**CHECKLIST ON ISO 22003-1:2022**

**FOOD SAFETY – PART 1: REQUIREMENTS FOR BODIES PROVIDING AUDIT AND CERTIFICATION OF FOOD SAFETY MANAGEMENT SYSTEMS**

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| **Certification Body** | **:** |  |
| **Address** | **:** |  |
| **Scope** | **:** |  |
| **Date of Assessment** | **:** |  |
| **Type of Assessment** | **:** |  |
| **Team Leader/Assessor** | **:** |  |

**Legend:** C – Complies, O – Observation, T – To Address at Audit, N – Nonconformity, N/A – Not Applicable, F – Further information required

| **Section** | **General Regulations Point** | **Comments** (Manual and/or procedure references) | **Finding** |
| --- | --- | --- | --- |
| **5** | **GENERAL REQUIREMENTS**  |  |  |
|  | Does the CB comply with the requirements given in Clause 5 of ISO/IEC 17021-1:2015? |  |  |
| **6** | **STRUCTURAL REQUIREMENTS**  |  |  |
|  | Does the CB comply with the requirements given in Clause 6 of ISO/IEC 17021-1:2015? |  |  |
| **7** | **RESOURCE REQUIREMENTS** |  |  |
| **7.1** | **Competence of management and personnel** |  |  |
| **7.1.1** | **General considerations** |  |  |
|  | Does the CB define the certification functions for which competence identified in accordance with Annex C? |  |  |
| **7.1.2** | **Determination of competence criteria** |  |  |
|  | Does the CB define the technical areas in accordance with Annex A?The competence criteria, specifying required knowledge and skills, in Annex C shall apply. |  |  |
| **7.1.3** | **Evaluation processes** |  |  |
|  | Does the CB evaluate the evaluation processes, in particular, the individual’s knowledge relating to food safety, including knowledge of specific prerequisite programmes (PRPs), food safety hazards and control measures related to the categories within which the CB personnel operate? These shall have been identified for these categories under the requirements of 7.1.2.Do evaluators of the CB have knowledge of (one or more) evaluation methods (see ISO/IEC 17021-1:2015, Annex B)? Does the evaluators demonstrate the ability to apply them? |  |  |
| **7.1.4** | **Other considerations** |  |  |
|  | Does the CB comply with the requirements given in Clause 7.1.4 of ISO/IEC 17021-1:2015? |  |  |
| **7.2** | **Personnel involved in the certification activities** |  |  |
|  | Does the CB comply with the requirements given in Clause 7.2 of ISO/IEC 17021-1:2015? |  |  |
| **7.3** | **Use of individual external auditors and external technical advisors** |  |  |
|  | Does the CB comply with the requirements given in Clause 7.3 of ISO/IEC 17021-1:2015? |  |  |
| **7.4** | **Personnel Records** |  |  |
|  | Does the CB comply with the requirements given in Clause 7.4 of ISO/IEC 17021-1:2015? |  |  |
| **7.5** | **Outsourcing** |  |  |
|  | Does the CB comply with the requirements given in Clause 7.5 of ISO/IEC 17021-1:2015? |  |  |
| **8** | **INFORMATION REQUIREMENTS** |  |  |
| 8.1 | Does the CB comply with the requirements given in Clause 8 of ISO/IEC 17021-1:2015? |  |  |
| 8.2 | Do the certification documents identify in detail the categories and subcategories in Table A.1 to which the FSMS applies? |  |  |
| 8.3 | Does the CB not authorise the use of the FSMS certification mark on the product and the product packaging? Product packaging, refers to in ISO/IEC 17021-1:2015, Clause 8, shall cover all product packaging, both primary (which contains the product) and any outer or secondary packaging. |  |  |
| 8.4 | Does the CB not permit the use of any statement on product packaging that the client has a certified FSMS? This includes all product packaging, both primary product packaging (which contains the product) and any outer or secondary packaging. |  |  |
| **9** | **PROCESS REQUIREMENTS** |  |  |
| **9.1** | **Pre-certification activities** |  |  |
| **9.1.1** | **Application** |  |  |
|  | Does the CB require the applicant organisation to provide the information concerning products and processes relevant to determination of the audit duration, as per Annexes A and B? |  |  |
| **9.2** | **Application review** |  |  |
| 9.1.2.1 | Does the CB comply with the requirements given in Clause 9.1.2 of ISO/IEC 17021-1:2015? |  |  |
| 9.1.2.2 | Does the CB use Annex A to define the relevant scope for the organisation applying for certification? Does the scope statement:* identify the category(s) or subcategory(s) in scope of certification for each site or sites;
* briefly describe the main types of activities/processes for the products and/or services that are audited by the CB?
