



MINISTRY OF INVESTMENT, TRADE AND INDUSTRY
DEPARTMENT OF STANDARDS MALAYSIA

**ACB FOOD - REQUIREMENTS FOR THE ACCREDITATION OF BODIES
OPERATING CERTIFICATION OF
FOOD SAFETY ASSURANCE PROGRAMMES**

Issue 1, 12 June 2025

(Supplementary to MS ISO/IEC 17021-1)



ACCREDITATION OF CERTIFICATION BODIES (ACB) SCHEME

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Introduction

This document shall be used by the Department of Standards Malaysia (JSM) to provide criteria for the assessment and accreditation of bodies operating certification of Food Safety Assurance Programmes based on MS ISO/IEC 17021-1.

The numbering of clauses in this document correspond to the clauses of MS ISO/IEC 17021-1, however, as not all clauses necessitate interpretation, there may be breaks in the numbering sequence. Certification Bodies (CBs) are also reminded of the need to comply with any relevant statutory and legislative requirements.

This document cancels and replaces the following documents:

- i. ACB-Good Manufacturing Practice for Food (GMP) – Standards Malaysia Requirements for the Accreditation of Bodies Operating Certification of Good Manufacturing Practice for Food to MS 1514, Issue 1, 18 June 2013; and
- ii. ACB-HACCP – Standards Malaysia Requirements for the Accreditation of Bodies Operating Certification of HACCP Systems to MS 1480, Issue 6, 14 October 2013.

1 Scope

This document shall be read in conjunction with MS ISO/IEC 17021-1, Accreditation Policy (AP) documents, ACB Policy Series and relevant requirements published by JSM.

This document sets out the requirements for accreditation of bodies operating certification of Food Safety Assurance Programmes based on ISO/IEC 17021-1. Food Safety Assurance Programmes offered by JSM are such as but not limited to the following:

- i. Food Safety Management Systems (FSMS)
- ii. Food safety according to Hazard Analysis and Critical Control Point (HACCP) Systems
- iii. Good Manufacturing Practice (GMP) for Food

Not all clauses in this document are applicable to all Food Safety Assurance Programmes. Where specified, the clauses are only applicable to the specific Food Safety Assurance Programme.

Please refer to **Appendix 1** for food class categories.

2 Normative references

2.1 This document refers to the following standards and documents. For all references, the latest edition of the document applies:

- i. Food Act 1983 [Act 281] and its Regulations
- ii. CXC 1-1969– General Principles of Food Hygiene
- iii. MS ISO/IEC 17021-1 – Conformity Assessment – Requirements for bodies providing audit and certification of management systems, Part 1: Requirements
- iv. ISO 22003-1 – Food safety, Part 1: Requirements for bodies providing audit and certification of food safety management systems
- v. MS ISO 22000 – Food safety management systems – Requirements for any organization in the food chain
- vi. MS 1480 – Food safety according to Hazard Analysis and Critical Control Point (HACCP) system
- vii. MS 1514 – Good Manufacturing Practice (GMP) for Food
- viii. IAF MD 2 – IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems
- ix. IAF MD 4 – IAF Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes
- x. IAF MD 11 – IAF Mandatory Document for the Application of ISO/IEC 17021-1 for Audit of Integrated Management Systems
- xi. IAF MD 12 – Accreditation Assessment of Conformity Assessment Bodies with Activities in Multiple Countries
- xii. IAF MD 16 – Application of ISO/IEC 17011 for the Accreditation of Food Safety Management Systems (FSMS) Certification Bodies
- xiii. IAF MD 23 – Control of Entities Operating on Behalf of Accredited Management Systems Certification Bodies

- xiv. Accreditation Policy 4 (AP 4) - Policy on The Requirements for Key Personnel of Conformity Assessment Bodies

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000, ISO/IEC 17021-1, the related food safety assurance programme standard (i.e. ISO 22000 for FSMS, MS 1480 for HACCP and MS 1514 for GMP) and the following terms and definitions apply:

3.1 Full time equivalent employees (FTE)

The effective number of personnel consist of full-time personnel involved within the scope of certification including those working on each shift. Non-permanent (seasonal, temporary and contracted personnel) and part time personnel who will be present at the time of the audit shall be included in this number.

3.2 Food

Food includes every article manufactured, sold or represented for use as food or drink for human consumption or which enters into or is used in the composition, preparation, preservation, of any food or drink and includes confectionery, chewing substances and any ingredient of such food, drink, confectionery or chewing substances.

(SOURCE: Food Act 1983)

3.3 Food chain

Sequence of the stages in the production, processing, distribution, storage, and handling of a food and its ingredients, from production to consumption.

Note 1 to entry: The food chain also includes the production of materials intended to come into contact with food or raw materials.

Note 2 to entry: The food chain also includes service providers.

(SOURCE: ISO 22000:2018 modified – Removed the word “primary” from the definition and Note 1 to entry deleted as the scope of this document does not cover the production of feed and animal food)

3.4 Food Hygiene

All measures and conditions necessary to ensure safety and suitability of food for human consumption taking into account its intended use.

(SOURCE: MS 1514:2022)

3.5 Food safety

Assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.

