certification body
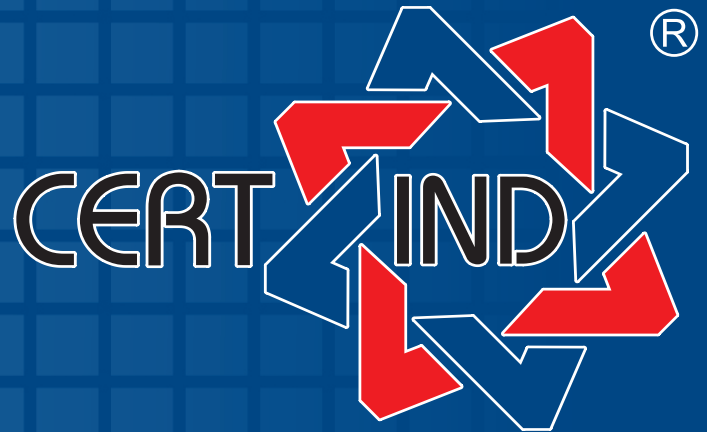
CERT IND ®

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FSSC 22000 vs. 5 Certification Scheme
Rules for FSSC 22000 Certification

REQUIREMENTS FOR THE CERTIFICATION PROCESS

1. CONTRACT process

The certification bodies have to be licensed by the Foundation for the food chain categories for that provide certification services.

1.1 Application

1.1.1 CERTIND shall collect and document the information from the applicant organization in an application form which details the minimum information as required in the ISO/IEC 17021-1 and ISO/TS 22003, and additional Scheme requirements.

1.1.2 Application forms

CERTIND will require completion of an official application and self- assessment questionnaire forms, signed by an authorized representative of the applicant organization.

It is the responsibility of the applicant organization to ensure that adequate and accurate information is shared with CERTIND about the details of the applicant organization.

The details shall include at least the following:

a) The proposed certification scope

b) The number of workers in management and production

c) Details of shifts

d) Number of production lines

e) Number of HACCP studies

f) Details of other certified management systems (such as ISO 22000 or ISO 9001) or GFSI recognized certification schemes.

g) When applicable: details related to a request for a transition audit from ISO 22000 or another GFSI recognized scheme to FSSC 22000

h) When applicable: information regarding organizations with off-site storage, separate head office and off-site activities

1.2 Scope

CERTIND shall assess the scope proposed by the organization on the application forms and review it against the requirements in Self- assessment questionnaire for Food chain categories.

1.3 Audit duration

1.3.1 CERTIND shall calculate the audit time based on the information gathered from the organization's application and following the requirements of ISO/IEC 17021-1, ISO/TS 22003 and FSSC 22000 or according IAF MD5 and IAF MD 11:2019 to which additional FSSC time shall be added.

1.3.2 Transition to FSSC 22000

1) When transitioning from Dutch HACCP, ISO 22000 or an equivalent GFSI recognized certification to FSSC 22000 certification, the transition audit is based on the FSSC recertification audit time.

The transition audit shall result in an FSSC 22000 certificate with a validity of three (3) years.

2) Transition to FSSC 22000-Quality is only possible when the organization has a valid ISO 22000 or FSSC 22000 certificate AND a valid ISO 9001 certificate. In this case, the audit duration is two-thirds of the initial combined audit time (see 4.3.4.) plus additional FSSC time.

1.4 Contract

A certification contract shall be in place between CERTIND and the organization applying for certification, detailing the scope of the certificate and referring to all relevant Scheme requirements.