 |  |  |
| 9.1.2.3 | Does the defined scope of certification not:* be misleading;
* 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 by the legal responsibility of the organisation’s activities;
* include any promotional statements, brands or claims?
 |  |  |
| **9.1.3** | **Audit programme** |  |  |
| 9.1.3.1 | Does the CB comply with the requirements given in Clause 9.1.3 of ISO/IEC 17021-1:2015? |  |  |
| 9.1.3.2 | Does the CB have a process for choosing the audit timing and season so that the audit team has the opportunity of auditing the organisation operating on a representative number of product lines and/or services covered by the scope of certification? | , |  |
| **9.1.4** | **Determining audit time** |  |  |
| 9.1.4.1 | Does the CB comply with the requirements given in Clause 9.1.4 of ISO/IEC 17021-1:2015? |  |  |
| 9.1.4.2 | Does the CB have documented procedures for determining audit time, time needed to plan and accomplish a compete and effective audit of each client’s FSMS?In determining the audit duration, does the CB use the methodology described in Annex B of ISO 22003-1:2022?Does the CB record the audit time determined and the justification for the determination? |  |  |
| 9.1.4.3 | In determining and documenting audit time needed, does the CB determine: |  |  |
| a) | the time for audit preparation; |  |  |
| b) | the minimum duration for auditing for each site for on-site or remote auditing, as specified in Clause B.1, B.2 and B.3 and Table B.1; |  |  |
| c) | the time for reporting and, if applicable, conducting post-audit activities; |  |  |
| d) | where additional meetings are necessary (e.g. review meetings, coordination, audit team briefing), an increase in audit time can be required; |  |  |
| e) | where required and agreed, the time needed to ensure effective remote auditing or use of information and communication technology (ICT)? |  |  |
| 9.1.5 | **Mulit-site sampling** |  |  |
| 9.1.5.1 | Does the CB comply with the requirements given in Clause 9.1.5. of ISO/IEC 17021-1:2015? |  |  |
| 9.1.5.2 | When multi-site sampling is undertaken, does sampling of multi-site organisation over all activities (see the criteria given in 9.1.5.3)? |  |  |
| 9.1.5.3 | Does the CB demonstrate that the sampling of sites does not undermine effective auditing? |  |  |
|  | Where multi-site sampling is undertaken, does the CB justify and document the rationale based on the following conditions: |  |  |
|  | sites are operating under one centrally controlled and administered FSMS; |  |  |
|  | sites subject to sampling are similar (food chain subcategory, geographical location, processes and technologies, size and complexity, regulatory and statutory requirements, customer requirements, food safety hazards and control measures); |  |  |
|  | the central function is part of the organisation, clearly identified and not subcontracted to an external organisation; |  |  |
|  | all sites have a legal or contractual link with the central function; |  |  |
|  | the central function has organisational authority to define, establish and maintain the FSMS; |  |  |
|  | all sites are subjected to the organisation’s internal audit programme and have been audited; |  |  |
|  | audit findings at a site are considered indicative of the entire FSMS and corrective actions are implemented accordingly; |  |  |
|  | the central function is responsible for ensuring that outcomes of performance evaluation and customer complaints from all sites are collected and analysed; |  |  |
|  | the organisation’s FSMS is subject to central management review; |  |  |
|  | the central function has authority to initiate continual improvement of the FSMS? |  |  |
| 9.1.5.4 | The use of multi-site sampling is permitted for categories A and B. Sampling may be applied to multi-site organisations, with the minimum sample size being the square root of the total number of sites: √ (x), rounded up to the next whole number.Does the CB take the square root sample per risk category based on production complexity of the sites (e.g. open field plant production, perennial plant production, indoor production, open field livestock production, indoor livestock production)? |  |  |