(SOURCE: CXC 1-1969)

3.6 Good Manufacturing Practice (GMP)

A set of requirements that controls the operational conditions within a food establishment allowing for the production of safe food.

(SOURCE: MS 1514:2022)

3.7 HACCP Plan HACCP Study

Documentation or set of documentation prepared in accordance with the seven principles of HACCP to ensure control of hazards which are significant for food safety in the product under consideration and its intended use.

3.8 High risk area

A physically segregated area, designed to a high standard of hygiene, where practices relating to personnel, ingredients, equipment, packaging & environment aim to prevent product contamination by pathogenic micro-organisms.

4 Principles

Principles are not requirements.

5 General requirements

Same as MS ISO/IEC 17021-1.

6 Structural requirements

In addition to MS ISO/IEC 17021-1, the requirements of IAF MD 23 - Control of Entities Operating on Behalf of Accredited Management Systems Certification Bodies shall apply.

7 Resource requirements

7.1 In addition to MS ISO/IEC 17021-1, for CBs operating GMP and HACCP Food Safety Assurance Programmes, the certification functions for which competence shall be identified are those given in Appendix 3.

7.2 In addition to MS ISO/IEC 17021-1 and Accreditation Policy 4 (AP 4) - Policy on The Requirements for Key Personnel of Conformity Assessment Bodies, the CB shall have sufficient personnel having appropriate technical knowledge and proficiency

to carry out their responsibilities. CB's personnel shall be qualified, skilled and knowledgeable in the scope of work sought or accredited and possess the education and work experiences as follows:

7.3 Auditors

7.3.1 Education

The certification body shall ensure that auditors have the knowledge corresponding to a post-secondary education in related science-based disciplines with at least a course related to food sciences.

7.3.2 Training

The certification body shall ensure that auditors have successfully completed training in:

- a) audit techniques based on ISO 19011;
- b) relevant certification standards (i.e. ISO 22000 for FSMS, MS 1480 for HACCP, MS 1514 for GMP); and
- c) food safety training conducted by Ministry of Health (MOH).

Note 1: Refer to AP 4 for the type of food safety training that needs to be attended by auditors based on Food Safety Assurance Programme.

Note 2: If there are transition to the certification standards, the auditors do not need to re-attend the training.

7.3.3 Work experience

For a first qualification of an auditor in one or more categories, the certification body shall ensure that the auditor has a minimum of four years of full-time work experience in the food-chain-related industry, including at least two years of work in quality assurance or food safety functions within food production or manufacturing, retailing, inspection or enforcement, or the equivalent.

The number of years of total work experience may be reduced by one year if the auditor has completed an appropriate degree or higher education.

7.3.4 Audit experience

7.3.4.1 For an initial qualification of an auditor, the certification body shall ensure that:

- a) within the last three years the auditor has performed at least twelve audit days in the related Food Safety Assurance Programme (i.e. FSMS audit based on MS ISO 22000, HACCP audit based on MS 1480, GMP audit based on MS 1514) in at least four organizations under the supervision of a qualified auditor.

Note: Audit days comprise and inclusive of initial (stage 1 and stage 2), surveillance, and/or recertification. These proposed amendments are to support b) below.

- b) The auditor shall have demonstrated in audits under guidance and supervision that they have gained experience in the entire process of auditing Food Safety Assurance Programmes, including review of documentation and food safety hazards in the applicable food chain categories, implementation audit and audit reporting.

7.3.4.2 For an initial qualification to become a Lead Auditor, the certification body shall ensure that the lead auditor has performed at least four (4) audit days in the related food safety assurance programme (i.e. FSMS audit based on MS ISO 22000, HACCP audit based on MS 1480, GMP audit based on MS 1514) under supervision of a qualified lead auditor.

7.3.4.3 For extension to a new subcategory, the certification body shall demonstrate that the auditor has attended food-safety-related training in the new subcategory. In addition, the auditor shall also demonstrate that the auditor has either:

- a) six (6) months of work experience in the new subcategory, or
- b) three (3) food safety assurance programme audits in the new subcategory.

Note: In qualifying the auditors for a particular Food Safety Assurance Programme, the CB may consider the common elements of the Food Safety Assurance Programmes. For example, an auditor who has conducted FSMS audits may also be qualified to conduct GMP and HACCP audits. Similarly, an auditor who has conducted HACCP audits may also be qualified to conduct GMP audits. However, an auditor who has conducted a GMP audit may only be qualified for GMP.

7.3.4.4 For maintaining the qualification of the auditor, the certification body shall ensure the auditors have performed a minimum of five (5) audits within three (3) years in the related Food Safety Assurance Programme (i.e. FSMS audit based on MS ISO 22000, HACCP audit based on MS 1480, GMP audit based on MS 1514).

Note: The five (5) audits within the three (3) years are the accumulative number of audits within three (3) years. It is not necessary that five (5) audits to be completed in a particular year.

7.4 Personnel Making Certification Decisions

The certification body shall ensure that the personnel who are reviewing audit reports and making the decision on granting, maintaining, renewing, reducing, extending, suspending, withdrawing certification have the knowledge and training in the relevant food safety standard and has the same requirements as Clause 7.3.1 to Clause 7.3.5. For Clause 7.3.2 c), the personnel shall attend the training, however, the examination is not mandatory.

