

AIBI-CS Overview of the FSSC PR3C: 22000 Certification Scheme and Specific Service Requirements



Any Update to this Document is Posted on the [AIB International website](#).

Introduction

This document provides a guide for applicants and suppliers about how AIB International CS evaluates and certifies food companies against FSSC 22000 Food Safety Systems which includes ISO 22000, ISO/TS 22002 – 1 or ISO/TS 22002 – 4 or ISO/ TS 22002-6 or ISO/TS 22002 – 2 or ISO/TS 22002 – 5 and additional requirements based on the decisions of the FSSC 22000 Board of Stakeholders and published by the Foundation on www.fssc22000.com and provide details on specific requirements in addition to PR4 Rules for Certification.

The AIB International CS Quality System is designed to meet the requirements of ISO/IEC 17021-1. Many of the documents that are part of this system are provided at various stages of the certification process. AIB International CS has received accreditation from UKAS to provide FSSC certification services, according to the requirements of ISO/IEC 17021-1:2015 & provisions within ISO/TS 22003:2013.

AIBI-CS will maintain accreditation in line with ISO/IEC 17021-1:2015 and the requirements of UKAS as nominated accreditation body.

In the case there is a change to the accreditation status of AIB International CS, written notification is provided to the Foundation within 3 working days detailing the circumstances leading to this and the action plans authorized to recover accreditation.

When conducting an evaluation AIBI-Certification Services may subcontract to AIB International, use independent contractors or full time AIBI-CS employees.

AIB International Certification Services, Inc.

AIB International Certification Services, Inc. (AIBI-CS), a wholly owned and legally separate subsidiary of AIB International provides certification services to organizations around the world within the food industry and associated services. The Certification Office of AIB International CS is located in Manhattan, Kansas, USA. AIBI-CS's General Manager provides oversight for AIBI-CS.

AIBI-CS has an Impartiality Governing Board composed of impartial members who do not work for AIBI-CS who are however, stakeholders in GFSI schemes including FSSC 22000 food safety systems. The Board meets according to the ISO/IEC 17021-1 and ISO/IEC 17065 requirements and oversees compliance to the whole certification scheme.

AIBI-CS will ensure full compliance with all FSSC 22000 Scheme owner requirements, participate in Integrity audits, Integrity Desk Top audits, Training programmes and attend webinars and review scheme owner updates and take all relevant action in a timely manner.

FSSC 22000 – Food Safety Systems

FSSC 22000 is a certification scheme for Food Safety Systems based on ISO 22000 - the International Standards Organisation (ISO) Food Safety Management System Standard, Pre requisite programs ISO/TS 22002 - 1 (Prerequisites Programs on food safety for Food manufacture) and/or ISO/TS 22002 - 4 (Prerequisites Programs on food safety for Food Packaging Manufacture) and/ or ISO/TS 22002 – 6 (Prerequisites Programs on food safety for Feed and Animal Food Production) or ISO/TS 22002 – 2 (Prerequisites Programs on food safety for Catering or ISO/TS 22002 – 5 (Prerequisites Programs on food safety for Transport & Storage Services and additional requirements based on the decisions of the FSSC 22000 Board of Stakeholders and

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published by the Foundation on www.fssc22000.com. The Board of Stakeholders (BoS) Decision list is a document which contains decisions applicable to 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.

FSSC 22000 is a certification program based on HACCP principles; designed to provide international harmonization in the field of food safety for all participants in the food supply chain. These documents combine generally recognized key elements to ensure food safety along the food chain with interactive communication; system management; control of food safety hazards through pre-requisite and HACCP plans; and continual improvement and updating of the management system. The use of the FSSC 22000 system will ensure participants have a Food Safety System acceptable worldwide that will demonstrate a company's commitment to the manufacturing of safe products.

To progress with the certification program after the initial inquiry stage, the following stages of the certification process will be followed.

Application Stage

AIBI-CS will forward a copy of the application form (REC10) with a number of other documents that will include:

- an Overview of the AIBI Certification Scheme (this document)
- the Rules for Certification and Use of the AIBI-CS Logo (PR4) that must be followed by both parties
- additional information if required

In order to progress further, the application form should be completed and returned to the AIBI-CS office. At this stage if you have any questions, please contact the office.

AIBI-CS will forward the Certification Agreement and other documents that are needed for contract purposes and to allow the evaluation and certification stages to take place. Every effort will be made by AIBI-CS to carry out the audit on the date(s) requested by the client. In the case of a surveillance audit, similar documentation will be sent to make sure that the exact scope or any other changes are known in advance. An audit plan for all types of audit will be forwarded to client in advance of the agreed audit date.

