TÜVNORD

Description of the Certification procedure

FSSC 22000 Version 7

CONTENT

If you should require any further information then please do not hesitate to contact us. We will be please to help you.

Please contact us via mail to info.tncert@tuev-nord.de.

The rules and descriptions of service and performance regarding certification according to the FSSC 22000 apply alongside our offer. They are valid alongside the general Conditions of Certification.
Further applicable documents and rules can be found on the FSSC website (www.FSSC22000.com)
The auditors are selected by the Head of the Certification Body of TÜV NORD CERT GmbH in accordance with their approvals for the particular sector and their qualification.
The client accepts the requirements of FSSC 22000:

- Share information concerning the certified organization with the Foundation, Accreditation Body, the Global ACI, GFSI and governmental authorities when required. This includes capturing information in the FSSC Assurance Platform related to the (certified) organization, audits and certification processes;
- Sharing of information regarding the certification status with external parties
- Display information with regards to the certified status on the website of the Foundation in the FSSC 22000 Register of Certified Organizations.
- Registration and maintaining of information concerning organizational, audit and certificate data in the FSSC Assurance Portal.
- For the purposes of the FSSC 22000 Integrity Program, to allow assessors from the Foundation on their premises to witness the CBs auditors during FSSC 22000 audits.

In the case of a product recall, the client shall inform the certification body immediately and will describe the details regarding the incident. For its part, the certification body will take suitable steps in order to assess the situation and its impact on the certification and will take appropriate action
The following mailbox shall be used for the information of the CB: tncert-food-recall@tuev-nord.de

1. CERTIFICATION PROCEDURE

1.1. General

The audit requirements for FSSC 22000 certification consist of:

- ISO 22000:2018 Food Safety Management System
- Relevant prerequisite programs (PRPs) for the sector based on the ISO 22002-x series as referenced in the scheme Part 1, Table 1; and
- FSSC 22000 additional requirements

Annual audits shall take place to ensure certificate validity or that recertification is granted before the expiry date of the certificate. Surveillance audits shall be conducted within the calendar year. The 3-year certification cycle shall be respected.
The customer shall communicate any local holidays or shutdowns in a timely manner to facilitate audit scheduling
The audit shall be conducted over a continuous number of days.
The audit shall be carried out in a mutually agreed language. An interpreter may be added to the team.
A site is required to be operational when conducting FSSC 22000 audits. When there is no production, the audit must be rescheduled.

1.2. Audit Preparation

Following signing of the contract, the auditor prepares for the audit based on the questionnaire filled in by the customer and the calculation sheet, and discusses and agrees the further procedure with the organization to be audited.
During preparation for the surveillance or recertification audit, the organizations to be audited have the duty to report fundamental changes in their organisational structure or changes in procedure to the certification body.
The organization shall ensure that the relevant products and/ or services and related processes for the scope of certification are in place and can be assessed during the audit.

1.3. Audit Stage 1

The Stage 1 audit is conducted in order to

- audit the management system documentation of the customer,
- assess the site and site-specific conditions of the customer and hold discussions with the personnel of the organization in order to determine the degree of preparedness for the Stage 2 audit,
- assess the status of the customer and his understanding of the requirements of FSSC 22000 particular with regard to identification of key performance or significant aspects, processes, objectives and operation of the management system,
- collect necessary information regarding the scope of the management system, processes and location(s) of the client, and related statutory and regulatory aspects and compliance (e.g. food safety legal aspects of the client's operation, associated risks, etc.),
- review the allocation of resources for stage 2 audit and agree with the client on the details of the stage 2 audit,
- evaluate if the internal audits and management review are being planned and performed, and that the level of implementation of the management system substantiates that the client is ready for the stage 2 audit.

If nonconformities were identified in the stage 1 audit, these must be corrected by the customer before the stage 2 audit.

If at the end it cannot be established positively that the customer is ready for the Stage 2 Audit, the audit is broken off after the Stage 1 Audit.

The lead auditor is responsible for the coordination of the activities of the stage 1 audit and if necessary for coordination and cooperation of the auditors concerned amongst themselves.