Note: The personnel involved may choose to sit for the examination. However, the results of the examination do not impact on qualifying the personnel to review audit

reports and making the decision on granting, maintaining, renewing, reducing, extending, suspending, withdrawing certification.

8 Information requirements

In addition to the requirements of MS ISO/IEC 17021-1, the following applies:

8.2 Certification documents

Certificates shall be issued with the following statement:

“This certified client has been audited by a team consisting of (an) MOH qualified auditor(s)”

9 Process requirements

In addition to the requirements of MS ISO/IEC 17021-1, the following applies:

9.1 Pre-certification activities

9.1.1 Application

9.1.1.1 In addition to the requirements of MS ISO/IEC 17021-1, the certification body shall require the applicant organisation to provide detailed information concerning the following:

- a) GMP/PRP elements,
- b) description of products,
- c) process flow,
- d) HACCP plan/study (if applicable),
- e) effective number of employees,
- f) number of shifts,
- g) location(s) or address, multisite, and
- h) seasonality factors (if any).

9.1.1.2 The certification body shall require the applicant organization to provide the information concerning products and processes relevant to determination of the audit duration, as per Appendices 1 and 2.

9.1.1.3 For transfer of certification, the requirements of IAF MD 2 - IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems shall apply.

9.1.2 Application review

In addition to MS ISO/IEC 17021-1:

9.1.2.2 The CB shall use Appendix 1 to define the relevant scope for the organization applying for certification. The scope statement shall:

- Identify the category(s) or subcategory(s) in scope of certification for each site; and
- Briefly describe the full activities/processes for the products and/or services from beginning to end that are audited by the certification body.

9.1.2.3 The defined scope of certification shall 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.

9.1.4 Determining audit time

In addition to MS ISO/IEC 17021-1:

9.1.4.1 The certification body shall have documented procedures for determining audit time, and for each client, the certification body shall determine the time needed to plan and accomplish a complete and effective audit of the client's Food Safety Assurance Programme. In determining the audit duration, for HACCP and GMP certification bodies, the certification body shall use the methodology described in Appendix 2. The audit time determined by the certification body, and the justification for the determination, shall be recorded including justification for any reductions or additions.

9.1.4.2 In cases where more than one (1) of the Food Safety Assurance Programmes are integrated, a reduction in audit duration is possible. The integrated audit duration shall be determined and recorded as follows:

- Calculate the audit duration for each scheme separately (including scheme restrictions and allowed reductions);
- Add the audit durations together;
- Determine the degree of reduction considering a maximum of 20% reduction can be made on the integrated duration. The reduction range based on integration is 0% to 20% determined by the level of integration of overall business strategy, management reviews, approach to policy, objectives, systems, processes, internal audits and effective corrective action to prevent reoccurrence;
- If the integrated audit includes GMP, the GMP audit duration can be excluded from the calculation.

9.1.5 Multi-site sampling

For HACCP and GMP, in addition to ISO/IEC 17021-1, the following shall apply:

9.1.5.1 A multi-site organization having an identified central function at which certain food safety assurance programme activities are planned, controlled or managed, and

a network of sites at which such activities are fully or partially carried out. Examples of possible multi-site organisations are:

- Organisations operating with franchises;
- Service organisations with multiple sites offering a similar service;
- Organisations with multiple branches.

Sampling of multi-site organisations shall cover all activities (see the criteria given in 9.1.5.2)

9.1.5.2 The certification body shall demonstrate that the sampling of sites does not undermine effective auditing. When multi-site sampling is undertaken, the certification body shall justify and document the rationale based on the following conditions:

- a) Sites are operating under one centrally controlled and administered food safety assurance programme;
- b) 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);
- c) The central function is part of the organisation, clearly identified and not subcontracted to an external organisation;
- d) All sites have a legal or contractual link with the central function;
- e) The central function has organisational authority to define, establish and maintain the food safety assurance programme;
- f) All sites are subject to the organisation's internal audit programme and have been audited;
- g) Audit findings at a site are considered indicative of the entire food safety assurance programme and corrective actions are implemented accordingly;
- h) The central function is responsible for ensuring that outcomes of performance evaluation and customer complaints from all sites are collected and analysed;
- i) The organisation's food safety assurance programme is subject to central management review;
- j) The central function has authority to initiate continual improvement of the food safety assurance programme.

NOTE: The central function is where operational control and authority from the top management of the organisation is exerted over every site. There is no requirement for the central function to be located in a single site.

9.1.5.3 The use of multi-site sampling is only permitted for category E and only facilities with limited preparation or cooking (e.g. re-heating, frying). For organisations

with 20 sites or fewer, all sites shall be audited. For organisations with more than 20 sites, the minimum number of sites to be sampled shall be 20 plus the square root of the total number of other sites: $y = 20 + \sqrt{(x-20)}$, rounded up to the next whole number. This applies to the initial certification, to surveillance and to recertification audits.

The use of multi-site sampling is not permitted for any other categories identified in Appendix 1.

9.1.5.4 Where multi-site sampling is permitted, the certification body shall ensure (e.g. via contractual arrangements) that the organisation has conducted an internal audit for each site within one year prior to certification and when applicable the effectiveness of corrective actions shall be available. Following certification, the annual internal audit shall cover all sites of the organisation included in the certification scope of the multi-site organisation and ongoing effectiveness of corrective actions shall be demonstrated.