This contract shall detail or have reference to the agreements between CERTIND and the organization which shall include but are not limited to:

1) ownership of the certificate and the audit report content shall be held by the Certification Body;

2) at the request of food safety authorities, information related to the certification and auditing process shall be shared;

3) conditions under which the certification contract can be terminated;

4) conditions under which the certificate can be used by the certified organization;

5) terms of confidentiality in relation to information gathered by the Certification Body during the certification process;

6) the certified organization allows CERTIND to share information when required by law from governmental authorities and/or the Foundation;

7) procedures for nonconformity management;

8) procedures for complaints and appeals;

9) inclusion of information on the certified status of the organization on the FSSC 22000 website and in the Portal;

10) cooperation in allowing witness assessments by the Accreditation BODY and/or the Foundation when requested;

11) communication obligations of certified organizations to CERTIND within 3 working days related to the following:

a) any significant changes that affect the compliance with the Scheme requirements and obtain advice of CERTIND in cases where there is doubt over the significance of a change;

b) serious events that impact the FSMS, legality and/or the integrity of the certification which include legal proceedings, prosecutions, situations which pose major threats to food safety, quality or certification integrity as a result of natural or man-made disasters (e.g. war, strike, terrorism, crime, flood, earthquake, malicious computer hacking, etc.);

c) public food safety events (such as e.g. public recalls, calamities, food safety outbreaks, etc.);

d) changes to organization name, contact address and site details;

e) changes to organization (e.g. legal, commercial, organizational status or ownership) and management (e.g. key managerial, decision-making or technical staff);

f) changes to the management system, scope of operations and product categories covered by the certified management system;

g) any other change that renders the information on the certificate inaccurate.

2. Planning and managing audits

2.1 General

1) Annual audits shall take place to ensure certificate validity or that recertification is granted before the expiry date of the certificate.

2) The annual audit shall be carried out on-site at the premises of the organization and is a full audit against all Scheme requirements.

3) The audit shall be carried out in a mutually agreed language. An interpreter may be added to the team by CERTIND to support members of the audit team.

4) CERTIND is expected to operate discretely in case of emergencies (e.g. fire, major catastrophic event, another audit on-going).

5) CERTIND shall perform the stage 1 and stage 2 audits for initial certification according to the requirements of ISO/IEC 17021-1.

6) The interval between stage 1 and stage 2 audits shall not be longer than 6 months. Stage 1 shall be repeated if a longer interval is needed.

7) The 3-year certification cycle (ISO/IEC 17021-1 §9.1.3) shall be respected at all times.

2.2 Multiple functions across more than one site

2.2.1 Head Office functions

1) In all cases where functions pertinent to the certification are controlled by a Head Office (such as procurement, supplier approval, quality assurance etc.), the Scheme requires that those functions are audited, interviewing the personnel described in the food safety management system as having the (delegated) authority and responsibility for these functions. This Head Office audit shall be documented.

2) The functions at the Head Office shall be audited separately where they are not part of a site being assessed.

3) Every site belonging to the group shall have a:

    a. separate audit,

    b. separate report and

    c. separate certificate.

4) The Head Office audit shall be carried out prior to the site audit(s).

5) The subsequent audit at the site(s) shall include a confirmation that the requirements set out by Head Office are appropriately incorporated into site specific documents and implemented in practice.

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

7) All individual sites shall be audited within a time frame of 12 months from the audit of the Head Office.

8) The Head Office cannot receive a separate certificate.

9) The Head Office is mentioned on the site certificate

2.2.2 Off- site activities

1) Where one manufacturing or service process is split 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 FSMS and that they are the sole receiver/customer of each other.

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

3) The scope statement shall show the audited locations with activities per location (on the certificate or as an Annex to the certificate).

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

2.2.3 Multi- site certification

Multi-site certification (including sampling) is only allowed for the following food chain (sub)categories:

1) A – Animal Farming

2) E – Catering

3) FI – Retail/wholesale

4) G – Storage and distribution.

When applying multi-site certification, shall be applied the requirements of ISO/TS 22003:2013 sampling regime and the FSSC 22000 requirements for Head Office.

Each site (plus the central function) shall have its own report. The certificate shall be a group certificate.

2.2.4 Unannounced audits

2.2.4.1 Frequency

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

2) The certified organization can voluntary choose to replace all surveillance audits by unannounced annual surveillance audits. Recertification audits may be conducted unannounced at the request of the certified organization.

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

2.2.4.2 Execution

1) CERTIND 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.