Contract Aspects of the Certification Scheme

The signed documents (Application and Certification Agreement) form the basis of the contract. Terms and conditions and specific scheme requirements are detailed later in this document.

Pre-assessment

A pre-assessment evaluation can be carried out if the applicant is not sure if they will meet all the aspects of the certification standard. A pre-assessment is not mandatory to achieve FSSC certification. This involves an audit against the agreed scope and a report detailing possible non-conformances that are found.

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Audit and Certification Stage

Once all the final application stage documentation has been received by AIBI-CS, an auditor will carry out the evaluation in the agreed time scale, on the agreed date(s) and in a mutually agreed language. Guidance on the time scale will be provided for each site. AIBI-CS will operate discretely in the case of emergencies (e.g. fire, major catastrophic event, another on-going audit).

Certification is open to all companies' food manufacturing or related products or services. Applicants who wish to become certified are required to fill in the appropriate application forms giving full details of all locations and types of operations.

FSSC does not allow the application of multi-site certification for food chain categories C, D & I, as described in ISO/TS 22003 and ISO/IEC 17021-1. Each location requires a separate audit, report and certificate, and will be entered separately on the FSSC database. FSSC does offer exceptions for two main categories of organizations that have multiple locations and want to apply for certification. The two exception categories are:

- Organizations where some functions pertinent to the certification are controlled by a head office separate to the manufacturing location(s). In this case the head office does not receive a standalone certificate. The Head Office audit shall be carried out prior to the site audits and the subsequent audits at the site(s) shall include a confirmation that the requirements set out by the head office are appropriately incorporated into site specific documents and implemented in practice. All individual sites will be audited within a timeframe of 12 months from the audit of the Head Office.
- Organizations where a single manufacturing process is split between different sites that are part of the same legal entity, operate under the same FSMS and are the sole receiver/customer of each other. Storage facilities at another location shall also be included in the same audit provided they meet the requirements set above. The 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.

For new applicants, the first stage referred to as **Stage 1**, is conducted to assess the preparedness of the client for the audit. Any areas of concern that could be classified as a nonconformity shall be resolved before the Stage 2 audit. At this stage the following shall be reviewed:

- Identification of PRPs as defined in ISO/TS 22002-1 / ISO/TS 22002-4 / ISO/TS 22002-6 and how appropriate they are to the business
- Processes and methods for identification and assessment of the organizations food safety hazards and subsequent selection and categorization of control measures
- Food safety legislation is in place for relevant sector of the organization
- Food Safety Management System [FSMS] designed to achieve food safety policy
- FSMS implementation program justifies proceeding to the audit (stage 2)
- Validation, verification and improvement programs conform to the requirements of the FSSC 22000 (ISO 22000 + ISO/ TS 22002 – 1 or ISO/TS 22002 – 4 or ISO/TS 22002 - 6) system.
- FSMS documents and arrangements are in place to communicate internally and with relevant suppliers, customers and interested parties

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Once the client considers their system is in compliance, the next step referred as **Stage 2**, is scheduled within 6 months of the Stage 1, otherwise a further desk top review will be required. The scope of the Stage 2 is to evaluate the implementation and effectiveness of the food safety system. The initial certification audit (stage1 and stage2) cannot be performed unannounced.

Clients can combine the Stage 1 and 2, but Stage 2 is only allowed to be conducted when 1) non-conformities from Stage 1 have been properly addressed and implemented and 2) System implementation allow an evaluation of the systematic implementation of the standard's clauses. When the auditor finds the facility is not prepared for Stage 2, the audit can be stopped and the facility will be held accountable for all charges and will have to schedule dates for a revisit to complete the certification audit.

The Stage 2 audit will cover all aspects and interactions of ISO 22000, Applicable Prerequisite Programs (Good Manufacturing Practices) and FSSC Additional requirements described in FSSC22000 Part2 and the Decision List of the Board of Stakeholders: Requirements for certification, version 5.1 November 2020 published by the Foundation on www.fssc22000.com. This audit also includes a review of:

- Monitoring, measuring, reporting and reviewing objectives of the FSMS
- The FSMS and performance with regards legal compliance
- Operational control of processes
- Internal auditing and management review
- Management responsibility for food safety policy

A certificate is granted if all nonconformities are resolved as follows:

- **Critical** – Certificate is immediately suspended within 3 working days for a maximum period of 6 months. The client shall provide AIBI-CS with objective evidence of investigation into causative factors, exposed risks and proposed CAP within 14 calendar days after the audit. A follow up audit of a minimum one day onsite duration shall be conducted between 6 weeks to 6 months' time frame to verify closure of the Critical NC and effective implementation of the corrective actions. The certificate shall be withdrawn when the Critical is not effectively solved within the 6-month time line. For Certification audits, a full certification audit shall be repeated.
- **Majors** – Client shall provide objective evidences of the investigation into the causal factors and exposed risks and a proposed corrective action plan within 14days from the last audit date. The Major NC shall be fully closed out within further 14days by implementing the agreed corrective action plan. A follow up audit can be conducted to verify implementation of the corrective action and closure of the Major. A desktop review will suffice in case documentary evidences support the closure of the Major. A Critical NC is raised in the case of non-completion of the approved corrective action plan and current certificate suspended.
- **Minors** – The client shall provide AIBI-CS with objective evidence of the correction, evidence of an investigation into causative factors, exposed risks and a proposed corrective action plan. AIBI-CS approval shall be completed within 28days from the last audit date. Exceeding the timeframe of 28days shall result in certificate suspension. Corrective actions shall be completed within 12 months after the audit. Implementation of the corrective action plan shall be reviewed at the latest at the next scheduled on-site audit. A Major NC on management responsibility and allocation of resources is raised in the event of non-completion of the approved action plan at the next scheduled on-site audit.

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For all audit types, the required data and documentation, shall be entered in the FSSC portal at least 28 calendar days after the certification decision is concluded and with a maximum of 2 months after the last day of the audit. Information on the certified status of the client will be displayed on the FSSC22000 website and in the Portal. The mandatory data in the portal shall be entered in English

Certificates may only be granted or withdrawn by AIBI-CS and will be awarded to clients that conform to the relevant Standard. This award will also be subject to clients complying with certification rules that will be periodically updated and reviewed as necessary. The certificate and reports remain the property of AIBI-CS. Certification is conditional on initial audit, routine surveillance audits and any other situation or audits that verify continual conformance with Scheme requirements and the 3 years cycle shall be respected at all times.

AIBI-CS may carry out extra partial or total audits at a short notice to investigate complaints, in response to changes within the certified client, or as a follow up on suspended clients. The certification body will describe and make known in advance to the certified client the conditions under which the short notice audits are to be conducted. The cost of these additional audits shall be covered in full by the client. Additional care will be exercised in the selection and assignment of the audit team.

Transition audits are allowed from Dutch HACCP, ISO22000 and GFSI recognised schemes with equivalent scopes. For FSSC22000-Quality, transition audits are allowed for clients holding a valid ISO2200, FSSC22000 and a valid ISO9001 certificate. Transition audits consist the start of a new certification cycle and as such a stage 2 audit is required, where conduct of a stage 1 audit is at the discretion of AIBI-CS. The FSSC2200 or FSSC22000-Quality certificate issued will have a validity of 3 years, from the date of initial certification decision, with subsequent 3 year cycles.

Certification Status

Certification is valid for 3 years after the date of the initial certification decision; the 3 years certification cycle shall always be respected. In the intermediate period, surveillance audits are carried out. Surveillance audits will be conducted annually. Each surveillance audit will cover all scheme requirements, ISO 22000, relevant PRP documents and FSSC 22000 plus use of marks and references to certification. At each audit, all groups of products covered by the scope of certification need to be observed by the auditor. A plan will be drawn up confirming all areas will be covered during each surveillance audit. Surveillance audits will also include assessment of:

- Internal audits and management review
- Actions taken on non-conformances raised at the previous audit
- Treatment of complaints
- Effectiveness of the FSMS with regard to achieving the Food Safety Policy
- Progress of planned activities aimed at continual improvement
- Continuing operational control and implementation of PRPs and HACCP
- Review of any changes
- Use of marks and/or any other reference to certification

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Maintaining certification is dependent on successful annual surveillance audits and on a full re-certification audit prior to the end of the 3-year's period to ensure certificate is granted prior to the expiry date of the current one.

Surveillance activities include at least one unannounced audit in the 3-year's certification cycle. The certified client can voluntarily choose to replace all surveillance audits by unannounced annual surveillance audits. Where there are legitimate business reasons, blackout days may be agreed in advance to avoid periods of extreme inconvenience during which the client would find it difficult to participate fully and/ or there is no production.

AIBI-CS sets the date of the unannounced audit typically between 8-12 months after the previous audit, but respecting recertification planning. The consequence of this may be that the audit is not conducted annually. The site shall not be notified in advance by AIBI-CS, of the date of the unannounced audit. AIBI-CS decides which of the scheduled surveillance audits shall be chosen for the unannounced audit. In the event that the certified client refuses to participate in the unannounced audit, the certificate shall be suspended immediately, and AIBI-CS shall withdraw the certificate, if the unannounced audit is not conducted within a six-month timeframe. If access is denied to the auditor the client will be liable for all costs. Head offices controlling certain functions pertinent to certification are not audited during the unannounced audit. Where head office activities are part of the site audit, they will be unannounced. Secondary sites and off-site storage, warehousing and distribution facilities will be audited during the unannounced audit. The unannounced audit takes place during normal operational working hours including night shifts when required. If not all Scheme requirements can be audited, an announced follow up audit shall be scheduled within 4 weeks.