|  | The use of multi-site sampling is permitted for categories F and G, and only for re-heating-type of facilities (e.g. event catering, coffee shops, pubs) for category E and only for facilities with limited preparation or cooking (e.g. re-heating, frying) (see Table A.1).For organisations with 20 sites or fewer, does the CB audit all site?For organisations with more than 20 sites, does the CB determine the minimum number of sites to be sampled be 20 plus the square root of the total number of other sites: y = 20 + √ (x – 20), rounded up to the next whole number? This applies to the initial certification, to surveillance and to recertification audits. |  |  |
|  | Does the CB not use multi-site sampling for any categories other than categories A, B, E, F and G? |  |  |
| 9.1.5.5 | Where multi-site sampling is permitted, does the CB ensure (e.g. via contractual arrangements) that the organisations had conducted an internal audit for each site within one year prior to certification and where applicable the effectiveness of corrective actions is available? Following certification, does the CB ensure that the annual audit covers all sites of the organisation included in the certification scope of the multi-site organisation and ongoing effectiveness of corrective actions are demonstrated?  |  |  |
| 9.1.5.6 | Where multi-site sampling is permitted, does the CB define and utilise a sampling programme to ensure an effective audit of the FSMS where the following conditions apply: |  |  |
|  | At least annually, an audit of the central function for the FSMS shall be performed by the CB prior to the sampled site audits.  |  |  |
|  | At least annually, audits shall be performed by the CB on the required number of sampled sites.  |  |  |
|  | Audit findings of the sampled sites shall be assessed to ascertain if there indicate an overall FSMS deficiency and therefore can be applicable to some or all other sites. |  |  |
|  | Where audit findings of the sampled sites are considered indicative of the entire FSMS, corrective actions shall be implemented accordingly.  |  |  |
|  | For organisations with 20 sites or fewer, all sites shall be audited. |  |  |
|  | Does the CB increase the size of sample or terminate the site sampling where the FSMS subject to certification does not indicate the ability to achieve the intended results? |  |  |
| 9.1.5.7 | Does the CB ensure the sample is partly selective and partly random to result in a representative range of different sites being selected, ensuring all processes covered by the scope of certification will be audited? |  |  |
|  | Does the CB select at least 25% of the sample at random? Does the CB select the remainder so that the differences among the sites selected over the period of validity of the certification are as large as possible? |  |  |
|  | Does the CB consider the following aspects for the site selection? |  |  |
| a) | results of internal audits, management reviews or previous audits; |  |  |
| b) | records of complaints, product withdrawals/recalls, and other relevant aspects of corrective action; |  |  |
| c) | variations in the site characteristics; |  |  |
| d) | other relevant changes since the last audit? |  |  |
| 9.1.5.8 | If any site has a major nonconformity and satisfactory corrective action have not been implemented in the agreed time frame, does the CB not grant or maintain the certification for the whole multi-site organisation pending satisfactory corrective action? |  |  |
| 9.1.5.9 | Does the CB identify and include in the scope of certification the processes of the FSMS implemented at each sampled site? |  |  |
| **9.1.6** | **Multiple management systems standards** |  |  |
|  | Does the CB comply with the requirements given in Clause 9.1.6 of ISO/IEC 17021:2015? |  |  |
| **9.2** | **Planning audit** |  |  |
|  | Does the CB comply with the requirements given in Clause 9.1.6 of ISO/IEC 17021-1:2015?  |  |  |
