BSI Certification Requirements

BSI Standard Terms and Conditions
Addendum

ISO 22000:2018

Inspiring trust for a more resilient world.

Contents

Inspiring trust for a more resilient world.

Inspiring trust for a more resilient world.

Revision History

Rev No	Revision Date	Author	Approved by	Page No	Sec. No	Brief Description of Change
1	December 2020	Ana Cicolin	Todd Redwood	New document		
2	May 2021	Ana Cicolin	Todd Redwood	21	7	Aligned confidentially clause with the BSI Terms and Conditions
3	September 2023	Nadia Azevedo	Ana Cicolin	24 24 25	9 10	Update about complaints and appeals information Inclusion of ISO 22003-1:2022 Scheme Information and upgrade requirements.
4	January 2024	Nadia Azevedo	Ana Cicolin	All	All	Complete review and update to add ISO 22003-1:2022 requirements
5	March 2024	Nadia Azevedo	Ana Cicolin	22 23	6 8.4	Made clear the use of logo and certification statements in accordance with ISO 22003-1:2022 requirements

Inspiring trust for a more resilient world.

1   Introduction

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). ISO 22000 establishes the food safety management system (FSMS) requirements for any organization in the food chain. The adoption of a FSMS is a strategic decision for an organization that can help to improve its overall performance in food safety.

The potential benefits to an organization of implementing a FSMS include the ability to consistently provide safe foods and products and services that meet customer and applicable statutory and regulatory requirements; addressing risks associated with its objectives and the ability to demonstrate conformity to specified FSMS requirements.

2   Accreditation Status and BSI Scope of Accreditation

BSI holds a valid global ISO/IEC 17021-1:2015 accreditation. The accreditation for ISO 22000 is scoped in accordance with ANAB (for all categories except J) and JASANZ accreditation rule and ISO 22003-1:2022.

3   The Recognition Process

The following section outlines the steps that apply during the BSI recognition process for ISO 22000. 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.

Inspiring trust for a more resilient world.

3.3 Certification Contract

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

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

- Seek an appreciation of the nature and scope of your site's activities, structure and location(s), including any activities for which certification is being excluded; and

- Determine the status of system documentation and implementation including organizational policies, objectives and targets.

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

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

A self-assessment or pre-assessment audit can assist in identifying gaps in your site's ISO 22000 System so that corrective action can occur before engaging BSI for a full certification audit. It can be conducted using internal resources, an ISO 22000 consultant, or an ISO 22000 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

ISO 22000 certification is site and product specific. When activities are carried out in different premises but are overseen by the same senior, operational, and technical management, and are covered by one ISO 22000 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 ISO 22000 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.

Category		Subcategory		Coverage (Examples of included activities)
A		AI	Farming of animals for meat/ milk/ eggs/honey	Raising animals (other than fish and aquaculture) used for meat production, egg production, milk production or honey production. Growing, keeping, trapping and hunting (slaughtering at point of hunting).

	Farming or handling of animals			Associated temporary packing without modification or processing of the product.
		AII	Farming of fish and seafood	Raising fish and seafood used for meat production. Growing, trapping and fishing (slaughtering at point of capture). Associated temporary packing without modification or processing of the product.
B	Farming or handling of plants	**BI**	Farming - Handling of plants (other than grains and pulses)	Growing or harvesting of plants (other than grains and pulses): horticultural products (fruits, vegetables, spices, mushrooms, etc.) and hydrophytes for food. On farm storage of plants (other than grains and pulses), including horticultural products and hydrophytes for food.
		BII	Farming - Handling of grains and pulses	Growing and harvesting of grains and pulses for food. Handling grains and pulses. On farm storage of grain and pulses for food.
		BIII	Pre-process handling of plant products	Activities on harvested plants that do not transform the product from original whole form, including horticultural products and hydrophytes for food. These include cleaning, washing, rinsing, fluming, sorting, grading, trimming, bundling, cooling, hydro-cooling, waxing, drenching, aeration preparing for storage or processing, packing, repacking, staging, storing and loading.
C	Food, ingredient and pet food processing	**C0**	Animal – Primary Conversion	Conversion of animal carcasses intended for further processing including lairage, slaughter, evisceration, bulk chilling, bulk freezing, bulk storage of animals and game gutting, bulk freezing of fish and storage of game.
		CI	Processing of perishable animal products	Production and packaging including fish, fish products, seafood, meat, eggs and dairy requiring chilled or frozen temperature control. Processing of pet food from animal products only.
		CII	Processing of perishable plant-based products	Processing and packaging including fruits and fresh juices, vegetables, grains, nuts, pulses, frozen water-based products, plant-based meat and dairy substitutes. Processing of pet food from plant products only.
		CIII	Processing of perishable animal and plant products (mixed products)	Processing and packaging including pizza, lasagne, sandwiches, dumplings and ready-to-eat meals. Includes off-site catering kitchens. Includes products of industrial kitchens not offered for immediate consumption. Processing perishable pet food from mixed products.