The purpose of the recertification audit is to confirm the continued conformity and effectiveness of the food safety system as a whole. The fulfilment of all requirements is evaluated. The audit also includes a review of the system over the whole period of certification, including previous surveillance audit reports. AIBI-CS determines if another 3-year certification can be awarded on the basis of the recertification audit, the review of the system over the whole period and complaints received from users of the certification. If there have been significant changes in the system, a new Stage 1 may be required. The certified organization can voluntarily choose to conduct unannounced the recertification audit.

Unannounced audits

(As documented in Version 5.1 Upgrade Process Dated 23 Feb 2021 version 2.0)
https://www.fssc22000.com/wp-content/uploads/2021/02/Version-5.1-Upgrade-Process_Feb-2021.pdf

During the upgrade process to FSSC 22000 v 5.1 unannounced audits may be conducted where needed in order to meet the 3yearly audit requirements.

As an exception during the COVID-19 pandemic, it is allowed to contact the certified organisation 48 hours in advance of the unannounced audit. The unannounced audit may then be conducted as an on-site audit, by utilising the ICT audit approach 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 organisation and remains subject to the remainder of the requirements as set out in the Full Remote Addendum.
<https://www.fssc22000.com/wp-content/uploads/2020/10/20.1005-FSSC-Full-Remote-Audit-Addendum-v1-October-2020.pdf>

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In the case 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 organisation. Justification for not conducting the planned unannounced audit shall be recorded in the audit report. The subsequent audit in 2022 shall then be conducted unannounced, the audit programme adjusted accordingly and applicable to all types of audits (surveillance or recertification).

FSSC audits using ICT (Information and Communication Technology)

FSSC 22000 audits as a split process utilizing ICT is a voluntary approach and shall be mutually agreed between AIB International and the certified organization prior to the audit.

The ICT audit approach consists of 2 main steps:

- 1) Remote audit consisting of a document review and interviews with key personnel using ICT. The focus of the remote audit will be on the ISO 22000 components of the Scheme and include as a minimum document/procedure reviews, HACCP plans and 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 and internal audits
- 2) On-site audit 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.

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

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

In the first instance, AIB International shall conduct an assessment to determine, in conjunction with the certified organization, whether the ICT audit approach is a viable option. This assessment shall be conducted and documented for each audit involving all members of the audit team and the audited organization representative.

The following shall be considered when conducting the assessment:

- a) Maturity of the certified organization's FSMS and performance history;
- b) 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;
- c) The ICT tools to be utilized;
- d) Whether the certified organization has the ability to provide a representative capable of communicating in the same language as the auditor.
- e) Whether the CB and the certified organization have the capability and ability to conduct the remote audit in the chosen medium/forum of the remote audit.
- f) Impact on audit duration and audit planning e.g. where more time might be required due to the use of ICT.

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If the ICT audit approach is deemed to be a viable option, 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. A weak bandwidth or limited hardware capability may slow the process to the point of inefficiency.

The requirements of IAF MD4 shall be followed. This mandatory document defines the rules that AIB International shall follow to 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.

To prepare for the use of ICT, all certification, legal and customer requirements related to confidentiality, security and data protection should be identified and actions taken to ensure their effective implementation. This implies that both the auditor and the auditee agree to the use of ICT and with the measures taken to fulfil these requirements.

Both the remote audit and the onsite audit shall be conducted by an FSSC 22000 qualified auditor for the sub-category. The V5 onsite audit shall be conducted by the same FSSC 22000 approved auditor who conducted the remote audit to ensure continuity. In exceptional cases, a different auditor may be used by implementing a proper handover process.

The remote audit will typically be 1 day and the onsite verification audit the remainder of the total duration of the regular annual audit. The onsite audit cannot be less than 1 day and shall at least be 50% of the total audit duration. The total audit duration based on the calculation in Part 3 of the Scheme rules shall be met between the remote audit and the onsite audit. 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.

When compiling the audit plan for the remote audit, consideration should be given to appropriate durations and allow for more frequent breaks to enhance attention and reduce eye-strain. These breaks cannot be counted towards audit time. If 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. Provisions for ensuring audit time must be established.

The maximum timeline between the remote audit and the on-site audit 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 AIB International, that will be uploaded to the portal as part of the audit documentation.

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.

The ICT audit approach may be applied in the case of the regular, annual FSSC 22000 audits (surveillance and recertification audits) as part of the routine certification. It can also be applied to Stage 1 audits as described below and Head Office audits where the corporate functions are controlled separately.