2) The site shall not be notified in advance of the date of the unannounced audit and the audit plan shall not be shared until the opening meeting.

3) The unannounced audit takes place during normal operational working hours including night shifts when required.

4) Blackout days may be agreed in advance between CERTIND and the certified organization.

5) The audit will start with an inspection of the production facilities commencing within 1 hour after the auditor has arrived on site. In case of multiple buildings at the site the auditor shall, based on the risks, decide which buildings/facilities shall be inspected in which order.

6) All Scheme requirements shall be assessed including production or service processes in operation. Where parts of the audit plan cannot be audited, an (announced) follow-up audit shall be scheduled within 4 weeks.

7) CERTIND decides which of the surveillance audits shall be chosen for the unannounced audit.

8) If the certified organization refuses to participate in the unannounced audit, the certificate shall be suspended immediately, and CERTIND shall withdraw the certificate if the unannounced audit is not conducted within a six-month timeframe from the date refusal.

9) The audit of separate Head offices controlling certain FSMS processes pertinent to certification separate to the site(s) shall be announced. Where Head Office activities are part of a site audit, they shall be unannounced.

10) Secondary sites (off-site activities) and off-site storage, warehouses and distribution facilities shall also be audited during the unannounced audit.

2.2.5 Remote audits

Computer aided audit techniques (CAAT) may be used as a remote audit tool during FSSC 22000 audits provided according the requirements of IAF MD4.

2.2.6 Transfer of certification

CERTIND follows the requirements of IAF MD2 for transfer of certified organizations from another Certification Body.

2.2.7 Upgrade audits

The Foundation will issue instructions when upgrade audits are required. This typically occurs when there is a significant change to the Scheme requirements.

CERTIND shall:

1) follow the upgrade requirements as issued by the Foundation;

2) ensure all staff and auditors are familiar with the upgrade process;

3) additional audit time shall be recalculated and advised to the clients where applicable;

4) following the successful upgrade audit (including closure of nonconformities the certificate will be re-issued.

2.2.8 Transition Audits

1) Transition audits are allowed from Dutch HACCP, ISO 22000 and GFSI recognized certification programs with equivalent scopes. For FSSC 22000-Quality, transition audits are allowed for organizations holding a valid ISO 22000, FSSC 22000 and a valid ISO 9001 certificate.

2) Transition audits are the start of a new certification cycle and shall therefore be a stage 2 audit (a stage 1 may be performed at the discretion of the CERTIND).

3) The FSSC 22000 certificate/FSSC 22000-Quality certificate issued shall have a validity of 3 years.

2.2.9 Allocation of audit team

1) All audit team members shall meet the competence requirements set out by the Foundation FSSC 22000.

2) The audit team shall have the combined competence for the food chain sub-categories supporting the scope of the audit and following the requirements of ISO/IEC 17021-1.

3) The FSSC 22000-Quality audit is a fully integrated audit and the audit team shall meet the competence requirements set out by the Foundation FSSC 22000.

4) Audit teams conducting integrated FSSC 22000 and ISO 9001 audits (FSSC 22000-Quality) shall collectively meet the relevant FSSC 22000-Quality auditor specifications.

5) The lead auditor shall always be a FSSC 22000 qualified auditor.

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

2.2.10 Management of serious events

1) CERTIND shall have a process to review planned audits when a serious event affects a certified organization and the audit cannot be performed as planned.

2) CERTIND shall assess the risks of continuing certification and establish a documented policy and process, outlining the steps it will take in the event a certified organization is affected by a serious event.

3) The outcome of the Risk Assessment and planned actions shall be recorded. Deviations from the audit program and their justification for changes shall be recorded. Certification Bodies shall establish in consultation with certified organizations a reasonable planned course of action.

4) This includes situations where due to security and/or visa issues in the Country, an audit cannot be performed as unannounced (e.g. when an auditor requires to be in contact with the organization at all times, due to security reasons or a visa must be requested in advance).