1.4. Audit Stage 2 – Certification Audit

The customer receives an audit plan at the beginning of the stage 2 audit. The plan is agreed with the customer in advance.
The audit begins with a start-up meeting, in which the participants are introduced to each other. The procedure to be followed in the audit is explained. Within the framework of the audit at the organization's

premises, the auditors review and assess the effectiveness of the management system which has been installed. The basis for this is standard FSSC 22000 respectively.
The task of the auditors is to compare the practical application of the management system with the documented processes and to assess them in relation to fulfilment of the requirements of the standard. This is achieved by means of questioning of the employees, examining the relevant documents, records, orders and guidelines and also by visiting relevant areas of the organization
A final meeting takes place at the end of the on-site audit. At least those employees take part in the audit who have management functions within the organization and whose areas were included in the audit. The lead auditor reports on the individual elements and explains the positive and negative results. If nonconformities are established, the lead auditor can only recommend the organization for issue of the certificate after acceptance or verification of the corrective actions by the audit team, see Section 7 "Management of nonconformities". Attention must be drawn to this fact in the final meeting.
The audit is documented in the audit report (the documentation must be separate for stage 1 and stage 2 audits) and is completed by means of further records (e.g. audit questionnaire and hand-written records)

1.5. Award of Certificate

The certificate is issued when the certification procedure has been reviewed and released by the head of the certification body or his deputy or nominated representative. The person who reviews and releases the procedure may not have participated in the audit.
The certificate can only be issued when the nonconformities have been accepted or verified by the audit team.
The certificates are valid for 3 years.
The audit report and the certificate will be uploaded in the FSSC Assurance Portal https://portal.fssc22000.com).
FSSC 22000 charges a fee per site and year for registration in the Database. This amount is invoiced by TÜV NORD CERT and then passed to the Foundation.

2. SURVEILLANCE AUDIT

The company data are updated before the surveillance audit, in order to take any changes which have a significant influence on the area of activity or the operational methods of the client into consideration.
Surveillance audits must be conducted once per year during the period of validity of the certificate.
Surveillance audits shall be performed prior the due date / planning-relevant date. The planning-relevant date for the annual surveillance audit, which follows the initial certification audit, may not be later than 12 months after the last day of the stage 2 audit. The planning-relevant date controls all the surveillance audits.

3. UNANNOUNCED AUDITS

At least one unannounced surveillance audit shall be undertaken after the initial certification audit and within each three-year period thereafter.
The client can voluntary chose to replace surveillance audits and/or re-certification audits by unannounced annual surveillance audits.
The initial certification audit (stage 1 and stage 2) shall be performed announced.

The site will not be informed in advance about the date of the unannounced audit. It takes place during normal operational working hours including night shifts when required.
Blackout dates may be agreed.
If parts of the company/processes cannot be audited, an announced follow-up audit shall be scheduled within 28 calendar days, whilst meeting the calendar year requirement.

If the client refuses to participate in the unannounced audit, the certificate shall be suspended within 3 working days of the date of refusal. The certificate will be withdrawn if the unannounced audit is not conducted within a six-month timeframe from the date of suspension.

The audit of separate head offices must be announced. Where head office activities are part of a site audit, the audits shall be unannounced.
Secondary sites (off-site activities) and off-site storages, warehouses and distribution facilities shall also be audited during the unannounced audit.

4. RECERTIFICATION AUDIT

The audit for recertification has to be conducted before the expiry date of the certificate. A tolerance period of max. 6 months is then available for evaluation of the corrective actions and for any necessary re-audits and also for the decision on recertification within the framework of the release procedure.
In the recertification audit, a review of the documentation of the management system of the organization takes place and an on-site audit is conducted, whereby the results of the previous surveillance programme(s) over the period of the certification are to be taken into consideration. All requirements of the standard are audited.
Activities related to the recertification audit may include a stage 1 audit if there are significant changes in the management system or in connection with the activities of the organization (e.g. changes to the law). Changes to the FSMS system must be submitted in advance by the client in writing along with the corresponding documents.
The audit methods used in the recertification audit correspond to those used in a stage 2 audit.

5. CONDUCTING OF AUDITS USING INFORMATION AND COMMUNICATION TECHNOLOGY (ICT)

The standard method for conducting audits is a via full on-site audit. The company can now apply for an audit as split process utilizing ICT.
The ICT audit approach consist of 2 main steps:

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

The audit is finalized when both parts are finished.
The timeline for completion of the audit (remote + on-site) shall not exceeded 30 calendar days.
In case of a serious event, the timeline may be extended to a maximum of 90 calendar days, based on a risk assessment.

Prior to the remote-audit an assessment has to be done under consideration of IAF MD4, to determine if the ICT audit approach would be a viable option. The maturity of the FSMS and the performance history shall be considered.
The ICT shall be tested with the company before the planned remote audit to confirm that the ICT is appropriate, suitable and effective.
Where the ICT utilized is not functioning properly or preventing/ hampering a robust audit, the audit shall be aborted.
The calculation of the audit time is done based on FSSC 22000 Annex 9.
In case of initial certification the stage 1 audit can be performed remotely. Stage 2 shall be conducted as a full on-site audit.
In case of annual surveillance audits, the full audit shall be completed within the calendar year. Where the ICT approach is applied to the first surveillance audit following an initial certification, both parts have to take part not later than 12 month after the date of certification decision for the initial audit.
If an unannounced audit is due, the on-site 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.
Where the timelines for surveillance audits are exceeded, the full surveillance audit shall be conducted on-site or the certificate shall be suspended. Re-certification which consists of remote and on-site audit shall be completed prior to the expiry of the existing certificate.

