as having the (delegated) authority and responsibility for these functions. The functions at the head office shall be audited separately where they are not part of a site being assessed.

Every site belonging to the group shall have a: separate audit, separate report and separate certificate

The head office audit shall be carried out prior to the site audit(s). The subsequent audit at the site(s) shall include a confirmation that the requirements set out by head office are appropriately incorporated into site specific documents and implemented in practice.

The site audit reports and certificates shall show which FSMS functions and/or processes have been audited at the Head Office.

All individual sites shall be audited within a time frame of 12 months from the audit of the head office.

The Head Office cannot receive a separate certificate. The Head Office is mentioned on the site certificate.

At each site audit, the implementation of the corrective actions shall be verified and reported. In the event where non-conformities are raised in a head office audit, these are assumed to have an impact on the equivalent procedures applicable to all sites. Corrective actions shall therefore address the communication across all certified sites within the group and appropriate actions for impacted sites. Such nonconformities and corrective actions shall be clearly identified in the relevant section of the site audit report.

4.2 Off-site activities

Where one manufacturing or service process is split across more than one physical address, all locations may be covered in one audit, considering that the different addresses are:

- part of the same legal entity;
- under the same FSMS;
- the sole receiver/customer of each other.

Storage facilities at another location shall also be included in the same audit considering they meet the requirements mentioned above.

The certificate scope statement shall show the audited locations with activities per location.

The audit report shall include all relevant requirements at all locations and allow audit findings to be identified as site specific.

Cross docking is considered as an offsite activity provided that:

- part of the same legal entity;
- under the same FSMS.

4.3 Multi-site certification

A multi-site organization is an organization having an identified central function (hereafter referred to as a central office – but not necessarily the headquarters of the organization) at which certain FSMS activities are planned, controlled or managed, and a network of sites at which such activities are fully or partially carried out.

Examples of possible multi-site organizations are:

- organizations operating with franchises;
- a manufacturing company with one or more production sites and a network of sales offices;
- service organizations with multiple sites offering a similar service;
- organizations with multiple branches.

BSI can certify a multi-site organization under one management system, providing that the following conditions apply:

- all sites are operating under one centrally controlled and administered FSMS;
- an internal audit has been conducted on each site within one year prior to certification;
- audit findings of the individual sites shall be considered indicative of the entire system and correction shall be implemented accordingly.



Multi-site certification (including sampling) is only allowed for category G (Transport and storage).

A multi-site organization need not be a unique legal entity, but all sites shall have a legal or contractual link with the central function of the organization and be subject to a single management system, which is laid down, established and subject to continuous surveillance and internal audits by the central function.

The central function shall be audited at least annually and before the BSI audits of the (sampled) sites. If necessary, a small number of the sample sites may be audited prior to the audit of the central function.

One audit report may be produced for the multi-site organization, including the central function information and specific information about each site audited. The summary sections of the audit report shall clearly reflect what was audited at each site with supporting objective evidence.

Alternatively, separate reports may be produced for the Central function and each of the sites, respectively.

The certificate shall be a group certificate.

4.3.1 Sampling methodology

Multi-site certification (including sampling) is only allowed for category G (Transport and storage).

To apply the sampling plan for category G, the related organization shall have more than 20 sites operating similar processes within the category. This applies to the initial certification, to surveillance and to recertification audits. BSI shall justify its decision on sampling for multi-site certification using the related CRF (contract review form).

Th basis for determining the sample site shall include the below to ensure an effective audit of the FSMS:

- For organizations with 20 sites or less, all sites shall be audited.
- The sampling for more than 20 sites shall be at the ratio of 1 site per 5 sites as indicated on the table below. All sites shall be randomly selected and, after the audit, no sampled sites may be nonconforming.

