

# Information and Certification Requirements

ISO 22000



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## **Revision History**

Rev No	Revision Date	Page No	Sec. No	Brief Description of Change	
1	December 2020	New document			
2	May 2021	21	7	Aligned confidentially clause with the BSI Terms and Conditions.	
3	September 2023	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	All	All	Complete review and update to add ISO 22003-1:2022 requirements.	
5	March 2024	22 23	6 8.4	Made clear the use of logo and certification statements in accordance with ISO 22003-1:2022 requirements.	
6	November 2024	Entire document re-structured			

### 1 Scope

This information requirements document sets out terms which satisfy the related Accreditation and Scheme requirements and forms part of the Service Agreement between client and BSI as indicated in the SRF (Service Request Form) which is completed by your organization when applying for the ISO 22000 Scheme Certification.

The requirements included in this document does not cover all Scheme rules and therefore the complete Scheme requirements shall be found in the related ISO 22000 Scheme documents and followed at all times.

### 2 General Scheme description

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.

#### 2.1 Related normative requirements

- ISO 22000:2018
- ISO 17021:2015
- ISO 22003-1:2022
- IAF Mandatory Documents as applicable and appropriated in accordance with Scheme Rules.

## 3 BSI accreditation scope

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) accreditation rule.

### 4 BSI scope coverage

BSI can only operate (under ANAB accreditation) in the categories and subcategories covered by the accreditation, being as indicated below.

- A: Farming or handling of animals
- B: Farming or handling of plants
- C: Food, ingredient and pet food processing
- D: Feed and Animal food processing
- **E:** Catering/ food service
- F: Trading, retail and e-commerce
- G: Transport and storage services
- H: Services
- I: Production of packaging material
- K: Chemical and bio-chemical

Note 1: BSI is not accredited for category J under ANAB.

### 5 Application process

BSI will require completion of an official application form, signed by an authorized representative of the applicant site. 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.

## 6 Certification agreement

BSI will have a legally enforceable agreement with your organization for the provision of the ISO 22000 certification activities in accordance with the relevant requirements.

## 7 Audit planning

Your site is required to make all necessary arrangements to allow the certification activities to take place in accordance with the Scheme requirements.

## 8 Certification cycle

The 3-year certification cycle shall be applied to ISO 22000. The first 3-year certification cycle begins with the initial certification decision. Subsequent cycles begin with the recertification decision. 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.

**Note:** Back-to-back (stage 01 and stage 2) audit is not a standard practice, but it is allowed as long as client is aware and in agreement about the risk of the stage 02 being postponed/cancelled if any critical issue, which does not allow BSI to proceed to stage 02, is identified in the stage 01. In addition to that, the related financial implications related to cancelation of stage 02 shall be mutually agreed between the BSI and client. Surveillance audits shall be conducted within the calendar year following RAM.

The RAM is determined by counting 4 months before expire certificate date. When needed, RAM deviation **may be applied provided that the requirements of ISO 22000 for planning the audits are followed.** 

**Note:** The date of the first surveillance audit, after the initial certification, shall not exceed 12 months from the initial certification decision date, otherwise the certification shall be suspended.

Recertification audits shall take place following RAM and in a timely manner when RAM deviation is needed allowing enough time for the certification process to be completed prior to the expiry of the certificate. Where the certificate expires prior to the recertification activities being undertaken, BSI can restore certification within 6 months, provided that the outstanding recertification activities are completed, otherwise a full initial certification audit (Stage 1 and Stage 2) shall be conducted.

## 9 Certification and audit process

BSI shall define the relevant scope for the organization applying for ISO 22000 certification and 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 by the legal responsibility of the organisations 'activities.

The conditions to not allow a scope to be excluded is not limited to but includes: a) when the product intended to be excluded is produced on the same production line as the certified scope; and/or b) when equipment and/or employees are shared between the scope intended to be excluded and the certified one.

Audits shall be carried out at the premises of the organization in accordance with the audit duration calculated and shall be conducted over a continuous number of days (excluding weekends when it is not a working day and public holidays).

Audits are to be scheduled when products representative of the scope of the audit are in production or are being handled. Where operations occur at times other than the usual working day, the audits must be scheduled to enable the auditor to be present to observe the operations.

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.

A minimum of 50% of the total audit duration shall be spent on auditing the operational food safety planning and the implementation of PRPs and control measures. This includes time spent auditing the facilities, conducting the traceability exercise(s) and reviewing the relevant records. Operational food safety planning does not include activities related to FSMS development, training, internal audit, management review and improvement.

## 9.1 Initial and continuing certification activity

The ISO 22000 certification audit consists of two stages:

The initial auditing for certification is always carried out at the production site of the applicant site and is conducted in two separate stages:

- 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 ISO 22000 scheme requirements. The objective of this audit is to assess the preparedness of your site to proceed to the stage 2 audit.
- The stage 2 audit substantiates top management's claim by auditing implementation of the food safety management system.
- The activities subject to the proposed certification scopes shall be assessed during the initial certification audit.

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.

The recertification audit must be planned and conducted in due time to enable timely renewal of the certificate before the expiry date.

- The purpose of this audit is to confirm the continuing conformity of the food safety management system as a whole with all ISO 22000 scheme requirements.
- 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.
- 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.

If the certified organization refuses surveillance or recertification audits to be conducted at the required frequencies, the certificate shall be suspended, and BSI shall withdraw the certificate if the audit is not conducted within a six-month timeframe from the date refusal.

#### 9.2 Non-conformance management

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.