9.1.5.5 Where multi-site sampling is permitted, the certification body shall define and utilize a sampling programme to ensure an effective audit of the food safety assurance programme where the following conditions apply:

- a) At least annually, an audit of the central function for the food safety assurance programme shall be performed by the certification body prior to the sampled site audits.
- b) At least annually, audits shall be performed by the certification body on the required number of sampled sites.
- c) Audit findings of the sampled sites shall be assessed to ascertain if these indicate an overall food safety assurance programme deficiency and therefore can be applicable to some or all other sites.
- d) Where audit findings of the sampled sites are considered indicative of the entire food safety assurance programme, corrective actions shall be implemented accordingly.
- e) For organisations with 20 sites or fewer, all sites shall be audited.

The certification body shall increase the size of sample or terminate the site sampling where the food safety assurance programme subject to certification does not indicate the ability to achieve the intended results.

9.1.5.6 The sample shall be partly selective and partly random and shall result in a representative range of different sites being selected, ensuring all processes covered by the scope of certification will be audited.

At least 25% of the sample shall be selected at random. The remainder shall be selected so that the differences among the sites selected over the period of validity of the certification are as large as possible.

The site selection shall consider, among others, the following aspects:

- 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) Variation in the site characteristics;
- d) Other relevant changes since the last audit.

9.1.5.7 If any site has a major nonconformity and satisfactory corrective action have not been implemented in the agreed time frame, certification shall not be granted or maintained for the whole multi-site organisation pending satisfactory corrective action.

9.1.5.8 The certification body shall identify and include in the scope of certification the processes of the food safety assurance programme implemented at each sampled site.

9.2 Planning audits

In addition to ISO/IEC 17021-1, the following shall apply:

9.2.2 Audit team selection and assignments

9.2.2.1 The certification body shall have a process for selecting and appointing the audit team to ensure category/subcategory competence needed to achieve the objectives of the audit are met. Additionally, the team members understand the requirements of the relevant food safety standards i.e ISO 22000 or MS 1480 or MS 1514. They shall have competences in the application of related Food Safety Assurance Programmes in the specific sector they are auditing. They shall be able to determine whether or not a particular organisation adequately complies with the requirements of the food safety standard.

9.2.2.2 The above requires that the audit team, deployed in each case by a certification body to conduct an audit of an organisation's Food Safety Assurance Programme, needs to know the requirements stipulated in the relevant food safety standard, audit processes, certification requirements and other relevant requirements. The audit team shall have the necessary competence, including sector or regulatory knowledge, to determine whether the practice covers these essential elements in a manner that gives adequate confidence that a Food Safety Assurance Programme can be assured to meet specified requirements.

9.2.2.3 The competencies required of the audit team shall be judged using the following as guidance:

- a) identification of scope of certification using the Food Chain Categories;
- b) products produced by the organization;

- c) the processes and control measures used by the organization;
- d) the relevant regulatory requirements; and
- e) the typical/specific hazards, critical control points and control measures associated with that combination of industry, product and process, where relevant.

9.2.2.4 Where Food Safety Assurance Programmes or other related management system audits are conducted as an integrated management system audit, there may be elements common to all systems. In determining auditor competence for common elements, the main principle is that the integrity of each audit is maintained. This requires appropriate competence to be deployed for all audit activities. It remains a matter of judgement which aspects of the Food Safety Assurance Programme or other audit can be performed by an auditor whose training and background are from another discipline, and whether any supplementary knowledge and/or training are required.

9.2.3 Audit plan

In addition to MS ISO/IEC 17021-1, the following shall apply:

9.2.3.1 Remote auditing activities

The requirements of IAF Mandatory Document 4 (IAF MD 4) - IAF Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes apply. In addition:

For Food Safety Assurance Programmes, audits shall be carried out at the client's premises in order to achieve the objectives stated above. In exceptional circumstances or events, all or part of the audit can take place off-site or remotely through the use of ICT and shall be justified. The evidence demonstrating that the objectives of the Food Safety Assurance Programme are fully achieved shall be provided. Audits that can be considered to be conducted remotely are as follows:

- a) Stage 1
- b) Surveillance
- c) Renewal
- d) Verification for closure of nonconformities

NOTE: Exceptional circumstances or events can include a very remote location, a natural disaster, a pandemic, a short seasonal production and other special situations.

The CB shall identify and document the risk assessment prior to conducting the remote audit.

Note: Among the considerations of the risk assessment by the CB can include:

- a) The client has a stable history. There has been no major nonconformance, complaint, or suspension on the client;

- b) Risk category of food products; and
- c) There have been no major changes in the client's Food Safety Assurance Programme.