Inspiring trust for a more resilient world.
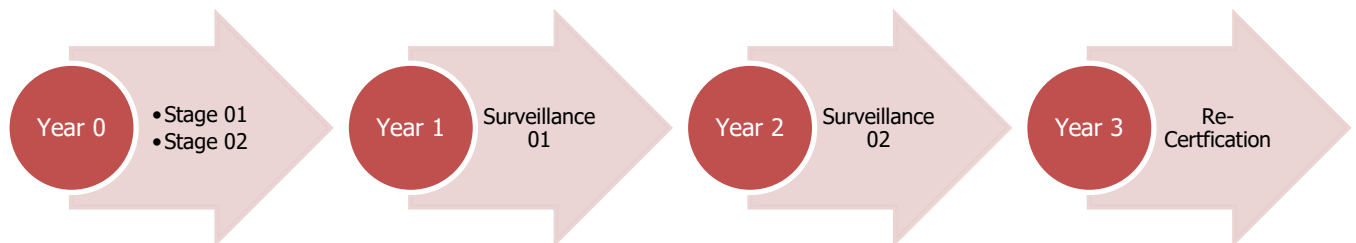
		CIV	Processing of ambient stable products	Processing and packaging of products stored and sold at ambient temperature, including canned foods, biscuits, snacks, oil, drinking water, beverages, pasta, flour, sugar and food-grade salt. Processing ambient stable pet food.
D	Feed and Animal food processing			Processing feed material intended for food and non-food producing animals not kept in households, e.g. meal from grain, oilseeds, by-products of food production. Processing feed mixtures, with or without additives, intended for food-producing animals, e.g. premixes, medicated feed, compound feeds.
E	Catering/ food service			Open exposed food activities such as cooking, mixing and blending, preparation of components and products for on-site direct consumer consumption or take away. Examples include restaurants, hotels, food trucks, institutions, work places (school or factory cafeteria), including retail with on-site preparation (e.g. rotisserie chicken). Includes reheating of food, event catering, coffee shops and pubs.
F	Trading, retail and e-commerce	**FI**	Retail / Wholesale	Storage and provision of finished products to customers and consumers (retail outlets, shops, wholesalers). Includes minor processing activities, e.g. slicing, portioning, reheating.
		FII	Brokering / Trading	Buying and selling products on its own account without physical handling or as an agent for others of any item that enters the food chain.
G	Transport and storage services			Storage facilities and distribution vehicles for perishable food and feed where temperature integrity shall be maintained. Storage facilities and distribution vehicles for ambient stable food and feed. Relabelling/ repackaging excluding open exposed product materials. Storage facilities and distribution vehicles for food packaging material.
H	Services			Services provisioned related to the safe production of food and feed, including water supply, pest control, cleaning services and waste disposal. *Note: There are many different types of services that can be provided in the food chain. Some of these services can fall outside the scope of a certification that includes FSMS. If the organization/ service is susceptible to introduce a food safety hazard within the food chain, the service can be considered within the scope.*

Inspiring trust for a more resilient world.

I	Production of packaging material	Production of packaging material in contact with food, feed and animal food. May include packaging produced on-site for use in processing.
J	Equipment *(BSI is not accredited for category J under ANAB)*	Equipment for food, feed or packaging processing, vending machines, kitchen equipment, processing utensils, filters, hygienic design of equipment and facilities.
K	Chemical and bio-chemical	Production of food and feed processing aids, additives (e.g. flavourings, vitamins), gases and minerals. Production of bio-cultures and enzymes.
Note: "Perishable" can be considered as food of a type or condition such that it can spoil and must be preserved in a temperature controlled environment.		

3.6 Certification Cycle

A three-year certification cycle shall be applied to ISO 22000 and shall be respected at all times. The first three-year certification cycle begins with the certification decision (original registration date). Subsequent cycles begin with the recertification decision.