6. SPECIAL AUDITS

Extension of scope audit
An extension of scope can be conducted within the framework of a surveillance audit, a recertification audit or at a time which is set independently.

Short Notice Audits
If the certification body gains knowledge of incidents which have an impact on the safety or legality of the product, the certification body is entitled to perform announced or unannounced audits at any time, and, following assessment of the situation and its effects, to withdraw the certificate(s).

7. TRANSFER OF CERTIFICATION FROM OTHER CERTIFICATION BODIES

Only certificates from accredited certification bodies can be taken over. Organizations with certificates which originate from non-accredited certification bodies are treated like new clients.
A "Pre-Transfer-Review“ must be conducted by a competent person from the certification body which is taking over the certificate. This review generally consists of an examination of important documents and a visit to the client.
Certificates which have been suspended, or where there is risk of suspension, may not be taken over.
Any nonconformities which have not been corrected should as far as practicable be clarified with the previous Certifier before the takeover. Otherwise they must be dealt with in the audit.
The surveillance programme is based on the programme which has been in place up to the time of the takeover of the certificate.

8. MULTIPLE FUNCTIONS ACROSS MORE THAN ONE SITE

Head office functions

Functions pertinent to certification are controlled by a head office have to be audited. This audit will be documented.
The functions at the head office shall be audited separately where they are not part of a site being assessed.
The audit has to be carried out prior to the site audits. The individual sites will be audited within a timeframe of 12 month, but typically as close to the site audits as possible.
Head Office audits can be performed remotely based on feasibility assessment

Off-site activities
Where one manufacturing or service process is splitted across more than one physical address, all locations may be covered in one audit provided that the different addresses are part of the same legal entity, under the same management system and they are the sole receiver/customer of each other.
Storage facilities can be included.
Cross docking is also considered as an off-site activity.

9. MULTI-SITE CERTIFICATION

For organisation with multiple locations sampling is applicable. This is allowed for the food chain (sub)category FII and.
All sites shall have a legal or contractual link with the central function of the organisation and subject to a single management system, which is laid down, established and subject to continuous oversight, surveillance and internal audts by the central function.
The central function shall be audited at least annually and before the sites. The site audits shall be conducted as close to the central function audit as possible, but always within 12 month of the central function audit.
At least one surveillance audit is undertaken unannounced after the initial certification audit and within each three years period thereafter.

The central function shall be impartial from the sites.
The central function shall take responsibility for coordinating, addressing and closing out of nonconformities raised at sites level in conjunction with the relevant sites. Failure of the central function or any of the sites to meet the Scheme requirements shall result in the whole organisation, including the central function and all sites, not gaining certification.

10. MANAGEMENT OF NON-CONFORMITIES

Minor NC:
If a Minor NC is identified in an audit, the client shall provide the objective evidence of an investigation into causative factors (root cause), exposed risks and evidence of effective implementation.
The documents has to be send to CB in between 21 calendar days after the last audit day, so that the approval can be done after 28 calendar days.
If the timeframe is exceeded, the certificate will be suspended. In the case of an initial audit, the Stage 2 audit shall be repeated within maximum 6 months of the last day of the previous Stage 2 audit.
Corrective action(s) (CA) shall be implemented by the organization within the agreed timeframe

The effectiveness of implementation of the corrective action plan shall be reviewed, at the latest, at the next scheduled audit. Failure to address a minor nonconformity from the previous audit could lead to a major nonconformity being raised at the next scheduled audit.

Major NC:
If a Major NC is identified in an audit, the client shall provide the objective evidence of an investigation into causative factors (root cause), exposed risks and evidence of effective implementation.
The CB reviews the corrective action plan and conducts an on-site follow-up audit to verify the implementation of the CA to close the major nonconformity. In cases where documentary evidence is sufficient to close the major nonconformity, performing of a desk review is possible. This follow-up will be done within 21 calendar days from the last day of the audit.
The major nonconformity has to be closed within 28 calendar days of the last day of the audit. When the major cannot be closed in this timeframe, the certificate will be suspended;
Where completion of corrective actions might take more time, the CAP shall include any temporary measures or controls necessary to mitigate the risk until the permanent corrective action is implemented. Evidence of these temporary measures shall be submitted within 21 calendar days and accepted by the CB within 28 calendar days from the last day of the audit. In addition, where temporary measures are accepted, the CB shall agree a suitable timeframe with the organization, to verify the effective implementation of the permanent corrective action, but not later than 6 months after the last day of the audit.
Where the 28 calendar days after the last day of the audit is exceeded the full Stage 2 audit shall be repeated.

