

IndiaHACCP Certification Scheme

Provisional Approval System for Certification Bodies



QUALITY COUNCIL OF INDIA

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0. Introduction

0.1 The Certification Bodies (CB), in order to operate under the **IndiaHACCP Certification Scheme**, hereinafter referred to as the Scheme, shall need to primarily comply with the requirements specified in ISO/IEC 17021-1 read with ISO 22003, and the additional requirements prescribed by the Quality Council of India (QCI) as the Scheme owner.

0.2 The CBs would not get an applicant and would not be able to offer their process for witnessing as part of accreditation process to the accreditation body to get accreditation, or to get the relevant scope added in their accreditation, if already accredited, unless they are approved under the Scheme.

0.3 Further, in order to launch the Scheme, it is necessary that some CBs are available at the beginning.

0.4 Therefore, it is necessary to establish a procedure for provisional approval of CBs under the Scheme till such time that they can get the scope added in their accreditation or get formally accredited from the **National Accreditation Board for Certification Bodies (NABCB)** and approved by the Scheme owner, QCI.

0.5 This document sets out the requirements to be fulfilled by CBs desirous of operating under the Scheme pending formal accreditation and approval.

1. Scope

1.1 This document defines the system for provisional approval for Certification Bodies to enable them to operate under the Scheme pending formal accreditation for the Scheme by NABCB as per the prescribed international standard(s).

1.2 This approval shall be valid for a period of one year within which the approved CB shall have to obtain formal NABCB accreditation.

2. Criteria for Approval

2.1 The CB desirous of operating under this Scheme shall meet the criteria as prescribed in clauses 3 and 4 of this document.

3. General Requirements

3.1 Legal Entity

3.1.1 The CB shall be a legal entity, or shall be a defined part of a legal entity, such that it can be held legally responsible for all its Certification activities. A governmental CB is deemed to be a legal entity on the basis of its governmental status. A CB, that is part of an organization involved in functions other than certification, shall be separate and identifiable within that organization.

3.2 Organizational Structure

3.2.1 The CB shall define and document the duties, responsibilities and reporting structure of its personnel and any committee and its place within the organization. When the CB is a defined part of a legal entity, documentation of the organizational structure shall include the line of authority and the relationship to other parts within the same legal entity.

3.3 Integrity

3.3.1 The CB and its personnel shall maintain integrity at all times. The CB shall implement adequate measures to ensure integrity.

3.4 Impartiality

3.4.1 The CB shall be impartial.

3.4.2 The CB shall be so structured and managed as to safeguard impartiality.

3.4.3 The CB and its personnel/ staff shall not engage in any activities that may conflict with their Impartiality.

3.4.4 The CB shall act impartially in relation to its applicants and certified clients.

3.4.5 The CB shall have a process to identify, analyze, evaluate, monitor, and document the threats to impartiality arising from its activities including any conflicts arising from its relationships, or from the relationships of its personnel on an ongoing basis.

- a) This shall include those threats that may arise from its activities, or from its relationships, or from the relationships of its personnel. Where there are any threats to impartiality, the CB shall document and demonstrate how it eliminates or minimizes such threats and document any residual risk. The demonstration shall cover all potential threats that are identified, whether they arise from within the CB or from the activities of other persons, bodies or organizations.
- b) Top management shall review any residual risk to determine if it is within the level of acceptable risk. When a relationship poses an unacceptable threat to impartiality, then certification shall not be provided.
- c) The risk assessment process shall include identification of and consultation with appropriate interested parties to advice on matters affecting impartiality including openness and public perception.

NOTE 1 Sources of threats to impartiality of the accreditation body can be based on ownership, governance, management, personnel, shared resources, finances, contracts, training, marketing and payment of a sales commission or other inducement for the referral of new clients, etc.

NOTE 2 One way of fulfilling the consultation with the interested parties is by the use of an impartiality committee.

3.4.6 The CB shall not certify a system on which it has provided consultancy, carried out internal audits or provided inhouse training, for a minimum of two years following the completion of consultancy/ internal audits / inhouse training.

3.4.7 The CB shall have a process to ensure that that they do not use personnel in audits or other certification activities if they have been employed by or involved in consultancy /training towards the organization, for a minimum of two years following the end of the employment/ consultancy / training.

3.5 Liability and financing

3.5.1 The CB shall evaluate its finances and sources of income and demonstrate that initially, and on an ongoing basis, commercial, financial or other pressures do not compromise its impartiality.

3.5.2 The CB shall be able to demonstrate that it has evaluated the risks arising from its certification activities and that it has adequate arrangements (e.g. insurance or reserves) to cover liabilities arising from its operations in each of its fields of activities and the geographic areas in which it operates.