#### 9.2.1 Minor nonconformity

- 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

#### 9.2.2 Major nonconformity

- 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.* 

9.2.3 Nonconformity management (for multi-sites)

When nonconformities are found at any individual site, either through the organization's internal auditing or from auditing by BSI, an investigation shall take place to determine whether other sites may be affected. Therefore, BSI requires 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 certification decision process, if any site has a major nonconformity, certification shall be denied to the listed sites of the multi-site organization, 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 the "problematic" site from the scope during the certification process. **Note:** categorization and timeline for non-conformity management is the same. Note that the timeline for non-conformity management starts counting after completing the central functions and all the related sites audits.

### 10 Audit reporting requirements

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 closing meeting.

These Non-Conformities and their categorization at the closing 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.

### 11 Certification decision

BSI is responsible for, and retain authority for, its decisions relating to certification, including the granting, refusing, maintaining of certification, expanding or reducing the scope of certification, renewing, suspending or restoring following suspension, or withdrawing of certification.

## 12 Certificate and audit report 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.

## 13 Auditing and certification status information

BSI may have to share the information of your organization relating to the certification and auditing process with the related Accreditation Body, the IAF and/or governmental authorities when required.

BSI will share the information regarding your certification status with external parties through the related platforms/ database.

## 14 Other persons attending the audit

It is a condition of undertaking an audit that the auditor may be accompanied by other personnel for training, assessment or calibration purposes. This activity may include:

- training of new auditors by BSI;
- witness audits by Accreditation Bodies and/or BSI;
- use of technical expert and/or translator and/ or observers.

By accepting the BSI contract your organization agrees to cooperate with such process.

## 15 Communication obligations

Your organization has the obligation to communicate with BSI within 3 working days the following:

- any significant changes that affect the compliance with the requirements and obtain advice of BSI in cases where there is doubt over the significance of a change;
- Serious events that impact the certified system, legality and/or the integrity of the certification, including situations that pose a threat to food safety or certification integrity as a result of Force majeure, natural or man-made disasters (e.g., war, strike, terrorism, crime, flood, earthquake, malicious computer hacking, etc.). BSI shall be contacted within 3 working days through critical.food@bsigroup.com.

- Changes to organization name, contact address and site details;
- Changes to organization (e.g., legal, commercial, organizational status or ownership) and management (e.g., key managerial, decisionmaking, or technical staff);
- Major changes to the certified system, scope of operations and product categories covered by the certified scope (e.g. new products, new processing lines, etc.);
- Any other change that renders the information on the certificate inaccurate.
- Any claim or threatened claim against BSI, any member or auditor has performed or is in the course of performing an Audit.
- Serious situations where the integrity of the certification is at risk and/or where BSI can be brought into disrepute. These include, but are not limited to:
  - notice and actions imposed by regulatory authorities as a result of a food safety issue(s), where additional monitoring or forced shutdown of production is required;
  - legal proceedings, prosecutions, malpractice, and negligence; and
  - fraudulent activities and corruption.
  - food safety events/product safety incidents (e.g., recalls, withdrawals, calamities, food safety outbreaks etc.).

In case your organization is affected by a product safety incident, BSI shall be notified within 3 working days through <u>food.recall@bsigroup.com</u> from the date of the incident.

The information related to the product incident will be evaluated and BSI will decide the course of action regarding action needed as well as the status of the certification.

Related definition as follows:

- **Product safety incident:** Food safety, authenticity or legality incidents, including product recalls, regulatory notice, food safety-related withdrawals or any other incidents affecting the safety of product.
- **Product Recall:** The removal by a supplier of 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 (Ref: GFSI Benchmarking Requirements \_Version 2020.1).

- **Regulatory notice:** Any notice (related to the scope of the certification), filing or other documentation required to be submitted to an Applicable Authority with respect to any Regulatory Clearance.
- **Product Withdrawal:** The removal of 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 (Ref: GFSI Benchmarking Requirements \_Version 2020.1)
- Notifiable product safety incidents: Any product safety incidents related to a product which is within the scope of the site's certification that shall be communicated to BSI as described in the following section. It includes cases where the product has already been consumed and therefore the client cannot recall/ withdraw the product.

## 16 Complaints and appeals

Please refer to BSI website for information related to complaints and appeals, including timeline and communication channel: Complaints and appeals.

## 17 BSI Impartiality

Impartiality is the governing principle of how BSI provides its services. Impartiality means acting fairly and equitably in its dealings with people and in all business operations. It means decisions are made free from any engagements of influences which could affect the objectivity of decision making.

Find detailed information here.

### 18 Misleading statement

Your organization is not permitted to use its certification in a manner that could bring BSI into disrepute. This includes making misleading or unauthorized statements.

## 19 BSI Mark of Trust and Accreditation Mark rules

The guideline related to access the marks and the related rules is available <u>here</u>.

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.

## 20 Scheme transition information

On 7 June 2022, ISO published ISO 22003-1:2022 (replacing ISO/TS 22003:2013) standard which supplements ISO/IEC 17021-1:2015 and covers food safety management systems (FSMS).

ISO 22003-1:2022 main changes focus, but are not limited, on the following:

- Incorporates all the requirements of ISO/IEC 17021-1:2015
- Adds new terms and definitions (including a new HACCP Study definition)
- Establishes technical and competence requirements
- Realignment of the food chain (Sub) categories, scope of certification
- Realignment of the audit duration calculation rule and multi-site sampling
- Expanding guidance on the use of the marks
- Updating on requirements for initial audits
- Changes and clarification on requirements for the certification process, competency and others.

There is **NO** change on the ISO 22000:2018 requirements. The standard has not changed version and remains the same as per 2018 version.

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.

Certified clients will be affected by the following changes:

- i. Requirements for audit time determination
- ii. Requirements for multi-site sampling
- iii. Scope of certification.