Critical NC:
A critical nonconformity is issued when a direct food safety impact without appropriate action by the organization is observed during the audit or when legality and/or certification integrity are at stake:

- The certificate will be suspended within 3 working days for a maximum period of six (6) months.
- The client must provide objective evidence of an investigation into causative factors (root cause), exposed risks and the proposed corrective action plan. This shall be provided to the CB within 14 calendar days after the audit.
- A separate audit will be conducted between six (6) weeks to six (6) month after the regular audit to verify the effective implementation of the corrective actions. This audit will be a full on-site audit (minimum on-site duration one day).
- After a successful follow-up audit, the certificate and the current audit cycle will be restored and the next audit shall take place as originally planned (the follow-up audit is additional and does not replace an annual audit). This audit will be documented and the report uploaded;
- The certificate will be withdrawn when the critical nonconformity is not effectively solved within the six (6) month timeframe.

When a critical NC is raised at an initial certification audit, the audit is failed, and the full certification audit shall be repeated

Handling of Nonconformities by using ICT Approach
Any nonconformities identified during the audit (remote and on-site) will be addressed in line with the scheme requirements. Where the audit is completed within 30 calendar days, one nonconformity report is completed and the timeline for the NC closure starts at the end of the on-site audit.
In case of a serious event where the 30 calendar days for the audit completion is exceeded, the NCs of the remote audit shall be recorded. The timeline for closure of the NCs starts at the last day of the remote audit. For the NCs raised up during the on-site audit, the timeline starts after the last day of the on-site audit.

Handling of Non-Conformities at Multi-site Organisations
Critical nonconformity: The certificate of the shall be suspended within 3 working days of issuing the critical nonconformity, regardless of wether the central function audit or site audits have been completed.
Major nonconformity:
Where the audit takes more than 28 calendar days to complete (central function and site audits), the organisation shall provide a corrective action plan including any temporary measures or controls necessary to mitigate the risk until the nonconformity can be closed.If no corrective action plan is provided within 28 days the certificate shall be suspended.
The timeline for closure the nonconformities starts at the end of the audit, after completion of the central function audit and all site audits.

11. LOGO USE

Certified organizations are entitled to use the FSSC 22000 logo. The FSSC 22000 logo may be used on the organization's printed matter, website and other promotional material.
The FSSC 22000 logo is not allowed to be used on:

- a product,
- its labelling,
- its packaging,
- certificates of analysis or certificates of conformatnce
- in any other manner that implies FSSC 22000 approves a product, process or service and
- where exclusions to the scope of certification apply.

The requirements for size, colour and shape are determined in the current version of the FSSC 22000 Scheme Document, which can be found on the website. (www.fssc22000.com)

12. NOTIFICATION

The organization shall report significant changes to the CB within three (3) working days.
These include changes relating to:

- any significant changes that affect the compliance with the scheme requirements;
- serious events that impact the FSMS, legality and/or the integrity of the certification including situations that pose a major threat to food safety or certification integrity as a result of Force majeure natural or man-made disasters;

- serious situations where the integrity of the certification is at risk an/ or where the Foundation can be brought into disrepute. This include, but are not limited to:
  - Public food safety events (such as e.g. public recalls, withdrawals, calamities, food safety outbreaks, etc.)
  - 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.
- Changes to organization name, contact address and site details;
- Changes to organization and management;
- Major changes to the food safety management system, scope of operations and product categories covered by the certified management system (e.g. new products, new processing lines, etc.)
- Any other change that renders the information on the certificate inaccurate.

13. CERTIFICATE SUSPENSION, WITHDRAWAL OR SCOPE REDUCTION

Suspension:
The certification will be suspended when a critical nonconformity is issued and/or there is evidence that their client is either unable or unwilling to send objective evidences or to close the NCs in the determined timeframes.
A suspension of the certificate is also necessary when there is evidence that their client is either unable or unwilling to establish and maintain conformity with Scheme requirements.
The status of the certificate will be changed in the FSSC Assurance Portal within 3 working days.

Withdrawal:
The certification will be withdrawn when

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

The status of the certificate will be changed in the FSSC Portal within 3 working days.

Scope reduction:
When the client holds a certificate where the scope is not an accurate reflection of the management system for example due to changes at locations or the control of the organization.
It is not possible to exclude activities, processes, products or services from the scope of certification when those activities, processes, products or services can have an influence on the food safety of the end products as defined in the scope of certification.
In case of scope reduction the clients' management system certification is invalid beyond the revised certification scope statement. The scope of the certified organization will be changed in the FSSC Assurance Portal within 3 working days.