In the year where an unannounced audit is due, the ICT audit approach may be used. The prerequisite would be that the onsite part of the audit shall be conducted first, followed directly by the remote audit with a maximum period of 48 hours between the two audit components.

The full Stage 1 audit may be conducted off-site with the use of ICT. The objectives of the Stage 1 audit shall be met and to this end, ICT (i.e. live video) shall be included to also observe the work environment and facilities. The Stage 1 audit report shall reference that the audit was completed remotely, which ICT tools were used and the objectives achieved. The Stage 2 audit shall be conducted as a full onsite audit within 6 months of the Stage 1 or the Stage 1 shall be repeated. It is not permitted to use the ICT audit approach for the Stage 2 audit.

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Annual surveillance audits may be conducted using the ICT audit approach and both the remote and the onsite audit shall be completed within the calendar year. Where the ICT audit approach is applied to the first surveillance audit following an initial certification, the process shall be planned to ensure that the onsite component of the audit takes place before or not later than 12 months after the date of certification decision for the initial audit. Where the timelines as referenced above are exceeded, the full surveillance audit shall be conducted onsite and in line with the audit schedule or the certificate shall be suspended.

The re-certification audit may be conducted using the ICT audit approach. The remote audit combined with the onsite audit constitutes a complete re-certification audit and both processes shall to be completed prior to the expiry of the existing certificate.

Any nonconformities identified as part of the remote audit shall be addressed in line with the Scheme requirements including grading and timelines and be verified as part of the onsite audit. In the case of a critical nonconformity, the certificate shall be suspended and a full new onsite audit will be required to lift the suspension within 6 months. Where nonconformities are raised, a copy of the nonconformity report shall be left with the certified organization at the end of the remote audit.

Any nonconformities identified at the remote audit, shall be verified during the onsite audit and could be signed off at the onsite audit if not already closed out. As the audit process is not closed yet, AIB International may upgrade an NC raised at the remote audit to a higher level i.e. a major, should more evidence be found to support it or if a systemic issue is identified. Any nonconformities identified during the onsite audit shall follow the existing requirements of the scheme.

ICT tools may be used to close out minor and/or major nonconformities, depending on the nature of the nonconformity and the reliability of the ICT. Critical nonconformities require an onsite follow-up audit in all instances. Any nonconformities raised at either the remote or the onsite audit, shall be recorded on the NC record with the timeline for addressing nonconformities starting from the last day of the remote and the onsite audit respectively.

Following the remote audit, an interim audit report shall be compiled with summaries and objective evidence of the clauses audited during the remote audit as well as indicating the extent to which the ICT was used and the objectives achieved. The interim audit report is for AIB International use and not intended to be supplied to the certified organization, except for Stage 1 reports and Head Office reports where the corporate functions are controlled separately.

Following the onsite audit, the interim audit report shall be updated to produce the full certification audit report. The latter shall include all summarized information, findings and nonconformity details of the remote audit and onsite audit that covers all the Scheme requirements.

The full audit pack, consisting of the remote audit documentation and the onsite audit documentation shall be uploaded to the Portal within 2 months of the last day of the onsite audit.

The certification audit is only concluded once both the remote audit and the onsite audit have been successfully completed. Following completion of the full audit (step 1 & 2) and a positive certification decision, the audit process is complete and where applicable a new certificate may be issued.

FSSC audits Fully Remote

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 (refer Appendix 1 of the Scheme), supported by a risk assessment. Mutual agreement between AIB and the certified organization is required prior to conducting the full remote audit.

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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. The IAF Mandatory Document (MD) 4 for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes (latest version) is used by AIB as a normative document.

AIB will 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 now 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, AIB will conduct a risk assessment to determine the impact of the serious event on the current certification status of the certified organization as set out in Part 3 of the Scheme, clause 5.10. The elements of section 3 in IAF Information Document (ID) 3 Management of Extraordinary Events or Circumstances Affecting ABs, CABs and Certified Organizations, will be considered. The full remote audit option can only be utilized when the risk of maintaining certification is determined as being low.

Secondly, AIB will 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 will be considered when conducting the feasibility assessment:

- a) Maturity of the certified organization's FSMS and performance history;
- b) 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;
- c) The ICT tools to be utilized;
- d) Whether the certified organization and/or AIB have the ability to provide representative/s capable of communicating in the same language.
- e) Whether AIB 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.
- f) Impact on audit duration and audit planning e.g. where more time might be required due to the use of ICT.

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.

AIB has set criteria for assessing and approving the full remote audit process.

If the full remote audit is deemed to be a viable option, ICT means to be used will 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.

Suitable support and training is provided on the use of ICT to the auditor and any other members of the audit team, prior to the remote audit. Records of these trainings are kept by AIB.