Year 0 • Stage 01 • Stage 02 → Year 1 Surveillance 01 → Year 2 Surveillance 02 → Year 3 Re-Certfication

3.6.1 Planning Audits

The basis of timings applied to the certification and audit cycles for ISO 22000 scheme is that each certificate shall become attached permanently to a month for the CAVs (surveillances) and RAs (Re-certifications) 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.

The RAM is determined by counting 8 months from the initial certification decision date. Therefore, the RAM is 4 months in advance of the anniversary of the certification decision date and all audits following the initial certification decision date shall occur every 12 months, in the same month, in a regular pattern. Audits should occur in or prior to the RAM month

Regardless of the audit cycle, the certification cycle remains based on the expiration date. Audits should occur within or prior to the RAM month.

Inspiring trust for a more resilient world.

3.7   Audit Criteria

The audit criteria represents set of requirements used as a reference against which objective evidence is compared. ISO 22000 certification audit criteria shall include the requirements as below:

- ISO 22000:2018 requirements;
- The defined processes and documentation of the management system developed by the organization;
- Related statutory/regulatory requirements; and
- Related customer requirements.

3.7.1   Legal and Regulatory Audit Requirements

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

BSI will verify that the client has included legal and regulatory compliance in their ISO 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   Initial Certification Audit – Two Stage Audit process

BSI shall perform the stage 1 and stage 2 audits for initial certification according to the requirements of ISO/IEC 17021-1 and ISO 22003-1:2022. The interval between stage 1 and stage 2 audits shall not be longer than 6 months. Stage 1 shall be repeated if a longer interval is needed.

3.8.1 Stage 01

The objectives of stage 1 are to provide a focus for planning the stage 2 audit by gaining an understanding of the organization's FSMS and the organization's state of preparedness for stage 2 by reviewing the extent to which:

a) the organization has identified prerequisitie programs (PRPs) that are appropriate to the business (e.g. regulatory, statutory, customer and certification scheme requirements);

Inspiring trust for a more resilient world.

b) the FSMS includes adequate processes and methods for the identification and assessment of the organization's food safety hazards, and subsequent selection and categorization of control measures (combinations);

c) the FSMS includes adequate processes and methods for the identification and implementation of the relevant food safety legislation.

d) the FSMS is designed to achieve the organization's food safety policy;

e) the FSMS implementation programme justifies proceeding to the audit (stage 2);

f) the validation of control measures, verification of activities and improvement programmes conform to the requirements of the FSMS standard;

g) the FSMS documents and arrangements are in place to communicate internally and with relevant suppliers, customers and interested parties; and

h) if there is any additional documentation which needs to be reviewed and/or information which needs to be obtained in advance.

Stage 01 also aims to:

- Review the allocation of resources for stage 2 and agree the details of stage 2 with the client;

- Evaluate if the internal audits and management reviews are being planned and performed, and that the level of implementation of the management system substantiates that the client is ready for stage 2;

- Review the client´s management system documented information;

- Evaluate client´s site specific conditions to undertake discussions with client´s personnel to determine the preparedness for stage 2;

- Obtain necessary information regarding the scope of the FSMS, including client´s site, process and equipment used, levels of controls established and applicable statutory and regulatory requirements.

Where an organization has implemented externally developed combination of a FSMS, stage 1 shall review the documentation included in the FSMS to determine if the combination of control measures: is suitable for the organization, was developed in conformity with the requirements of ISO 22000 or other sets of specified FSMS requirements and is kept up to date. The availability of relevant authorizations shall be checked when collecting the information regarding the compliance to regulatory aspects.

The results of the stage 1 may lead to postponement or cancellation of the stage 2.

3.8.2 Stage 02

The purpose of stage 2 is to evaluate the implementation, including effectiveness, of the client's FSMS. The stage 2 shall include the auditing of:

- all ISO 22000 requirements;

- performance monitoring, measuring, reporting and reviewing against key performance objectives and targets;

- the client's management system ability and its performance regarding meeting of applicable statutory, regulatory and contractual requirements;

- operational control of the client's processes;

- internal auditing and management review;
- management responsibility for the client's policies.

3.9 Surveillance audits

Surveillance audits shall be conducted at least once a calendar year, except in recertification years. The date of the first surveillance audit following initial certification shall not be more than 12 months from the certification decision date.