	Total number of sites								
	Number of sites to be audited between 1 and 20	21	22	23	24	25	26	27	28
Number of sites above 20	0	1	2	3	4	5	6	7	8
Additional number of sites to audit	0	1	1	1	1	1	2	2	2
Number of sites to be audited	х	21	21	21	21	21	22	22	22



- At least annually, an audit of the central office for the FSMS shall be performed by the certification body;
- At least annually, surveillance audits shall be performed by the certification body on the required number of sampled sites.
- Audit findings of the sampled sites shall be considered indicative of the entire system and correction shall be implemented accordingly.
- The risk categories and performance of the sites shall be considered and might result in an increase in the sample size.
- Where sites are added to the group, an audit is required before adding them to the certificate either as a special audit or as part of the annual audit.
- Once every 3 years, the annual audit shall be conducted fully unannounced, including the central function and the site audits.

4.3.2 Requirements for the central function

The central function shall hold the contract with BSI and request to include multi-site sampling as part of the application process should they wish to include it.

It is the responsibility of the central function to ensure management commitment to the FSMS and have sufficient resources and technical capacity in place to support the system and the internal audit program. The central function shall be impartial from the sites (e.g. have different/ dedicated employees, governance, management etc.). The central function shall take responsibility for coordinating, addressing, and closing out of nonconformities raised at site level in conjunction with the relevant sites. Failure of the central function or any of the sites to meet the Scheme requirements, shall result in the whole organization, including the central function and all sites, not gaining certification.

Where certification has previously been in place, this shall initiate the BSI process to suspend or withdraw the certification.

4.3.3 Nonconformity management (for multi-sites)

Nonconformities raised at multi-site organizations shall follow the same scheme requirements established on this manual and:

- When nonconformities are found at any individual site, either through the organization's internal auditing or from auditing by BSI, investigation shall take place to determine whether the other sites may be affected. Therefore, BSI shall require the organization to review the nonconformities to determine whether or not they indicate an overall system deficiency applicable to other sites. If they are found to do so, corrective action shall be performed and verified both at the central function and at the individual affected sites. If they are found not to do so, the organization shall be able to demonstrate to BSI the justification for limiting its follow-up corrective action.
- BSI shall require evidence of these actions and increase its sampling frequency and/or the size of sample until it is satisfied that control is reestablished. At the time of the decision-making process, if any site has a major nonconformity, certification shall be denied to the whole multi-site organization of listed sites pending satisfactory corrective action.



- It shall not be admissible that, to overcome the obstacle raised by the existence of a nonconformity at a single site, the organization seeks to exclude from the scope the "problematic" site during the certification process.
- Where a critical nonconformity is identified, the certificate of the multi-site organization shall be suspended within 3 working days of issuing the critical nonconformity, regardless of whether or not all the site audits have been completed;
- Where a major nonconformity is identified and the audit takes more than 30 calendar days to complete (central function and site audits), the organization shall provide a corrective action plan including any temporary measures or controls necessary to mitigate the risk until the nonconformity can be closed.
- The timeline for closure of nonconformities start at the end of the audit after completion of the central function audit and all the site audits.

4.4 Unannounced audits

4.4.1 Frequency

BSI shall ensure that for each certified organization at least one surveillance audit is undertaken as an unannounced audit after the initial certification audit and within each three (3) year period thereafter.

The certified organization can voluntarily choose to replace all surveillance audits by unannounced annual surveillance audits. Recertification audits may be conducted unannounced at the request of the certified organization. When this situation applies, the PF1124 (FSSC v5.1 unannounced audit form & blackout dates) shall be completed by the certified organization.

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

Upgrade audits from v5 to v5.1 may be conducted unannounced where needed in order to meet the 3yearly unannounced audit requirements

4.4.2 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.

4.4.3 Actions if organization refuses to participate in the unannounced audit

If the certified organization refuses to participate in the unannounced audit, the certificate shall be suspended and BSI shall withdraw the certificate if the unannounced audit is not conducted within a sixmonth timeframe from the date refusal.