Use of remote technology ensures that adequate controls are in place to ensure a true representation of the site and a robust audit.

The requirements of IAF MD4 will be followed. This mandatory document defines the rules that AIB and its auditors follow to 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.

AIB has include the requirements of IAF MD4 in its procedures for the use of ICT and personnel competence.

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

The remote audit will be conducted by qualified FSSC 22000 auditor/s meeting the competency requirements linked to the scope of certification as set out in the Scheme.

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

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

- i 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;
- ii Transition audits – refer to Part 3, clause 5.8 of the Scheme;
- iii 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 AIB 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.
- iv To conduct a special audit based on the outcome of the serious event risk assessment.

For full remote audits, there is a need for effective planning 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 total audit duration based on the calculation in Part 3 of the Scheme rules need to be met. Where rounding is applied, durations will be rounded upwards to the nearest half day taking into account that additional time might be required to conduct the remote audit.

The audit plan and the audit program will clearly reflect that the audit is conducted fully remotely and linked to a serious event, as well as indicating the different types of ICT used during the course of the audit. When compiling the audit plan for the remote audit, consideration will be given to appropriate durations and allow for more frequent breaks to enhance attention and reduce eye strain. These breaks cannot be counted towards audit time. If time is consumed on issues such as network downtime, unexpected interruptions or delays, accessibility problems or other ICT challenges, this time will not be counted as audit time.

Remote audit activities follow the same principles and format of the on-site audit activities and includes a full audit against the Scheme requirements. 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. The full audit will be completed in a set timeframe that may be sub-divided over several days.

When it is required to make adjustments to the audit plan at the opening meeting the availability and feasibility to use ICT will also be reconfirmed. Measures to ensure confidentiality and data security will also be revised and agreed where applicable.

It is important that the ICT used is suitable to audit the on-site facilities, storage areas and manufacturing processes using streaming/live video with audio capacity through mobile or other wearable technology to allow confirmation of continued implementation of PRPs, observation of practices and processes and interviews with personnel. The site representative will need to take the camera or other video equipment (e.g. a laptop, mobile phone or tablet) into the production, storage and other areas to enable the auditor to witness, see and question any aspects and replicate an on-site facility and process walkthrough.

When using video for watching online live images it is important that the organization demonstrates veracity of images. If looking at images of a facility these can be compared with floor plans and flow

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diagrams for instance. Images of a geographical site that are observed can be compared with available satellite images or information available from Geographic Information Systems (GIS). Any video or similar technology does not require recording but a record shall be kept of the duration of the live video and what was covered. This is to be recorded in the audit report.

The responsibility of the effective application of remote auditing methods for any given audit lies with AIB and the lead auditor (in terms of performing audit activities).

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

The Audit report will comply with the requirements as set out in Annex 2 of the Scheme and clearly indicate that the audit was conducted as a full remote audit. An overview will 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 feasibility and risk assessment conducted will be uploaded to the FSSC portal as part of the audit documentation.

It remains the responsibility of AIB 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 will 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 will be updated and the reference to Full Remote Audit removed.

Minimum Audit Duration

FSSC 22000 5.1 has minimum audit durations which are to be applied to all audits for FSSC 22000 v 5.1 (initial, surveillance and recertification) are [as per ISO/TS 22003]

- a) The minimum audit duration (based on duration, number of HACCP studies, presence of management system certification and number of full-time equivalent staff) is 1 day.
- b) The minimum basis FSSC 22000 audit duration is 1.5 – 2 days depending on the FSSC additional time, however for categories C, D, I or K the minimum audit duration shall always be 2 days.
- c) The minimum audit duration for the annual audits shall always be respected.

The following exemption apply to the minimum audit duration:

- a) For organisations with a simple process, having 5 FTE or less and maximum 1 HACCP study, further reductions are allowed, but the total time shall be minimum 1 day for all types of audits.
- b) For organisations in category C, D, I or K that have simple processes, less than 20FTE 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, the CB shall ensure that the audit duration allows for an effective audit, covering the full FSSC 22000 requirements.

Requirements for organizations with multi-site certification (food chain category catering, transport & storage)

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The management of the central function shall ensure that sufficient resources are available and that roles, responsibilities and requirements are clearly defined for management, internal auditors, technical personnel reviewing internal audits and other key personnel involved in the FSMS.

An internal audit procedure and program shall be established by the central function covering the management system, central function and all sites. Internal auditors shall be independent from the areas they audit and be assigned by the central function to ensure impartiality at site level.

The management system, centralised function and all sites shall be audited at least annually or more frequently based on a risk assessment.