3. Audit Report

3.1 Written report

CERTIND shall provide a written report for each audit.

a) The audit report is to be treated confidentially by the CERTIND but shall be made available to Food Safety Authorities after approval of the organization.

b) The audit report shall confirm that all Scheme requirements are assessed, reported and a statement of (non) conformity given. The content of audit report shall comply with the requirements of Foundation FSSC 22000.

c) Both the procedural and operational conditions of the food safety management system shall be verified to assess the effectiveness of the food safety management system meeting the Scheme requirements and reported.

d) N/As shall be motivated in the report.

e) Exclusions from scope shall be assessed and justified in the audit report.

f) Deviations from the audit plan shall be motivated in the report.

g) Auditors shall report all nonconformities (NCs) at all audits. For each nonconformity (NC), a clear concise statement of the requirement, the NC, grade of the NC and the objective evidence shall be written.

h) Corrections, corrective action plans and their approval shall be included in the audit report.

i) A Head Office report shall contain as a minimum the NCs found at the HO. This report shall be uploaded. At each site audit the implementation of the corrective actions shall be verified and reported.

3.2 Nonconformities

In accordance with the definitions in the Scheme and as defined below, CERTIND is required to apply these criteria as a reference against which to determine the level of nonconformities for findings. There are three nonconformity grading levels:

a) minor nonconformity (shorted NC)

b) major nonconformity (shorted MNC)

c) critical nonconformity (shorted CNC)

In case of non-conformities noticed in a Head Office audit, these are assumed to have impact on the equivalent procedures applicable to all sites. Corrective actions shall therefore address issues of communication across the certified sites and appropriate actions for impacted sites. Such nonconformities and corrective actions shall be clearly identified in the relevant section of the site audit report and shall be cleared in accordance with CERTIND procedures before issuing the site certificate.

3.2.1 MINOR NONCONFORMITY

A minor nonconformity shall be issued when the finding does not affect the capability of the management system to achieve the intended results:

1) the organization shall provide CERTIND with *objective evidence of the correction, evidence of an investigation into causative factors, exposed risks and the proposed corrective action plan (CAP);*

2) CERTIND shall review the corrective action plan and the evidence of correction and approve it when acceptable. CERTIND approval shall be completed within three (3) months after the last day of the audit. *Exceeding this timeframe shall result in a suspension of the certificate*;

3) corrective action(s) (CA) shall be implemented by the organization within the timeframe agreed with CERTIND;

4) effectiveness of implementation of the corrective action plan shall be reviewed, *at the latest, at the next scheduled on-site audit.*

3.2.2 MAJOR NONCONFORMITY

A major nonconformity shall be issued when the finding affects the capability of the management system to achieve the intended results:

1) the organization shall provide CERTIND with *objective evidence of an investigation into causative factors, exposed risks and evidence of effective implementation*;

2) CERTIND shall *review the corrective action plan and conduct an on-site follow-up audit to verify the implementation of the CA to close the major nonconformity*. In cases where documentary evidence is sufficient to close out the major nonconformity, CERTIND may decide to perform a *desk review*. This follow-up shall be done *within 28 days from the last day of the audit*;

3) the major nonconformity shall be closed by CERTIND within 28 calendar days from the last day of the audit. *When the major cannot be closed in this timeframe, the certificate shall be suspended*;

4) where completion of corrective actions might take more time, the CAP shall include *any temporary measures or controls necessary to mitigate the risk* until the permanent corrective action is implemented.

3.2.3 CRITICAL NONCONFORMITY

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:

1) when a critical nonconformity is issued at a certified site *the certificate shall be immediately suspended for a maximum period of six (6) months*;

2) when a critical nonconformity is issued during an audit, the organization shall provide CERTIND with objective evidence of an investigation into causative factors, exposed risks and the proposed CAP. This shall be provided to CERTIND within 14 days after the audit;

3) a separate audit shall be conducted by CERTIND *between six (6) weeks to six (6) month* after the regular audit to verify the effective implementation of the corrective actions. This audit shall be a full on-site audit (with a minimum on-site duration of one day). After a successful follow-up audit, the certificate and the current audit cycle will be restored and the next audit shall take place as originally planned (the follow-up audit is additional and does not replace an annual audit). This audit shall be documented and the report uploaded;

4) *the certificate shall be withdrawn when the critical nonconformity is not effectively resolved within the six (6) month timeframe*;

5) in case of a certification audit (initial), the full certification audit shall be repeated.