A surveillance audit shall be planned in order to maintain confidence that the client's certified management system continues to fulfil requirements between recertification audits.

BSI shall develop its surveillance activities so that representative areas and functions covered by the scope of the management system are monitored on a regular basis and take into account changes to its certified client and its management system.

Surveillance audits are not necessarily full system audits and shall be planned together with the other surveillance activities so that BSI can maintain confidence that the client's certified management system continues to fulfil requirements between recertification audits. Between the two surveillance audits BSI shall ensure that the entire management system is audited as well as all ISO 22000 requirements covered. In addition to that each surveillance shall include as mandatory:

- internal audits and management review;
- a review of actions taken on nonconformities identified during the previous audit;
- complaints handling;
- effectiveness of the management system with regard to achieving the certified client's objectives and the intended results of the respective management system (s);
- progress of planned activities aimed at continual improvement;
- continuing operational control;
- review of any changes;
- use of certification/accreditation marks and/or any other reference to certification.

3.10 Re-certification

ISO 22000 re-certification shall be a full audit against all ISO 22000 requirements.

The purpose of the recertification audit is to confirm the continued conformity and effectiveness of the management system as a whole, and its continued relevance and applicability for the scope of certification.

A recertification audit shall be planned and conducted to evaluate the continued fulfilment against ISO 22000 requirements. This shall be planned and conducted in due time to enable for timely renewal before the certificate expiry date.

The recertification activity shall include the review of previous surveillance audit reports and consider the performance of the management system over the most recent certification cycle. Recertification audit activities may need to have a stage 1 in situations where there have been significant changes to the management system, the organization, or the context in which the management system is operating (e.g. changes to legislation).

Inspiring trust for a more resilient world.

The recertification audit shall addresses the following:

- the effectiveness of the management system in its entirety in the light of internal and external changes and its continued relevance and applicability to the scope of certification;

- demonstrated commitment to maintain the effectiveness and improvement of the management system in order to enhance overall performance;

- the effectiveness of the management system with regard to achieving the certified client's objectives and the intended results of the respective management system.

For any major nonconformity, the related correction and corrective actions shall be implemented and verified prior to the expiration of certification.

When recertification activities are successfully completed prior to the expiry date of the existing certification, the expiry date of the new certification can be based on the expiry date of the existing certification. The issue date on a new certificate shall be on or after the recertification decision.

If BSI has not completed the recertification audit or is unable to verify the implementation of corrections and corrective actions for any major nonconformity prior to the expiry date of the certification, then 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 certification within 6 months provided that the outstanding recertification activities are completed, otherwise at least a stage 2 shall be conducted. The effective date on the certificate shall be on or after the recertification decision and the expiry date shall be based on prior certification cycle.

3.10.1 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 and ISO 22003-1:2022 as follows:

- The duration of an audit day normally is eight (8) hours. In exceptional circumstances an audit day may be longer than 8 hours but shall never exceed 10 hours and then only in accordance with International Labor Organization (ILO) and national legislative requirements.

- The effective audit duration **does not include** a lunch break, planning, reporting and travel activities.

- The audit duration calculation for ISO 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 time does not include planning, reporting or travel activities, only actual auditing time. The audit time shall only apply to auditors that are fully qualified, approved as ISO 22000 auditors (provisional or lead auditors). Trainee auditors do not contribute to audit duration.

3.10.2 ISO 22000 Audit Duration Calculation

The total audit time (for a single site) is defined as T_s. In additional to that, BSI shall include appropriate time for the audit report.

- **Calculate the D_S** : Which is the total audit duration calculated according to ISO 22003-1:2022:

- $D_S = (T_D + T_H + T_{FTE})$, where:

Inspiring trust for a more resilient world.

- **T_D** = is the basic site audit duration for (sub)categories and scope of certification (includes one HACCP study), in days;

- **T_H** = is the number of audit days for additional HACCP studies;

  Note: A HACCP study corresponds to a hazard analysis for a family of products/ processes /services with similar hazards and similar processes and technology

- **T_{FTE}** = is the number of audit days per number of FTE employees.

  Note 01: When determining the number of employees involved in any aspect of food safety, it shall be expressed as the number full-time equivalent (FTE) employees

  When an organization deploys workers in shifts and the products and/or processes are similar in all shifts, the # of effective FTE will be calculated based on employees on the main shift (including seasonal workers) plus non-production staff having an impact on food safety.