Internal auditors shall meet at least the following requirements and this shall be assessed by AIB annually as part of the audit:

- Work experience: 2 years' full time work experience in the food industry including at least 1 year in the organization.
- Education: completion of a higher education course or in the absence of a formal course, have at least 5 years work experience in the food production or manufacturing, transport and storage, retailing, inspection or enforcement areas.
- Training:
For FSSC 22000 internal audits, the lead auditor shall have successfully completed a FSMS, QMS or FSSC 22000 Lead Auditor Course of 40 hours.
Other auditors in the internal audit team shall have successfully completed an internal auditor course of 16 hours covering audit principles, practices and techniques. The training may be provided by the qualified internal Lead Auditor or through an external training provider.
FSSC scheme training covering at least ISO 22000, the relevant prerequisite programs based on the technical specification for the sector (e.g. ISO/TS 22002-x; PAS-xyz) and the FSSC additional requirements – minimum 8 hours.

Internal audit reports shall be subject to a technical review by the central function, including addressing the non-conformities resulting from the internal audit. Technical reviewers shall be impartial, have the ability to interpret and apply the FSSC normative documents (at least ISO 22000, the relevant ISO/TS 22002-x; PAS-xyz and the FSSC additional requirements) and have knowledge of the organizations processes and systems.

Internal auditors and technical reviewers shall be subject to annual performance monitoring and calibration. Any follow-up actions identified shall be suitably actioned in a timely and appropriate manner by the Central function.

Certificate suspension, withdrawal or scope reduction

The following three (3) criteria apply:

- a) AIBI-CS shall suspend a certification when there is evidence that their client is either unable or unwilling to establish and maintain conformity with Scheme requirements within the time frames applicable to the clearance of major nonconformities (14days after the last audit day to submit a corrective action plan including root cause analysis and additional 14days to provide objective evidences for the closure of Major by the implementation of the corrective action).
- b) AIBI-CS shall withdraw a certification when there is evidence that their client is either unable or unwilling to establish and maintain conformity with Scheme requirements, within the timeframes applicable to the clearance of critical nonconformities (resolution of the Critical within 6 months).

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c) When AIBI-CS has evidence that their client holds a certificate whose scope exceeds their capability or capacity to meet, the certification scope will be reduced accordingly. Exclusions from scope of certification are not allowed when those activities, processes, products or services can have an influence on the food safety of the end products included in scope.

In case of withdrawal or suspension, the organizations' management system certification is invalid. AIBI-CS shall complete the following actions within 3 working days after the certification decision has been made:

- a) Immediately change the status 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.
- b) Inform the organization in writing of the withdrawal or suspension decision within three (3) days after the last day of the audit or any other intervention and confirm the decision.
- c) Ensure the organization takes steps to inform clients accordingly and to also include advertising and product labelling of applicable.

In case of scope reduction, the organizations' management system certification is invalid beyond the revised certification scope statement. AIBI-CS shall complete the following actions within 3 working days after the certification decision has been made:

- a) Immediately change the scope of the certified organization in the FSSC 22000 database and its own Register of Certified Organizations and shall take any other measures it deems appropriate.
- b) Inform the organization in writing of the scope change within three (3) days after the last day of the audit or any other intervention and confirm the decision.
- c) Ensure the organization takes steps to inform clients accordingly to include advertising and product labelling.

In the event that that the organization is either unable or unwilling to inform their clients themselves, AIBI-CS shall take appropriate steps to protect the integrity of its own Food Safety Management System certification service by using direct mail or advertising for example.

Whenever there is a change to the certification status of an organization certified by AIBI-CS and included in the FSSC Register of Certified Organizations, AIBI-CS will inform the Foundation within 3 working days for any certificate suspension or withdrawal or restoration of a suspended or withdrawn certificate.

Documentation and Supplementary Action

The evaluation report and associated documents shall be stored safely and securely for a period of six years by the Client (applicant/supplier) and AIBI-CS.

Appeals and Complaints

AIBI-CS will formally reply within 10 working days from the day of receipt. A person independent from the certification decision will handle and the result of the investigation/outcome will be finalised within 30 working days. In the event of an unsuccessful result, the supplier will be charged for conducting the investigation.

Changes in the Certification Scheme

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New information or changes with regards to the requirements in the FSSC 22000 scheme will be communicated by AIBI-CS to those parties involved, such as certificate holders and auditors (auditors and experts), within a period of one month from publication.

Exceptions to Confidentiality Requirements

Clients are aware that the certification rules established by the Foundation oblige AIBI-CS to provide the Foundation itself with information concerning the company, the certification process and the certification status, and that this is an exception to the confidentiality clause described by AIBI-CS in document PR4 Rules for Certification and Use AIBI-CS Logos. Moreover, at the request of food safety authorities or GFSI, information related to the certification and auditing process will be shared.