9.3 Initial certification

9.3.1 Stage 1 Audit

In addition to MS ISO/IEC 17021-1, the following shall apply for GMP and HACCP certification bodies:

The objectives of stage 1 are to provide a focus for the planning of stage 2 of the initial audit by gaining an understanding of the organization's Food Safety Assurance Programme and the organization's state of preparedness for stage 2. The certification body shall review the extent to which:

- a) the organization has identified PRPs that are appropriate to the business (e.g. regulatory, statutory, customer and certification scheme requirements);
- b) the Food Safety Assurance Programme includes adequate processes and methods for the identification and implementation of relevant food safety legislation;
- c) the Food Safety Assurance Programme implementation programme justifies proceeding to stage 2;
- d) the validation of control measures, verification of activities and improvement programmes conforms to the requirements of the Food Safety Assurance Programme standard;
- e) the Food Safety Assurance Programme documents and arrangements are in place to communicate internally and with relevant suppliers, customers and interested parties;
- f) there is any additional documentation which needs to be reviewed and/or information which needs to be obtained in advance.

In addition to the above, for HACCP certification bodies, the following shall also be reviewed:

- a) the Food Safety Assurance Programme includes adequate processes and methods for the identification and assessment of the organization's food safety hazards, and subsequent selection and categorization of control measures (combinations);
- b) the Food Safety Assurance Programme is designed to achieve the organization's food safety policy.

9.3.2 Stage 2 Audit

The stage 2 audit shall take place at the site(s) of the client. It shall include at least the following:

- a) review and verify implementation to meet the requirement of each of the Food Safety Assurance Programme elements as defined in the respective standard,
- b) verify the organisations Food Safety Assurance Programme and performance with regards to compliance with legal requirements,
- c) verify operational control of the organisations processes,
- d) verify the effectiveness of the control measures,
- e) review self-inspection and internal auditing,
- f) review management responsibility to determine the suitability and effectiveness of the Food Safety Assurance Programme;
- g) information and evidence about conformity to all requirements of the Food Safety Assurance Programme standard;
- h) The organisation's Food Safety Assurance Programme and performance with regards to legal compliance and PRP;
- i) Internal audit and management review
- j) management responsibility (including food safety team) for the organisation's food safety policies;
- k) links between the Food Safety Assurance Programme requirements, food safety policy, key food safety objectives and targets (consistent with the expectations in the respective standards), any applicable legal requirements, responsibilities, competence of personnel, operations, procedures, performance data and internal audit findings and conclusions.

In addition to the above, for FSMS and HACCP certification bodies, the certification body shall also review the following:

- a) key food safety objectives and targets; and
- b) Operational control including CCPs and/or OPRPs during processing of the food (CCPs and OPRPs are applicable for to HACCP and FSMS respectively);

Any part of the Food Safety Assurance Programme that is audited during the stage 1 audit and determined to be fully implemented, effective and in conformity with requirements, may not need to be re-audited during the stage 2 audit. However, the certification body shall ensure that the already audited parts of the food safety system continue to conform to the certification requirements. In this case, the stage 2 audit

report shall include these findings and shall clearly state that conformity has been established during the stage 1 audit.

The interval between stage 1 and stage 2 audits shall not longer than 6 months. The stage 1 audit shall be repeated if

- a) a longer interval is needed or
- b) there are other conditions or changes which have an impact on food hygiene and food safety

9.6 Maintaining certification

In addition to MS ISO/IEC 17021-1, the following shall apply:

9.6.1 Surveillance Audit

9.4.1.1 The certification body shall develop its surveillance activities so that representative areas and functions covered by the scope of the Food Safety Assurance Programme are monitored and maintained on a regular basis, and take into account changes to its certified organisations and its Food Safety Assurance Programme and include focus on the high-risk area(s).

Surveillance audit shall also include a review of:

- a) nonconformities resulting from previous audit;
- b) changes in PRPs;
- c) changes in control measures;
- d) changes in production systems and/or equipment,
- e) changes in personnel, their qualification level and/or allocation of responsibilities,
- f) anticipated changes on consumer usage and consumer groups
- g) training,
- h) relevant enquiries from external interested parties and/or complaints indicating health hazards associated with the product,
- i) changes in customer and regulatory requirements,
- j) new knowledge on hazards,
- k) verification activities, and

- l) other conditions or changes which have an impact on food hygiene and food safety.

In addition to the above, for HACCP certification bodies, the following shall also be reviewed:

- a) key food safety objectives and targets; and
- b) changes in operational control including CCPs and OPRPs during processing of food.

9.6.1.2 The conditions for granting, maintaining, extending, reducing, withdrawing or suspending of certification shall incorporate or otherwise address any relevant regulatory requirements, and withdrawal of certification relating to Food Safety Assurance Programmes shall be communicated to relevant regulators.

9.6.1.3 Where the certification body is obliged by law to provide certain information to a regulatory authority, the organisation shall be informed.

9.6.1.4 The report by the audit team shall include comments on the effectiveness of the Food Safety Assurance Programme implementation, and other issues relevant to food hygiene and safety.

9.6.2 Recertification Audit

9.6.2.1 The recertification audit shall include an on-site audit that addresses the following:

- a) the effectiveness of the Food Safety Assurance Programme in its entirety in the light of internal and external changes and its continued relevance and applicability to the scope of certification;
- b) demonstrated commitment to maintain the effectiveness and improvement of the Food Safety Assurance Programme in order to enhance overall performance;
- c) whether the operation of the certified Food Safety Assurance Programme contributes to the achievement of the food safety policy and objectives.
- d) the effectiveness of operational control(s) during processing of food.