4 Certification decision process
4.1 GENERAL

1) CERTIND shall conduct a technical review for all audits to agree with the audit reports content and outcome, NC's (objective evidence and grading) and effectiveness of corrections and corrective action plans. Following each technical review, CERTIND shall make a decision on the certification status of the organization (e.g. certify, continue certification, suspend, withdraw).

2) CERTIND shall keep documented information of decisions on certification status that have been considered and by whom. This information shall include: the names of those making each decision, and the date the decision was made.

Note: not all decisions may lead to issuing a new certificate.

4.2 CERTIFICATE DESIGN AND CONTENT

1) CERTIND shall issue FSSC 22000 certificates in accordance with the scope rules and certificate templates set out by the Foundation.

2) The FSSC 22000 logo shall be used by CERTIND on its certificates.

3) Head Office details shall be included, where applicable.

4) Where applicable Off site and Multi-site locations shall be listed, (including name, address and activities); details may be provided in an Annex to the certificate.

5) Dates on the certificates shall be as follows:

a) certificate decision date: date of at which a new decision is made after a certification or recertification audit (excluding regular surveillance audits). New certificate decision dates are also required in situations such as version changes of the Scheme and/or scope extensions/reductions. In these cases, the valid until date remains unchanged;

b) initial certification date (i.e. the certification decision date after the initial audit);

c) issue date: date certificate is issued to the client; or re-issue date when a new certificate is issued (e.g. because of version change, scope extension etc.);

d) valid until date certificate expires (maximum duration is 3 years).

4.3 CERTIFICATE SUSPENSION, WITHDRAWAL OR SCOPE REDUCTION

1) Suspension: CERTIND shall immediately suspend certification when a critical nonconformity is issued and/or there is evidence that their client is either unable or unwilling to establish and maintain conformity with Scheme requirements

2) Withdrawal: CERTIND shall withdraw a certificate when:

a) the status of suspension cannot be lifted within six (6) months;

b) the organization ceases its FSSC 22000 certification activities;

c) any other situation where the integrity of the certificate or audit process is severely compromised.

3) Scope reduction: When CERTIND has evidence that their client holds a certificate whose scope exceeds their capability or capacity to meet scheme requirements, CERTIND shall reduce the certification scope accordingly. CERTIND shall not exclude activities, processes, products or services from the scope of certification when those activities, processes, products or services can have an influence on the food safety of the end products as defined in the scope of certification.

4.3.1 ACTION UPON SUSPENSION, WITHDRAWAL AND SCOPE REDUCTION

1) In case of suspension or withdrawal, the organizations' management system certification is invalid. CERTIND shall:

a) immediately change the status of the certified organization in the Portal and its own Register of certified organizations and shall take any other measures it deems appropriate;

b) inform the organization in writing of the suspension or withdrawal decision within three (3) days after the decision was made;

c) instruct the organization to take appropriate steps in order to inform its interested parties.
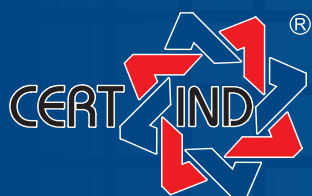
2) In case of scope reduction, the organizations' management system certification is invalid beyond the revised certification scope statement. CERTIND shall:

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 decision of change;

c) instruct the organization to take appropriate steps in order to inform its interested parties.

5 PORTAL DATA AND DOCUMENTATION

For all audit types, the required data and documentation shall be entered in the Portal at the latest 28 calendar days after the certification decision with a maximum of 4 months after the last day of the audit.

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