  When an organization deploys workers in shifts and the products and/or processes are NOT similar in all shifts, the # of effective FTE will be calculated based on the total # of FTE in all shifts (including seasonal workers) plus non-production staff having an impact on food safety.

  If the organization has only 01 shift, the # of effective FTE will be calculated based on employees from this shift (including seasonal workers) plus non-production staff having an impact on food safety.

Table 01: Variables for calculation of minimum audit duration

Category	Basic, site audit duration, in audit days T_D	Number of audit days for each additional HACCP study T_H	Number of audit days per number of employees (FTE on the man shift) T_{FTE}
A	1.0	0.25	
B	1.0	0.25	
C	2.0	0.50	
D	1.0	0.50	1 to 5 = 0
E	1.5	0.50	6 to 49 = 0.5
F	1.0	0.50	50 to 99 = 1.0
G	1.5	0.25	100 to 199 = 1.5
H	1.5	0.25	200 to 499 = 2.0
I	1.5	0.50	500 to 999 = 2.5
J	1.5	0.50	>1000 = 3.0
K	2.0	0.50	

In summary the ISO22000 calculation shall look as follow:

Inspiring trust for a more resilient world.

Audit Type	Calculation

IA	**IA (Initial Audit)** = D_s + Preparation Time + Report Time
	
	  o Stage 01: 1/3 of (D_s)
	  o Stage 02: 2/3 of (D_s) + Preparation Time + Report Time +*
	  o Stage 01 + Stage 02 = IA

CAV	**CAV 01** = (1/3 x D_s) + Preparation Time + Report Time +* **CAV 02** = (1/3 x D_s) + Preparation Time + Report Time +*
RA	**RA (Re-certification)** = (2/3 x D_s) + Preparation Time + Report Time+*

*= any other additional audit time need

- The minimum surveillance audit duration shall not be less than one-third of the initial certification audit duration, with a minimum of 1 audit day (0,5 audit day for categories A and B).

- The minimum recertification audit duration shall not be less than two-thirds of the initial certification audit duration, with a minimum of 1 audit day (0,5 audit day for categories A and B).

3.10.2.1 Multisite

The site audit duration of the central function shall be equal to or greater than D_s.

The site audit duration for each site audited shall be equal to or greater than half of D_s for that site.

The use of multi-site sampling is permitted for categories A and B. Sampling may be applied to multi-site organizations, with the minimum sample size being the square root of the total number of sites: $\sqrt{(x)}$, rounded up to the next whole number. The square root sample shall be taken per risk category based on production complexity of the sites (e.g. open field plant production, perennial plant production, indoor production, open field livestock production, indoor livestock production).

The use of multi-site sampling is permitted for categories F and G, and only for re-heating-type facilities (e.g. event catering, coffee shops, pubs) for category E and only for facilities with limited preparation or cooking (e.g. re-heating, frying). For organizations with 20 sites or fewer, all sites shall be audited. For organizations with more than 20 sites, the minimum number of sites to be sampled shall be 20 plus the square root of the total number of other sites: $y = 20 + \sqrt{(x - 20)}$, rounded up to the next whole number. This applies to the initial certification, to surveillance and to recertification audits.

The use of multi-site sampling is not permitted for any other categories other than the those listed above.

3.10.3 Rounding

If after the duration calculation the result is a decimal number, this shall be rounded downwards or upwards to the nearest half day under mathematical rounding rules (the automated calculators are already set for this rounding rule).

3.10.4 Additional Time

3.10.4.1 Use of translator:

Inspiring trust for a more resilient world.

Additional on-site audit time shall be added in case a translator is required to support the audit team. For translation the minimum time recommended to be added is 0.25 on site auditor day. The maximum time needed will depend about the percentage of duration that the translator will attend the audit.

3.10.4.2   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.

Both situations above refer to an extension of scope in a site already ISO 22000 certified. If the site is not ISO 22000 certified yet, it shall be treated as a new certification process based on the initial audit duration calculation.

3.10.4.3   ISO 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 ISO 22000 assessment.

3.10.5   Reduction in Time

- In cases of unusually high repetitive shifts or process a reduction, a coherent and consistent reduction can be applied on a company-to-company basis within the scope of certification.

