IndiaHACCP Certification Scheme

Certification Process

QUALITY COUNCIL OF INDIA

Institution of Engineers Building, 2nd Floor,

2, Bahadur Shah Zafar Marg, New Delhi - 110002, India

www.qcin.org

Certification Process

1. SCOPE

This document stipulates the requirements of the certification process to be followed by Certification bodies wishing to operate under the **IndiaHACCP Certification Scheme**, hereinafter referred to as the Scheme. The Certification Bodies shall carry out certification in accordance with ISO/IEC 17021 and ISO/TS 22003. To ensure a uniform and effective assessment and certification as per IndiaHACCP standard, additional specific requirements for certification process have been included in this document.

2. SCOPE OF CERTIFICATION

2.1 The scope of IndiaHACCP Certification Scheme covers organizations directly or indirectly involved in one or more steps of the food chain which includes the production of feed and also includes the production of materials intended to come into contact with food or raw material, located in India or abroad. The certification is granted only against the IndiaHACCP Criteria defined under the Scheme.

3. CERTIFICATION PROCESS

3.1 In addition to the requirements specified in ISO/IEC 17021 and ISO/TS 22003, the following additional specific requirements for certification shall apply.

3.2 Application

3.2.1 The CB shall provide the applicant with an up-to-date detailed description of the evaluation and certification procedures, and the documents containing the requirements for certification, the applicants' rights and the duties of certified organization (including fees to be paid by applicants and the certified organizations).

3.2.2 The above information along with the application format shall be made available on the CB's website.

3.2.3 The CB may design its own application format for the Scheme, however while designing of the form it shall ensure that the requirements as mentioned in Clause 9.1.1 ISO 17021-1 and Clause 9.2.1 ISO 22003 are addressed, and that the following information is obtained.

a) The general features of the organization, including the contact details; legal entity status; its functions and relationship in a larger organization, if any.

b) Details of the valid licence/registration issued by the relevant authorities / regulators along with scope of the authorization/ licence/ registration covered.

c) The desired Scope of certification including the stage (s) of the food chain (direct or indirect) , its functions, products being processed/manufactured or services being provided, its processes and operations, seasonality , number of shifts of operations.

d) The applicable regulatory requirements in english, particularly in case of foreign Regulatory requirements which maybe in other languages.

e) Information about any judicial proceedings relating to its operations, any proceedings by any Regulatory body or suspension/cancellation/withdrawal of any relevant approvals/ certifications under any Regulations or otherwise.

f) Any information considered essential for determining auditor competence and estimation of auditor man-days.

3.2.4 The prospective applicant organization shall declare whether it has been an applicant/certified under this Scheme with or by any other CB, and if yes then shall provide

the previous audit reports to the new CB. The CB may verify the information provided by contacting the previous CB.

3.2.5 Certification is granted only against the current relevant certification criteria. The CB shall review all applications for the above and ensure the same.

3.3 Application Review

3.3.1 The CB shall undertake an Application Review of the Application and the supplementary information received from the Applicant, in accordance with the requirements of Clause 9.1.2.1 of ISO 17021 and Clause 9.2.2 of ISO 22003.

3.3.2 Additionally the review of application shall also ensure the following:

a) the availability of the applicable regulatory requirements, in the English language.

b) the means are available to perform the certification activity;

c) examination of the licences issued by the regulatory body. The applicants shall have a valid authorization/ licences / registration from the concerned / relevant Regulator to undertake their business operations.

3.3.3 The Application review shall be undertaken by competent personnel with defined responsibilities and competence.

3.3.4 Based on the review of applications for certification, deficiencies observed, if any, shall be informed to applicant within a reasonable time not exceeding 7 days. Records of review shall be maintained. In case the information about the applicant and the system to be certified, as provided by the applicant, is not complete/sufficient for the purpose of conducting an application review, the CB shall have a procedure for obtaining additional information. The information thus received shall be recorded along with other information already received.

3.3.5 Only applications found to be completely filled and supported with all documents sought shall be accepted and registered in order of receipt with a unique identification number, acknowledged and records maintained.

3.3.6 Antecedents of the applicants shall be checked in relation to the Scheme. If the licence/registration issued by the Regulator / Authorized agency has been suspended / cancelled for a product or the factory during the last one year, the application from the same organization shall not be entertained.

3.3.7 Applications from organizations who have earlier either misused the certification, or have been implicated / convicted by the court, or whose earlier certificate was cancelled because of violation of terms & conditions/misuse of certification shall not be registered within three years of conviction/strictures by the court/cancellation of the certificate by any CB.

3.3.8 Applications from organizations found to be misusing the certification, while their application is being processed for grant of certificate, shall not be processed any further, and rejected after a due notice of 15 days. Fresh applications from them shall be treated as per clause 3.2 given above.

3.3.9 Requests for grant of certificates from ex applicants shall be processed like a fresh applicant and the entire procedure for grant of certificate be adhered to.