9.6.2.2 When, during a recertification audit, instances of nonconformity or lack of evidence of conformity are identified, the certification body shall define time limits for correction and corrective actions to be implemented prior to the expiration of certification.

9.6.2.3 Information for granting recertification

The certification body shall make decisions on renewing certification based on the results of the recertification audit, as well as the results of the review of the system

over the period of certification and complaints received from users of certification and any other relevant information (e.g. public information, sanction(s) from regulatory authorities)

9.6.3 Special Audits

9.6.3.1 Extensions of scope

9.6.3.1.1 The certification body shall respond to an application for extension to the scope of a certification already granted.

9.6.3.1.2 The certification body shall, in response to an application for extension to the scope of a certification already granted, undertake a review of the application and determine any audit activities necessary to decide whether or not the extension may be granted. The granting of extension of scope may need on site visit to verify changes for example in infrastructure, processing machine equipment, production capacity and warehousing facilities. This may be conducted in conjunction with a surveillance audit or separate audit.

9.6.3.2 Short-notice audits

It may be necessary for the certification body to conduct audits of certified clients at short notice to investigate complaints or in response to changes or as follow up on suspended clients. In such cases:

- a) the certification body shall describe and make known in advance to the certified clients the conditions under which these short notice visits are to be conducted, and
- b) the certification body shall exercise additional care in the assignment of the audit team because of the lack of opportunity for the client to object to audit team members.

10 Management system requirements for certification bodies

Same as MS ISO/IEC 17021-1.

APPENDIX 1: SCOPE OF ACCREDITATION (Normative)

The scope of accreditation for CBs operating certification of FSMS shall be as defined in ISO 22003-1.

The scope of accreditation of the CBs operating GMP and HACCP shall be defined based on the following food chain categories:

Table A.1- Scope of Accreditation

Cluster	Category		Subcategory		Examples of included activities
Processing food for humans	C	Food, ingredient and processing	C0	Animal – Primary conversion	Conversion of animal carcasses intended for further processing including lairage, slaughter, evisceration, bulk chilling, bulk freezing, bulk storage of animals and game gutting, bulk freezing of fish and storage of game.
			CI	Processing of perishable animal products	Processing and packaging including fish, fish products, seafood, meat, eggs and dairy requiring chilled or frozen temperature control.
			CII	Processing of perishable plant-based products	Processing and packaging including fruits and fresh juice, vegetables, grains, nuts, pulses, frozen water-based products (e.g. ice, ice confection, sorbet), plant-based meat and dairy substitutes.
			CIII	Processing of perishable animal and plant – Products (mixed products)	Processing and packaging including pizza, lasagne, sandwiches, dumplings and ready-to-eat meals. Includes off-site catering kitchens. Includes products of industrial kitchens not offered for immediate consumption.
			CIV	Processing of ambient stable products	Processing and packaging of products stored and sold at ambient temperature including canned food, biscuits, snacks, oil, drinking water, beverages,

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Cluster	Category		Subcategory		Examples of included activities
					pasta, flour, sugar and food-grade salt.
Catering/ food service	E	Catering/ food service			Open exposed food activities such as cooking, mixing and blending, preparation of components and products for on-site direct consumer consumption or take away. Examples include restaurants, hotels, food trucks, institutions, work places (school or factory cafeteria), including retail with on-site preparation (e.g. rotisserie chicken). Includes reheating of food, event catering, coffee shops and pubs.
Retail, transport and storage	F	Trading, retail and e-commerce	FI	Retail/ wholesale	Storage and provision of finished products to consumers and consumers (retail outlets, shops, wholesalers) which includes minor processing activities, e.g. slicing, portioning, reheating.
	G	Transport and storage service			Storage facilities and distribution vehicles for perishable food where temperature integrity shall be maintained. Storage facilities and distribution vehicles for ambient stable food. Relabelling/repackaging excluding open exposed product materials. Storage facilities and distribution vehicles for food packaging material.

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Cluster	Category		Subcategory		Examples of included activities
Auxiliary services	H	Services			Services provisioned related to the safe production of food including water supply.
Packaging material	I	Production of packaging material			Production of packaging material in contact with food. May include packaging produced on-site for use in processing.
Bio/chemical	K	Chemical and bio-chemical			Production of food processing aids, additives (e.g. flavourings, vitamins), gases and minerals. Production of bio-cultures and enzymes.

NOTE: “Perishable” can be considered as food of a type or condition such that it can spoil and must be preserved in a temperature-controlled environment

APPENDIX 2: MINIMUM AUDIT DURATION (Normative)

A.2.1 Minimum audit time

In determining the audit time needed for each site, as required in 9.1.4 of MS ISO/IEC 17021, the certification body should consider the minimum on-site duration for initial certification given in Table A.2.A for GMP and Table A.2.B for HACCP.

The minimum time includes stage 1 and stage 2 of the initial certification audit (see 9.2.3, MS ISO/IEC 17021) but does not include the time for preparation of the audit nor for writing the audit report.

The minimum surveillance audit time should be one-third of the initial certification audit time, with a minimum of 0.5 audit day. The minimum renewal time should be two-thirds of the initial certification audit time, with a minimum of 1.0 audit day.