- D_s cannot be reduced below 1 day (0,5 audit day for categories A and B)

3.10.5.1   Integrated audit

- In cases that FSMS is integrated with another relevant management system[note 01] (quality or food safety system) or food safety system (FSS[note 02]), a reduction in audit duration is possible.

- The combined audit duration shall be determined and recorded as follow:

  1. Calculate the audit duration for each scheme separately (including scheme restrictions and allowed reductions).

  2. Add the audit durations together.

  3. Determine the degree of reduction considering a maximum of 20% reduction can be made on the combined duration. The reduction range based on integration is 0% to 20% determined by the level of integration of overall business strategy, management reviews, approach to policy, objectives, systems, processes, internal audits and effective corrective action to prevent reoccurrence.

- *Note 01: "Relevant management system" means a quality or food safety system which covers the same processes, products and services.*

- *Note 02: FSS certification: a product certification that incorporates requirements based on the internationally accepted principles of food safety and management system components that support the production of safe food.*

Inspiring trust for a more resilient world.

3.10.6 ISO 22000 Follow Up Audits

In the case where a follow up audit is required, duration will depend on the objective of the follow up audit and so shall be analysis case by case.

3.11 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 Major and Minor.

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

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

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

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

3.12 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 ISO 22000 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.

3.12.1 Nonconformities Levels

All non-conformities raised in an ISO 22000 audits shall be addressed by the organization.

The non-conformities against ISO 22000 requirements shall be graded in 2 levels being minor and major.

- Minor non-conformity (NC): a minor NC is issued when the finding does not affect the capability of the management system to achieve intended results
- Major non-conformity (NC): a major NC is issued when the finding affect the capability of the management system to achieve intended results and/or when a direct food safety impact without appropriate action by the organization is observed during the audit and/or when a legality and/or certification integrity are at stake.

The audit team may identify opportunities for improvement.

Inspiring trust for a more resilient world.

3.12.2 Non-Conformity Management

<u>Minor</u>: The organization shall provide to BSI, the CAP (corrective action plan) including correction, root cause analysis and corrective action within 28 calendar days from the last day of the audit. BSI should review and approve it when acceptable, no later than 30 days from the last day of the audit.

Correction and corrective action shall be implemented by the organization within the timeframe proposed on the CAP by the organization and agreed by BSI. Evidence of implementation and its effectiveness shall be reviewed, at the latest, at the next scheduled audit.

Note: Failure to address a minor nonconformity from the previous audit could lead to a major nonconformity being raised at the next scheduled audit

<u>Major</u>: The organization shall provide to BSI the CAP (corrective action plan) including correction, root cause analysis and corrective action, within 21 calendar days from the last day of the audit. BSI shall review the corrective action plan and conduct a follow up audit (desk review or on site, up to auditor´s decision based on risk) within 28 calendar days from the last day of the audit to close the major NC. 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 plan is implemented.
Note: Major NCs must be closed prior to the issue/re-issue of a certificate.

3.13   Granting Certification

Certification of an ISO 22000 System shall be awarded to an organization with no outstanding non-conformities. Whilst the certificate is issued to the applicant site, it remains the property of BSI under the conditions outlined in the contract.

3.14   Multi-site certification

A multi-site organization is an organization having an identified central function 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;
- producer groups (for categories A and B);
- 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.

Sampling of multi-site organizations shall cover all activities.

When multi-site sampling is undertaken, the rationale to apply it will be based on the following conditions:

a) sites are operating under one centrally controlled and administered FSMS;

b) sites subject to sampling are similar (food chain subcategory, geographical location, processes and technologies, size and complexity, regulatory and statutory requirements, customer requirements, food safety hazards and control measures);

c) the central function is part of the organization, clearly identified and not subcontracted to an external organization;

Inspiring trust for a more resilient world.

d) all sites have a legal or contractual link with the central function;

e) the central function has organizational authority to define, establish and maintain the FSMS;

f) all sites are subject to the organization's internal audit programme and have been audited;

g) audit findings at a site are considered indicative of the entire FSMS and corrective actions are implemented accordingly;

h) the central function is responsible for ensuring that outcomes of performance evaluation and customer complaints from all sites are collected and analysed; the organization's FSMS is subject to central management review;

i) the central function has authority to initiate continual improvement of the FSMS.

NOTE The central function is where operational control and authority from the top management of the organization is exerted over every site. There is no requirement for the central function to be located in a single site.