4.5 Additional scheme / combined & integrated audit

Where the FSSC 22000 audit is undertaken in combination with other food safety audits as a combined audit, the duration shall be increased on the top of the 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 with the audit plan, with the contract review approved and also with the FSSC SMO(s) in PG. 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 in the contract review form. A separate report shall be created for each specific scheme.

4.6 Transfer of certification

BSI shall follow the requirements of GP031 (Transfer of Certification to BSI _ that takes into consideration IAF MD 2) for all FSSC 22000 transfers of certification.

It is not allowed perform transfer review process prior to the contract review stage have been successful concluded.

The programme of on-going surveillance or recertification shall be based on the previous certification cycle. The next "on cycle" audit can just be planned and delivered for clients that have successful completed the transfer process, hosting a BSI certificate. **CAV or Recertification cannot be delivered for clients that do not hold an active BSI certificate.**

4.7 Transition audits

Transition audits are allowed from ISO 22000 and GFSI recognized certification programs with equivalent scopes.

Transition audits are the start of a new certification cycle and shall therefore be a stage 2 audit.

The FSSC 22000 certificate issued shall have a validity of 3 years.

Transition audits are only allowed from a valid certificate issued by BSI. A transition audit 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 audit can be performed provided that the certificate is not expired and if the intended scope falls into one of the FSSC 22000 categories that BSI is accredited for.



4.8 Extension and reduction of scope

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 separate from the audit cycle being conducted as special audit.

(* This review shall be performed by an approved FSSC contract reviewer only).

Reduction of scope:

- Where during an assessment the assessor identifies that the client has ceased to perform a referenced activity and that this activity should be removed from the scope of certification, the assessment team leader shall advise this via audit report. It should be clear from the documentation provided which elements of the scope are being removed.
- When BSI has evidence that a client holds a certificate where scope exceeds the 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.

Any reduction in durations or visit cycles shall be reviewed and approved by an approved FSSC 22000 contract reviewer only.

4.9 Follow up audits

Definition of follow up audits: An additional audit to a regular audit for which an extra visit is required when the audit could not be completed in the planned time and/or the audit plan could not be realized completely or when on-site investigation of a (major) NC is required. As a follow-up is part of a regular audit, it shall be completed within a short time-frame from the main audit.

A follow-up audit is required in following situations:

- When not enough information can be obtained after an unannounced audit to take a certification decision. The missing parts shall be audited within 4 weeks (see PP 1286).
- After a major non-conformity for verification of the corrective action plan to close the NC. This follow-up shall be done within 28 calendar days from the last day of the audit.

For the above situations the follow-up audit is a part of a regular audit (initial, surveillance or recertification) and has to be completed before a certification decision can be taken. The follow-up activities shall be documented in the report of that regular audit.

4.10 Special audits

Definition of special audits: Audits at certified organizations that are performed on top of the annual surveillance/recertification audits.

Additional special audits shall be performed on top of FSSC audit and never as a replacement of the annual surveillance/ recertification audits.

Reasons to conduct a special audit may be for example:



- Scope extension in between regular audits
- Changes in the company (e.g. ownership)
- Short notice audits (see also ISO/IEC 17021-1 9.6.4) to follow up on complaints, after a major recall etc.
- To lift suspensions

Special audits may be conducted announced or unannounced and shall be reported separately from the regular audits.

The objective of a special audit is to assess whether the certificate is still valid. Therefore, a decision on the certification status shall be taken. This is a formal certification decision and shall be documented as such. A special audit can lead to a suspension or withdrawal of the certificate, or to an extension or reduction of the scope.

Special audits shall be recorded on PF1445 (FSSC Special Audit Report).

4.11 Short – notice audits

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

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.

5.2 FSSC 22000 v5.1 Documents

FSSC 22000 v5.1 scheme documents are available at FSSC Website.