Where there is no relevant certified management system in place, additional time should be added for the audit. To be considered relevant, a management system certificate should cover the scope of Food Safety Assurance Programme elements for the relevant product / service.

Other factors may necessitate increasing the minimum audit time (e.g. number of product and process types, number of product lines, number of people or type and variety of tasks affecting food safety, product development, in-house laboratory testing, sanitation, building area, infrastructure, need for a translator, complexity of operation, number of CCPs).

A.2.2 Calculation of minimum initial certification audit time

A.2.2.1 Minimum initial certification audit time for GMP

The minimum initial certification audit time for GMP certification audits shall be given as T_s , expressed in days, which is calculated, considering Table 3.A:

$$D_s = (T_D + T_{FTE} + T_{MS}) * CC$$

Where:

D_s is the total audit duration based on the subcategory level

T_D is the basis on-site audit time based on subcategory level;

T_{FTE} is the audit days for subcategory of establishments based on full time employees

T_{MS} is the audit days for absence of relevant management system

CC is the factor as multiplier for process or production complexity class

Table A.2.A: Variables for calculation of minimum audit duration for GMP certification

Subcategory (See Appendix 1)	D Basic on-site audit time (PRP)	FTE	CC Complexity Class	MS Absence of certified relevant management system (in audit days)
C0	1.0	$\leq 50 = 0.5$ $51 - 150 = 1.0$ $151 - 250 = 1.25$ $\geq 251 = 1.5$	Low CC = 1.0 Medium CC = 1.25 High CC = 1.5	0.5
CI	1.0			
CII	1.0			
CIII	1.0			
CIV	1.0			
E	1.5			
FI	1.5			
G	1.5			
H	1.5			
I	1.5			
K	1.0			

A.2.2.2 Minimum initial certification audit time for HACCP

The minimum initial certification audit time for HACCP certification audits shall be given as T_s , expressed in days, which is calculated, considering Table 3.B:

$$D_s = (T_D + T_H + T_{FTE}) * CC$$

Where:

D_s is the total audit duration based on subcategory level;

T_D is the basic audit duration for (sub) category and scope of certification (includes one HACCP study), in days;

T_H is the number of audit days for additional HACCP plans/studies

T_{FTE} is the number of audit days per number of FTE employees

CC is the factor as multiplier for process or production complexity class

Table A.2.B: Variables for calculation of minimum audit duration for HACCP certification

Subcategory (See Appendix 1)	D Basic on-site audit time (PRP + HACCP)	H For each additional HACCP Studies/ Plan	FTE Effective number of full-time employees	CC Complexity Class
C0	2.0	0.50	1 to 5 = 0 6 to 49 = 0.5 50 to 99 = 1.0 100 to 199 = 1.5 200 to 499 = 2.0 500 to 999 = 2.5 > 1,000 = 3	Low CC = 1.0 Medium CC = 1.25 High CC = 1.5
CI	2.0	0.50		
CII	2.0	0.50		
CIII	2.0	0.50		
CIV	2.0	0.50		
E	1.5	0.50		
FI	1.0	0.50		
G	1.5	0.25		
H	1.5	0.25		
I	1.5	0.50		
K	2.0	0.50		

Table A.2.A and A.2.B are based on 3 primary complexity classes (CC) of the nature of the processes or production of an organisation that fundamentally affect the food safety assurance programme audit time. They are:

High CC– Overall large establishments with complex operations involved in the production of food. Examples of the food product in this category are but not limited to refined sugar, refined oil, product in hermetically sealed containers, pasteurized, sterilized, UHT products, kitchens (hotels, restaurants, catering, food court).

Medium CC – Overall medium establishments with multiple operations involved in the production of food. Examples of the food products in this category are but not limited to flour, rice including milled rice, pasta, bread, smoked meat, cured fish, smoked fish, fish balls and fish cakes, dried vegetables.

Low CC – Micro/small establishments with simple operations involved in the production. Examples of the food products in this category are but not limited to ground spices, salt, cordials, salted or pickled products, ready cut pre-packaged foods, raw salads, frozen or chilled raw meat, poultry or fish (only cleaned and cutting before packaging).

The examples of the food products in each complexity class are as guidance. However, the certification body shall provide justification if deviation is made in the complexity class.

**APPENDIX 3: KNOWLEDGE AND SKILLS OF KEY PERSONNEL
(Normative)**

General

The following table specifies the knowledge and skills that a certification body shall define for specific certification functions in a GMP and/or HACCP certification body. “X” indicates that the certification body shall define the criteria and depth of knowledge and skills.

Table A.3: Table of knowledge and skills

Knowledge and skills	Certification functions		
	Conducting the application review to determine the audit team competence required, to select the audit team members, and to determine the audit time	Auditing and leading the audit team	Reviewing audit reports and making certification decisions
1. Ability to apply the application review requirements in this document, specific scheme rules and certification body procedures including: <ul style="list-style-type: none">– Categorizing the organization into food categories and subcategories in accordance to Appendix 1;– Determining the complexity of the organisation’s activities;– Calculating audit duration¹	X		
2. Ability to identify and to determine factors relevant to food chain categories (with reference to Appendix 1) and to the organisation, including: <ul style="list-style-type: none">– PRPs;– Food safety hazards;– Statutory and regulatory requirements;– Any specific seasonality factors related to the organisation and its food category or products;	X	X	X

¹ For the team leader, the ability to understand the principles of the audit duration calculation in order to alert the certification body in case of significant change.