Where multi-site sampling is permitted, the organization shall conduct an internal audit for each site within one year prior to certification and when applicable the effectiveness of corrective actions shall be available. Following certification, the annual internal audit shall cover all sites of the organization included in the certification scope of the multi-site organization and ongoing effectiveness of corrective actions shall be demonstrated.

Where multi-site sampling is permitted, a sampling programme will be implemented to ensure an effective audit of the FSMS where the following conditions apply:

a) At least annually, an audit of the central function for the FSMS shall be performed by the certification body prior to the sampled site audits.

b) At least annually, audits shall be performed by the certification body on the required number of sampled sites.

c) Audit findings of the sampled sites shall be assessed to ascertain if these indicate an overall FSMS deficiency and therefore can be applicable to some or all other sites.

d) Where audit findings of the sampled sites are considered indicative of the entire FSMS, corrective actions shall be implemented accordingly.

e) For organizations with 20 sites or fewer, all sites shall be audited.

BSI will increase the size of sample or terminate the site sampling where the FSMS subject to certification does not indicate the ability to achieve the intended results.

The sample shall be partly selective and partly random and shall result in a representative range of different sites being selected, ensuring all processes covered by the scope of certification will be audited. At least 25 % of the sample will be selected at random. The remainder will be selected so that the differences among the sites selected over the period of validity of the certification are as large as possible.

For the site selection BSI will consider, among others, the following aspects:

a) results of internal audits, management reviews or previous audits;

b) records of complaints, product withdrawals/recalls, and other relevant aspects of corrective action;

c) variations in the site characteristics;

d) other relevant changes since the last audit.

Inspiring trust for a more resilient world.

If any site has a major nonconformity and satisfactory corrective action have not been implemented in the agreed time frame, certification shall not be granted or maintained for the whole multi-site organization pending satisfactory corrective action.

The certification body shall identify and include in the scope of certification the processes of the FSMS implemented at each sampled site.

4 ICT (Information and Communication Technology) use in ISO 22000 Audits

The standard method for conducting ISO 22000 audits is either through full on-site audits as described on this global scheme manual or as ICT audit approach (remote + on site). Both of which are accredited.

The ISO 22000 full remote option is an **accredited, voluntary option <u>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</u>**, supported by a risk and feasibility assessment.

4.1 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):** ISO 22000 audit as a split process utilizing ICT. The ICT audit approach audit 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.

4.2 ICT audit approach

The ICT Audit Approach is voluntary and shall to be mutually agreed between the BSI and the certified organization prior to the audit. The ICT audit approach consists of 2 main steps:

- <u>Remote audit component</u> consisting of a document review and interview key personnel using ICT.
- <u>On-site audit component</u> focusing on the implementation and verification of the FSMS, the physical inspection of the production process and any requirements not covered during the remote audit.

4.3 Full remote

The ISO 22000 full remote option is an **accredited, voluntary option <u>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</u>**, supported by a risk and feasibility assessment. Mutual agreement between BSI and the certified organization is required prior to conducting the 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.

Inspiring trust for a more resilient world.

Note: Full remote audit IS NOT A DESK REVIEW. Full remote is an audit with client interaction by using ICT and not constitute at any point as a desk review to be performed only through documents review. Remote audit activities follow the same principles of the on-site audit activities.

4.3.1 Transfer of certification

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

4.4   Auditor Rotation

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

5   Certificate Suspension, Withdrawal or Scope Reduction

Suspension: BSI shall immediately suspend certification when there is evidence that the client is either unable or unwilling to establish and maintain conformity with ISO 22000 requirements. Besides that, BSI shall also suspend the certificate in cases when:

- the client's certified management system has persistently or seriously failed to meet certification requirements, including requirements for the effectiveness of the management system;
- the certified client does not allow surveillance or recertification audits to be conducted at the required frequencies;
- the certified client has voluntarily requested a suspension.

Under suspension, the client's management system certification is temporarily invalid. BSI shall restore the suspended certification if the issue that has resulted in the suspension has been resolved no later than six months after suspension. Failure to resolve the issues that have resulted in the suspension in a time established by BSI shall result in withdrawal or reduction of the scope of certification.

Withdrawal: BSI shall withdraw a certificate when:

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

5.1   Actions Upon Suspension, Withdrawal and Scope Reduction

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

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

6   Use of Marks (ANAB and BSI)

The instructions for use of the BSI FSMS certification and AB (Accreditation Body) marks are available here (GP045 – Marks of Trust - Clients Guidelines).