The FSSC 22000 scheme v5.1 standard is structured in 06 parts compiled in 01 manual, 02 appendices, 09 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: Normative 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
- Annex 8 E-learning requirements for training organizations
- Annex 8 CB requirements for the use of information and communication technology (ICT)
- Full remote audit addendum
- Guidance: Food Defense
- Guidance: Food Fraud Mitigation
- Guidance: Food Safety Culture
- Guidance: Transport Talk Cleaning

5.3 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.

5.3.1 Data ownership

A (certified) organization is the owner of an audit report (regarding the decision about who the report may be shared with), whilst BSI is responsible for the report data and therefore holds the ownership of the audit report content.

A (certified) organization is the certificate holder, not the owner. BSI is the data owner of the certificate data.

5.3.2 BSI Portal on FSSC Database

a) When requested by the certified organization, BSI shall actively provide the Certified Organization access to the associated Organization Profile, Audit and Certification data registered in the CB Portal using the available functionality.

b) The certified organization access will only be granted to authorized individual(s).



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 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.

BSI shall complete the following actions within 3 working days after the certification decision has been made:

- 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.

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

BSI shall complete the following actions within 3 working days after the certification decision has been made:

- 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;



PP1268

- 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 Agreement on information sharing

By accepting the BSI quote the certified organization allows BSI to share information relating to the certification and auditing process with the Foundation, GFSI and governmental authorities when required.

9.7 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 <u>critical.food@bsigroup.com</u>.

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
 - 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.

9.8 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



9.9 Winessing Assessment by CB

From time to time the accreditation body and /or the Foundation FSSC requires a performance ofa 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.

9.10 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.

9.11 FSSC Website

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

9.12 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.



• 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

10 Impartiality

10.1 In house and open FSSC external trainings

An auditor can conduct public FSSC 22000 training with attendance from a company that they are the certification auditor for. However, the same auditor cannot conduct in-house training and then deliver certification work (without a break of 02 years).

Note: in-house training means training provided in the client's site or attended only by one organization's team.

10.2 Consultancy

FSSC 22000/FSMS consultancy shall not be provided by either BSI or any part of the same legal entity for a period of 2 years prior to any certification activity.

10.3 Auditor rotation in FSSC 22000 certification audits

An auditor is not allowed to perform more than two (2), three (3)-year certification cycles at the same certified site either as lead auditor or team member. If an auditor starts auditing within a certification cycle, he/she will be rotated out after six (6) years for a minimum of one year.

11 Upgrade timeline from v4.1 to v5

Certified organizations that are still certified against v4.1 shall upgrade to v5 no later than 31 March 2021. After this timeline the v4.1 certificate will be suspended.

12 Upgrade Process from FSSC 22000 v5 to v5.1

12.1 Audit planning and timelines

The final date to audit against FSSC 22000 V5 is 31 March 2021. Upgrade audits to FSSC 22000 v5.1 shall be conducted from 1 April 2021 until 31 March 2022.

12.2 Audits

A v4.1 certificate cannot be upgraded to v5.1 directly during a surveillance audit. However, at a recertification audit conducted on or after 1 April 2021, a certificate can be upgraded from v4.1 to v5.1



directly if a certificate validity extension due to COVID-19 was in place. In this case, the first surveillance audit must be also be conducted in 2021 to meet the calendar year and certification requirements.

An upgrade audit requires a full system audit against the new FSSC 22000 v5.1 requirements and may be conducted unannounced where required to meet the three-yearly unannounced audit requirements.

As an exception during the COVID-19 pandemic, it is allowed to contact the certified organization 48 hours in advance of the unannounced audit. The unannounced audit may then be conducted as an onsite audit, by utilizing the ICT Audit Approach (remote + on site) or as a full remote audit. In the case of a full remote audit, the ICT needs to be tested during the 48-hour window and prior to starting the audit. The full remote option needs to be agreed with the organization and remains subject to the remainder of the requirements as set out in PP1623 (FSSC v5.1 Requirements for full remote audits).