Therefore, the client irrevocability authorizes AIBI-CS to communicate the results of the audits and any consequent action carried out according to FSSC 22000 to the Foundation, including the audit summary report, and the list of non-conformities and observations. This data will be inserted in the Foundation's on-line data base.

In particular it is recognized and clearly understood that the Foundation's on-line data base provides public access to the following basic details of a supplier's FSSC 22000 Certification status:

- name and location of the certified organization
- scope of the certification
- Identification number of the certificate
- date of the initial certification (Stage 2)
- expiry date of the certificate
- in case of suspension or withdrawal; the date of suspension or withdrawal.

Serious Events

The client shall inform AIBI-CS about serious events that impact food safety and / or the integrity of the certification and the organization's entry in the FSSC 22000 Register of Certified organizations.

The client shall report serious events to AIBI-CS immediately and these include at a minimum:

- legal proceedings, prosecutions and the outcomes of these related to food safety or legality,
- public food safety events (such as e.g. public recalls, calamities, etc.)
- extraordinary events which pose major threats to food safety or certification integrity such as war, strike, riot, political instability, geopolitical tension, terrorism, crime, pandemic, flood, earthquake, malicious computer hacking, other natural or man-made disasters.

AIBI-CS in turn will take appropriate steps to assess the situation and will take any appropriate action including additional verification activities. These activities may have implications for the certified status of the organization.

Product Recall

Clients shall notify AIBI-CS thru e-mail (gfsi@aibinternational.com) immediately and no more than 3 business days if they become aware of legal proceedings with respect to product safety or legality,

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in the event of a product withdrawal or recall (Class I, II, or III) or actions related to product safety or legality including, but not limited to:

- Boil water advisory
- Receipt of a raw material that is under recall (a reportable food under Reportable Food Registry.)
- Major threats to business continuity such as an earthquake, fire, flood, tsunami, force majeure that would require implementation of the Crisis Management Program related to quarantining products, equipment, production areas, or product storage areas. In this case, notification as soon as possible is required.

Formal written confirmation shall be kept at affected sites.

AIBI-CS will assess the situation and the implications for the certification, including further investigation, conduct an un-scheduled audit or Certificate withdrawal.

Data Ownership

Certified organizations are the owners of an audit report, whilst AIB-CS is responsible for the report data. Certified organizations are the certificate holders, not the owners. AIB-CS is the data owner of the certificate data.

AIB-CS implements a data quality control process that provides assurance for CB Portal Data Quality. The quality parameters include the following as a minimum:

- a) Completeness: All the mandatory data has been registered in the Portal;
- b) Timeliness: All the data has been registered in the Portal within the required timelines;
- c) Validity: The registered data values meet the Scheme requirements;
- d) Accuracy: The data is a true representation of the actual facts relating to the complete audit and the certification process;
- e) Consistency: The registered data in the Portal is a true representation of the data stored in AIB-CS internal system(s).

When requested by the certified organization, AIB-CS 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. AIB-CS shall ensure that Certified Organization access is only granted to authorised individual(s).

Scheme Certification Marks

Clients must comply with the certification scheme relating to the use of their marks of conformity and on information related to the product. Clients certified to the FSSC Scheme must follow the requirements detailed in FSSC22000 Parts 2 & 3: Requirements for certification and certification process, Version 5.1 Nov 2020

FSSC 22000 Fee Payment

AIBI-CS will collect, on behalf of the Foundation, the Administration Fee established by the Foundation itself. The fee is due irrespective of certification status. At the date of issue of this document, the Foundation's Administration Fee is 150 € per year.

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Certification Fees

These will be reviewed annually.

Terms of Business

The certification fees and any revisions are effective from 1 January each year.

Subsistence fees (hotel, meals, transportation, etc.) and travel fees, where applicable, are additional to the certification fees. AIBI-CS will try to minimize these costs by grouping work whenever possible.

Invoices will be raised in pounds Sterling (£) and should be paid in pounds Sterling (£) for audits conducted in Europe, the Middle East and Africa.

Invoices will be raised in US\$ and should be paid in US\$ for audits conducted in the US.

Invoices will be raised in CA\$ and should be paid in CA\$ for audits in Canada.

Invoices will be raised in MXN pesos and should be paid in MXN pesos for audits conducted in Mexico.

Payment should be made within 30 days from the date of invoice. Failure to settle invoices in the specified time will be taken into account for ongoing certification and could result in withdrawal or suspension of certification.

Queries

If you require any more information or clarification on any aspect of the certification process please contact:

AIB International
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Manhattan, KS 66505-3999
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Fax: +1 785 537 0106
Email: gfsi@aibinternational.com

The office is open from 0800 to 1700 Monday to Friday. It will be closed on national holidays.

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