Knowledge and skills	Certification functions		
	Conducting the application review to determine the audit team competence required, to select the audit team members, and to determine the audit time	Auditing and leading the audit team	Reviewing audit reports and making certification decisions
<ul style="list-style-type: none"> – Specific cultural and social customs related to the categories and geographic areas to be assessed; – Specific factors required to audit the food safety assurance programme, food product, process, or service 			
3. Ability to identify the auditor competencies required for categories and subcategories in accordance with Appendix 1 and certification body procedures.	X	X	X
4. Ability to apply generic audit principles, practices, techniques, as specified in this document, sufficient to conduct certification audits and to evaluate internal audit processes.		X	X
5. Ability to conduct and manage an audit to achieve the audit objectives within the agreed time frame. For the team leader, the ability to facilitate meetings for the effective exchange of information and the ability to make assignments or re-assignments where necessary.		X	
6. Knowledge of the terminology, practices and processes common to an/the organisation's business sector sufficient to understand the sector's expectations in the context of the standard/scheme or other normative documents.		X	X
7. Knowledge of general organisation types, size, governance, structure and workplace practices, information, and data systems,		X	X

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Knowledge and skills	Certification functions		
	Conducting the application review to determine the audit team competence required, to select the audit team members, and to determine the audit time	Auditing and leading the audit team	Reviewing audit reports and making certification decisions
documentation systems and information technology.			
8. Knowledge of the role and impact of the leadership of the organisation and the ability to evaluate whether the top management of the organisation under audit is demonstrating commitment to the Food Safety Assurance Programme, providing adequate resources and achieving the intended outcomes.		X	
9. Ability to apply normative documents being specified for certification sufficient to determine if its scope and audit duration is appropriate and that the scheme/standard has been effectively implemented and conforms to requirements.		X	
10. Knowledge related to types of products or processes of a client sufficient to understand how such an organisation can operate, and how the organisation can apply the requirements of the standard/scheme or other relevant normative documents.	X	X	
11. Ability to identify ² : <ul style="list-style-type: none"> – Biological hazards*; – Chemical hazards*; – Physical hazards*; – Allergens; – Food safety labelling requirements; – Food safety regulations that are relevant to the food chain category 		X	X

² It is not expected that the certification decision function requires competence specific to the food chain category.

*Only applicable for HACCP

Knowledge and skills	Certification functions		
	Conducting the application review to determine the audit team competence required, to select the audit team members, and to determine the audit time	Auditing and leading the audit team	Reviewing audit reports and making certification decisions
(see Appendix 1) and their recognised control mechanisms. Ability to evaluate the organisation's capacity to identify and meet applicable (country of production/country of destination) food safety regulation and labelling requirements.			
12. Ability to apply the principles of food safety, HACCP, hazard assessment and hazard analysis in the food chain (sub)category ^{3*} . Ability to apply scheme requirements including, but not limited to: - Outsourced processes		X	X
13. Ability to apply food chain (sub) category practices and vocabulary in relation to: - Food chain relationships; - Best practice with respect to PRPs and control measures; - Common food chain processes; - Production technologies and processing terms; - Common equipment; - Facility design; - Packaging types and attributes; - Microbiological terms and names; - Chemical terms and names; - Good laboratory practices; - Local terminology.		X	

³ It is not expected that the certification decision function requires competence specific to the food chain category.

*Only applicable for HACCP

Knowledge and skills	Certification functions		
	Conducting the application review to determine the audit team competence required, to select the audit team members, and to determine the audit time	Auditing and leading the audit team	Reviewing audit reports and making certification decisions
<p>14. Understanding the organisation and its responsibilities for external communication⁴.</p> <p>Understanding the organisational structures, cultures and communication methodologies.</p> <p>Ability to assess whether the organisation is meeting required communication objectives.</p>		X	X
15. Ability to evaluate audit reports, corrective action documentation and other information needed to make a certification decision			X
<p>16. Ability to communicate effectively to fulfil their function within the certification process.</p> <p>For audit team members, ability to communicate effectively with persons at any level of an organisation, including top management, using appropriate terms, expressions and speech.</p>	X	X	X
<p>17. Ability to read and write to fulfil their function within the certification process.</p> <p>For audit team members, ability to read and write with sufficient speed, accuracy and comprehension to record, take notes, and effectively communicate audit findings and conclusions.</p>	X	X	X
18. Ability to present audit findings and conclusions to be easily understood.		X	

⁴ It is not expected that the certification decision function requires competence specific to the food chain category.

Knowledge and skills	Certification functions		
	Conducting the application review to determine the audit team competence required, to select the audit team members, and to determine the audit time	Auditing and leading the audit team	Reviewing audit reports and making certification decisions
For presenting in a public forum (e.g. closing meeting) audit findings, conclusions, and recommendations appropriate to the audience.			
19. Ability to interview to obtain information to their relevant function within the certification process. Ability to interview by asking open-ended, well formulated questions and listening to understand and evaluate the answers.		X	

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