Inspiring trust for a more resilient world.

It is not authorized the use of the FSMS certification mark or any statement that the client has a certified FSMS on the product nor the product packaging, both primary packaging (which contains the product) and any outer or secondary packaging.

7   Confidentiality

BSI standard terms and conditions apply.

8   Additional Obligations

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

- Continued compliance with the relevant systems standard(s) or code(s) of practice;

- Compliance with BSI's Standard Commercial Terms and Conditions and obligations as specified in this document as well as other guidance documentation that may be specifically provided from time-to-time;

- Conduct of regular internal reviews of your system, with appropriate documentation of such reviews and of any subsequent corrective actions;

- Notification to BSI of any significant changes in the structure (key responsibilities and management system), ownership and operations of your site to enable the impact of such changes on the certified ownership system to be evaluated; and

- Notification to BSI of any litigation or serious events or matters that relate to the scope of your certification within twenty-four (24) hours of the event.

8.1   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.

8.2   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.

8.3   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.

Inspiring trust for a more resilient world.

8.4   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.

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.

8.5   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 ISO 22000 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.

8.6   Management of extraordinary serious event

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

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

- Product Recall: 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 or is with retailers or caterers and is available for sale (GFSI 2020.1).

- Product Withdrawal: The removal of a product by a supplier from the supply chain that has been deemed to be unsafe, which has not been placed on the market for purchase by the end consumer (GFSI 2020.1).

In case your organization is affected by any other 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/cyber hacking, etc.), BSI shall be contacted within 03 working days through critical.food@bsigroup.com.

Inspiring trust for a more resilient world.

8.7   Observers

- From time to time BSI requires an observer to be in attendance at an audit. This may be related to training of new staff and witness assessment of existing staff. It is a requirement of certification that your site allows these activities to occur.

- BSI will, at all times, ensure that the use of observers is kept to a minimum and your site will be advised prior to the assessment activity.

- The observer does not take an active part in an assessment.

- By accepting the ISO 22000 BSI quote your organization accept cooperate with such process

8.8   Witnessing Assessment by BSI

From time to time the accreditation body requires a performance of a witnessing process. By accepting the ISO22000 BSI quote your organization accepts to cooperate with such processes that can be conducted on site or remotely in which the normal confidentially requirements apply.

8.9   Technical Experts (TEs) used by BSI

BSI may need to use a TE during an ISO 22000 audit. By accepting an ISO 22000 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   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. Where necessary a Review Committee will be established and operated.

- All complaints shall be notified to the Global Complaints and Appeals Coordinator – complaints@bsigroup.com

Appeals relating to the reconsideration of a decision made by BSI shall be considered if received within 21 calendar days of the decision or closing meeting of an audit. Appeals shall be made in writing by the client.

- All appeals received shall be forwarded to the Global Complaints and Appeals Coordinator appeals@bsigroup.com .

10   BSI Accreditation and Transition Period

BSI successfully upgraded its accreditation from ISO/TS 22003:2013 to ISO 22003-1:2022.

ISO 22000:2018 (under ISO 22003-1:2022 requirements) audits can already be delivered by countries.

The latest transition start date is 01 April 2024. From this date on all ISO 22000:2018 audits shall be delivered under the ISO 22003-1:2022 requirements.

Transition end date is March 2025.

Inspiring trust for a more resilient world.

Certified clients will be mainly affected by the following changes:

i)   Requirements for audit time determination

ii)   Requirements for multi-site sampling

iii)   Scope of certification

10.1   ISO 22000:2018 Audits

The transition audit is going to be the regular audit within the certification cycle, whether it is a surveillance or recertification audit and will be delivered as per the requirements of ISO 17021-1:2015 AND ISO 22003-1:2022.

10.2   ISO 22000:2018 Certificates

Once the client has successfully completed the transition audit followed by a positive certification decision, the certification reviewer will decide if the certificate needs to be re-issued.

- For the recertification upgrade audits → all certificates are going to be re-issued as per normal process.

- For Surveillance upgrade audits → the certificates need to be re-issued only for clients which the (sub) categories were impacted by the change made on the ISO 22003-1:2022 and/or in case client has any change on their scope (extension or reduction).

Note → Clients whose transition audit has not been completed within the transition timeline: will withdrawn their certificate.

Inspiring trust for a more resilient world.