| **9.3** | **Initial certification** |  |  |
| 9.3.1 | Does the CB comply with the requirements given in Clause 9.3 of ISO/IEC 17021-1:2015? |  |  |
| 9.3.2 | Does the CB ensure that the objectives of stage 1 audit are to provide a focus for planning stage 2 audit by gaining an understanding of the organisation’s FSMS and the organisation’s state of preparedness for stage 2 audit by reviewing the extent to which: |  |  |
|  | the organisation has identified PRPs that are appropriate to the business (e.g. regulatory, statutory, customer and certification scheme requirements); |  |  |
|  | the FSMS includes adequate processes and methods for the identification and assessment of the organisation’s food safety hazards, and subsequent selection and categorisation of control measures (combinations); |  |  |
|  | the FSMS includes adequate processes and methods for the identification and implementation of relevant food safety legislation; |  |  |
|  | the FSMS is designed to achieve the organisation’s food safety policy; |  |  |
|  | the FSMS implementation programme justifies proceeding to stage 2; |  |  |
|  | the validation of control measures, verification of activities and improvement programmes conform to the requirements of the FSMS standard; |  |  |
|  | the FSMS documents and arrangements are in place to communicate internally and with relevant suppliers, customers and interested parties; |  |  |
|  | there is any additional documentation which needs to be reviewed and/or information which needs to be obtained in advance? |  |  |
| 9.3.3 | Where an organisation has implemented externally developed elements of a FSMS, does the CB review the documentation included in the FSMS in stage 1 to determine if the combination of control measures:* + is suitable for the organisation;
	+ was developed in conformity to the requirements of ISO 22000 or other sets of specified FSMS requirements;
	+ is kept up to date?
 |  |  |
| 9.3.4 | Does the CB check the availability of relevant authorisations when collecting the information regarding the compliance to regulatory aspects? |  |  |
| 9.3.5 | For FSMS, does the CB carry out stage 1 at the client’s premises in order to achieve the objectives stated above? In exceptional circumstances or events, all or part of stage 1 can take place off-site or remotely through the use of ICT, does the CB provide the justification? Does the CB provide the evidence demonstrating that stage 1 objectives are fully achieved. |  |  |
| 9.3.6 | The interval between stage 1 and stage 2 shall not be longer than six months. Does the CB repeat stage 1 if a longer interval is needed? |  |  |
| 9.3.7 | Does the CB comply with the requirements given in Clause 9.3.1.3 and 9.3.1.4 of ISO/IEC 17021-1:2015? |  |  |
| **9.4** | **Conducting audits** |  |  |
|  | Does the CB comply with the requirements given in Clause 9.4 of ISO/IEC 17021-1:2015? |  |  |
| **9.5** | **Certification decision** |  |  |
|  | Does the CB comply with the requirements given in Clause 9.5 of ISO/IEC 17021-1:2015? |  |  |
| **9.6** | **Maintaining certification** |  |  |
| 9.6.1 | Does the CB comply with the requirements given in Clause 9.6 of ISO/IEC 17021-1:2015? |  |  |
| 9.6.2 | Where the CB conducts unannounced audits as part of surveillance activities, does the CB describe and make known in advance to the certified clients the conditions under which such audits will be organised and conducted? |  |  |
| **9.7** | **Appeals** |  |  |
|  | Does the CB comply with the requirements given in Clause 9.7 of ISO/IEC 17021-1:2015? |  |  |
| **9.8** | **Complaints** |  |  |
|  | Does the CB comply with the requirements given in Clause 9.8 of ISO/IEC 17021-1:2015? |  |  |
| **9.9** | **Client records** |  |  |
|  | Does the CB comply with the requirements given in Clause 9.9 of ISO/IEC 17021-1:2015? |  |  |
| **10** | **Management system requirements for certification bodies** |  |  |
|  | Does the CB comply with the requirements given in Clause 10 of ISO/IEC 17021-1:2015? |  |  |