3.6 Publicly Available Information

3.6.1 The CB shall maintain a website for providing information about the Scheme and its certification activities under the Scheme, including the following;

- a) The CB shall maintain and make publicly available information describing its certification processes for granting, maintaining, extending, renewing, reducing, suspending or withdrawing certification, and about the certification activities and geographical areas in which it operates.
- b) The CB shall make publicly available information about applications registered and certifications granted, suspended or withdrawn under the Scheme.
- c) The CB shall make publicly available its processes for handling appeals and complaints.

3.7 Confidentiality

3.7.1 The CB shall ensure confidentiality of information obtained in the course of its certification activities by having a suitable system.

3.8 Certification agreement

3.8.1 The CB shall have a legally enforceable agreement for the provision of certification activities to its client. In addition, the CB shall ensure its certification agreement requires that the client comply at least, with the specific requirements as prescribed in the relevant accreditation standards (ISO 17021-1 and ISO 22003) and the Scheme document.

3.9 Responsibility for decision on certification

3.9.1 The CB shall be responsible for, shall retain authority for, its decisions relating to certification, including the granting, maintaining, recertifying, expanding and reducing the scope of the certification, and suspending or withdrawing the certification.

3.10 Use of certificates and marks of conformity

3.10.1 The IndiaHACCP Certification Scheme does not allow for affixing of any Mark on the products The CB shall ensure that the applicants and the certified clients are not affixing any mark on products or the product packaging that maybe interpreted as denoting product conformity.

3.10.2 The CB shall have rules governing the use of any statement on product packaging-or in accompanying information that the certified client has an IndiaHACCP system approved under this Scheme.

3.11 Fee

3.11.1 A fee shall be charged to the client for various activities of the scheme, in a non discriminatory manner. The CB's fee structure shall be publicly accessible and also be provided on request. The CB shall notify and obtain consent to its fee structure from the clients prior to grant of certification. As and when the fee undergoes a change, the same shall be communicated to all applicants and clients certified under this Scheme for their acceptance.

4 Technical Requirements

4.1 Personnel

4.1.1 The CB shall have, as part of its own organization, personnel, either employed or on contract, having sufficient competence for managing the certification operations for this Scheme.

4.1.2 The CB shall have defined processes for selecting, training, and formally authorizing and monitoring the performance its personnel involved in carrying out the various certification activities and for selecting technical experts, if needed, as per the requirements of this Scheme.

4.2 Competence

4.2.1 The CB shall define the competence of the personnel involved in application review, auditing and review and decision making.

4.2.2 **Competence of Auditor** - Every person undertaking audits shall have the appropriate qualification, training, experience and skills to perform it.

a) Education - The CB shall ensure that auditors have at least post-secondary education preferably diploma/graduation in any stream of science relevant to food sector that includes general microbiology and general chemistry. It shall also ensure that they have the knowledge of products, processes, good manufacturing and hygienic practices, and testing, as per applicable Regulation. For any exemption the Certification Bodies shall approach the scheme owner.

- b) Work Experience – The auditors shall have at least 5 years of full time post qualification experience in food chain related industry, including at least two years of work in food safety within manufacturing, retailing, inspection or enforcement, or the equivalent for the two years work experience.
- c) Training - The CB shall ensure that auditors have successfully completed training in audit techniques and training in food safety standard or equivalent.
- d) Audit Experience – The CB shall ensure that within the last three years, the auditor has performed at least 20 man-days of food safety audits covering principles of HACCP in at least 4 organizations, under the leadership of a qualified auditor, and this demonstration has met with acceptance of the qualified auditor. The time spent by the observer/trainee shall not count towards time spent on audit.

For maintaining the qualification of the auditor, the CB shall ensure that auditor has performed a minimum of 5 man-days of food safety audits covering principles of HACCP per year. CB shall define competence for other personal involved in certification systems other than auditing functions.

4.3 Personnel records

4.3.1 The CB shall maintain up-to-date personnel records, as per requirements of the Scheme, of each of its personnel involved in its certification / inspection activities.

4.4 Outsourcing/subcontracting

4.4.1 The CB operating the Scheme shall not outsource any activity.

4.5 Certification Process

4.5.1 The CB shall manage the process of certification as per the documented 'IndiaHACCP Certification Scheme - Certification Process' prescribed under the Scheme.

4.5.2 The CB shall maintain records to demonstrate that the certification process is effectively fulfilled.

4.5.3 The CB shall ensure the requirements of the Scheme are met with at any point in time.

4.5.4 The CB shall certify only under the Scheme.

4.5.5 The CB shall have written agreement with the certified organization on the use of the certificate.

4.5.6 The CB shall have a process to handle appeals by the organization against any CB decision.

4.5.7 The CB shall have a process to handle complaints from the users of the services of the CB or any other stake holder.