In cases where the unannounced surveillance audit is due in 2021 but cannot be conducted unannounced as a direct result of COVID-19, the unannounced audit may be replaced by an announced audit if agreed with the certified organization and approved by the T&C FSSC 22000 manager using PF1124 (FSSC v5.1 unannounced audit form & blackout dates). Justification for not conducting the planned unannounced audit shall be recorded in the audit report in the "Audit details" section. The subsequent audit in 2022 shall then be conducted unannounced, the audit program adjusted accordingly and is applicable to all audit types (surveillance or recertification).

The table below provides normal v5.1 upgrade scenarios including unannounced audit (UA) requirements and where 2020 audits are postponed into 2021 as a result of COVID-19. The unannounced audits indicated in the table below reflect the minimum requirements to meet the 3 yearly unannounced audit requirement and does not account for the exception linked to COVID-19 as referenced in this document.

2018	2019	2020	2021	2022
V4.1 Upgrade S1	V4.1 52 UA	V5 Recert	a) V5 S1 in Q1 2021 OR b) V5.1 Upgrade S1 if on or after 1 April 2021	a) V5.1 Upgrade S2 UA in Q1 2022 b) V5.1 S2 UA within calendar year
V4.1 Upgrade S1	V4.1 52 UA	V5 Recert postponed to 2021 due to COVID-19 (validity extension)	a) V5 Recert in Q1 2021 OR b) V5.1 Recert if on or after 1 April 2021 and within extension window AND in both cases (a+b) V5.1 S1 within calendar year	V5.1 S2 UA within calendar year
V4.1 Upgrade S2	V4.1 Recert	V5 Upgrade S1	a) V5 S2 UA in Q1 2021 OR b) V5.1 Upgrade S2 UA if on or after 1 April 2021	a) V5.1 Recert in Q1 2022 b) V5.1 Recert before certificate expiry

2018	2019	2020	2021	2022
V4.1 Upgrade S2	V4.1 Recert	V5 Upgrade S1 postponed to Q1 2021 due to COVID-19	V5 S1 in Q1 2021 AND V5.1 S2 UA within the calendar year	V5.1 Recert
V4.1 Recert	V4.1 S1 Announced	V5 Upgrade S2	V5.1 Recert	V5.1 S1 UA within calendar year
V4.1 Recert	V4.1 S1 Announced	V5 upgrade S2 postponed to Q1 2021 due to COVID-19	V5 Upgrade S2 in Q1 2021 AND V5.1 Recert within the validity window	V5.1 S1 UA within calendar year
V4.1 Recert	V4.1 S1 UA	V5 Upgrade S2	a) V5 Recert in Q1 2021 OR b) V5.1 Recert if on or after 1 April 2021	a) V5.1 Upgrade S1 UA in Q1 of 2022 b) V5.1 S1 UA within calendar year
V4.1 Recert	V4.1 S1 UA	V5 Upgrade S2 postponed to Q1 2021 due to COVID-19	V5 Upgrade S2 in Q1 2021 AND V5.1 Recert within the validity window	V5.1 S1 UA within calendar year

Source: FSSC V5.1 Upgrade process paper

12.3 Audit duration

Version 5.1 no longer permits the "mathematical rounding down" of audit durations and also has included new requirement regarding minimum audit duration for category C, I and k as detailed and therefore your local BSI team may be in contact to confirm your organizational details to ensure a correct audit duration is calculated for future v5.1 audits.

12.4 Certificate

The v5.1 certificate shall be issued after a successful v5.1 upgrade audit followed by a technical & certification decision.

12.4.1 Managing the remaining v5 certificates

The transition period for FSSC v5.1 ends on 31 March 2022, by then all v5 certificates which have not been upgraded to v5.1 will be suspended on the FSSC Portal for a maximum period of six (6) months. If the suspension is not lifted within the suspension period, the certificate will be withdrawn.

12.5 FSSC Portal

The FSSC portal will be updated by BSI in accordance with each organization's progress status regarding the transion process.