5 Approval Process

5.1 Application

5.1.1 Any organization interested in approval as a CB for the purpose of this Scheme may apply to QCI in the prescribed application format along with the prescribed application fee. The applicant shall also enclose the required information and documents as specified in the application form.

5.1.2 The filled in application form for approval shall be duly signed by the CEO/ authorized representative/s of the CB seeking approval.

5.1.3 On receipt of the application form, it will be scrutinized by the secretariat at QCI and those found complete in all respects will be processed further.

5.2 Assessment Process

5.2.1 On review of the application for completeness, an assessment team comprising a team leader and member(s)/technical expert(s) will be nominated by QCI for the purpose of assessment at applicant's office and other locations, if required. Under normal circumstances, the assessment at Head Office will be for a total of 2 man days including the TE. In case the applicant CB already holds an accreditation as a CB, the assessment duration may be reduced.

5.2.2 The names of the members of the assessment team along with their CVs will be communicated to the applicant CB giving it adequate time to raise any objection against the appointment of any of the team members, which will be dealt with by QCI on merits. All assessors/technical experts nominated by QCI have signed undertakings regarding confidentiality and conflict of interest.

5.2.3 The assessment team leader shall provide an assessment plan to the applicant CB in advance of the assessment.

5.2.4 The date(s) of assessment shall be mutually agreed to between the applicant CB and the QCI/assessment team.

5.2.5 The Office assessment will begin with an opening meeting for explaining the purpose and scope of assessment and the methodology of the assessment. The actual assessment process shall cover review of the documented system of the organization to assess its adequacy in line with the assessment criteria as specified. It will also involve verification of the implementation of the system including scrutiny of the records of personnel competence and other relevant records and demonstration of personnel competence through means like interviews, etc. In short, it will be an assessment for verifying technical competence of the applicant CB for operating under the Scheme.

5.2.6 At the end of the Office assessment, through a formal closing meeting, all the nonconformities and concerns observed in the applicant CB's system as per the assessment criteria and the assessment team's recommendation to QCI, shall be conveyed to the applicant CB.

5.2.7 QCI may decide, based on the report of office assessment or otherwise, to undertake witness assessment(s) of actual evaluation or any part of the certification process by the applicant CB.

5.2.8 In case the applicant CB already holds FSMS accreditation from NABCB, the assessment process for provisional approval for the same accreditation scope would only involve an offsite review of documents, on the basis of which the application would be processed for provisional approval as CB under the Scheme.

5.3 Decision

5.3.1 Based on the report(s) of assessment, and the action taken by the applicant on the nonconformities/concerns, if any, QCI shall take a decision on granting provisional approval to the applicant as CB under the Scheme

6. Validity of Approval

6.1 The approval shall be valid for a period of one year, after ensuring

- a) complete compliance to these provisional approval criteria based on evaluation reports,
- b) certification scheme requirements, and
- c) satisfactory resolution of nonconformities and concerns raised, if any

6.2 The CB shall obtain formal accreditation as per ISO 17021-1 and ISO 22003 from NABCB within one year of approval by QCI.

6.3 QCI shall witness at least one audit during the period of approval. This may be waived of in case a witness report from NABCB is provided.

6.4 Based on the request of CB and review of previous approval status, it may be decided to extend the period of validity; in such a case, the CB shall be assessed covering both office and witnessing on site, as decided by QCI, prior to such an extension.

6.5 The approval shall be subject to suspension/withdrawal with due notice of 15 days in the event of any noncompliance to the requirements of the Scheme.

6.6 The approved CB shall inform QCI without delay about any changes relevant to its approval, in any aspect of its status or operation relating to;

- a) Its legal, commercial, ownership or organizational status,
- b) The organization, top management and key personnel,
- c) Main policies, resources, premises and scope of approval, and
- d) Other such matters that may affect the ability of the CB to fulfill requirements for approval.

6.7 QCI shall examine such information and decide on the issue on merits with or without an on-site verification.

7. Fee

7.1 The following fee structure shall apply:

- a) Application fee - INR 10,000/-
- b) Man day charges - INR 20,000/- per manday
- c) Travel / stay - On actuals
- d) Corrective actions review Charges – These shall be charged after one round of review of corrective actions based on extent of review required.

7.2 In addition, the CB shall pay to QCI an amount of INR 1000/- per certificate, for the certificates issued to the certified organizations.

7.3 QCI at its discretion may revise/ levy any other fee necessary with due notice to the CB.