3.3.10 The CB shall clearly identify the responsibilities and establish internal time lines for responding to enquiries from prospective applicants, application review and feedback to organization's as well for registration of application and these shall be reasonable as per the activities involved in the relevant process step.

3.3.11 Based on the Application Review, the CB shall determine;

a) **the time required** for conduct of the audit (Stage 1 and Stage 2 as well as surveillance and renewal audits) as stipulated in ISO/TS 22003 cl 9.1.4 and Annex B. In addition to the onsite audit time and preparation and reporting time as stipulated in ISO/TS 22003, clause 9.1.4. and Annex B, additional time would be required for auditing and reporting on **regulatory compliance**. The CB shall depending on the type of regulatory requirements for hygiene and sanitary practices applicable to the organization add half manday (0.5 manday) for auditing and reporting on the compliance to the generic regulatory requirements relating to hygiene for example as stated in Part 2 of Schedule 4 of the FSSAI Regulations on Licensing, and one manday (1 manday) for auditing compliance to sector specific hygienic and sanitary practices for example as stated in Part 3, Part 4 or Part 5 of Schedule 4 of the FSSAI Regulations on Licensing, as applicable. This additional time shall be added for all audits - initial, surveillance and renewal audit. Details of the duration of the audit shall be incorporated in the audit report.

b) **an appropriate audit team and the decision maker** competent for the certification scope applied for. This shall be done in accordance with the requirements specified in the document **" IndiaHACCP Certification Scheme - Requirements for Certification Bodies".**

3.3.12 The name of each applicant organization shall be displayed on the CB's website

3.4 Preparation and Planning for audit

3.4.1 Prior to the certification audit, the CB, shall communicate the composition of the audit team to the applicant organization for identification of conflict of interest if any. If required sufficient background information in respect of the audit team members shall be provided to the organization. Any objections to the team by the applicant shall be examined on merit.

3.4.2 The nominated audit team shall study the applicable regulatory requirements relating to food safety that would constitute one of the certification criteria for certification.

3.4.3 The nominated audit team shall prepare an audit plan and communicate the same to the Organization and the audit team members in accordance with Clause 9.2.3 of ISO 17021.

3.4.4 The audit team shall determine if the organization is a multi site organizations, and in that case the sampling of the sites for auditing for conformance to the applicable certification criteria shall be in accordance with Cl 9.1.5 of ISO 22003.

3.5 Initial certification audit

3.5.1 The initial certification audit shall be conducted in two stages: stage 1 and stage 2. Both the audits shall be conducted onsite.

3.5.2 During the initial certification audit (stage 1 and 2) all requirements of this scheme shall be evaluated. This includes IndiaHACCP Criteria, IndiaGHP Criteria, the applicable regulatory requirements for food safety, and the requirements in this Scheme.

3.5.3 The process for conducting certification audits (Stage 1, stage 2, surveillance and renewal audits) shall be in accordance with clause 9.4 of ISO 17021.

3.5.4 All audits (Stage 1, stage 2, surveillance and renewal audits) shall include a comprehensive site tour and shall cover a representative number of product lines, categories and sectors covered by the scope of certification.

3.5.5 Stage 1 Audit

3.5.5.1 Stage 1 audit shall be performed at the applicant organization's premises in order to evaluate the preparedness of the organization for stage 2 for all requirements of 9.2.3.1 of ISO/TS 22003.

3.5.5.2 The site tour during Stage 1 shall include the review of implementation of representative sampling of the GHPs to evaluate the preparedness of the organization.

3.5.5.3 Deficiencies observed with respect to the certification criteria during the Stage 1 evaluation shall be informed in writing to the applicant.

3.5.5.4 The information gathered during stage 1 audit shall be used for making adjustment in audit time and/or audit team competence for stage 2 audit, as necessary.

3.5.5.5 The Stage 2 evaluation by CB shall take place only after necessary actions on the identified deficiencies have been taken and confirmed by applicant. The CB may seek documentary evidence or organize an additional onsite visit, if necessary, to verify the implementation of corrective actions.

3.5.6 Stage 2 Audit

3.5.6.1 The Stage 2 shall be conducted at the organization's premises in order to evaluate the implementation, including effectiveness, of the organization's IndiaHACCP based system for compliance to the requirements of IndiaHACCP Criteria, in accordance with the clause 9.2.3.2 of ISO/TS 22003.

3.5.6.2 The CB shall during the Stage 2 audit evaluate whether the organization has implemented and maintained the necessary GHPs in fulfillment of the requirements of the applicable regulations relating to food safety and the IndiaGHP Criteria. For verification, a site tour of the organization facility shall be part of the audit.

3.5.6.3 The site tour during Stage 2 shall also include the review of implementation of all CCPs as also a representative sampling of the GHPs. The tour shall include all areas that might influence food safety.

3.5.6.4 The CB shall under this Scheme audit for regulatory compliance on a sampling basis, ensuring that the sample is sufficient to provide an assurance of compliance to Regulations . Auditing for Regulatory compliance under this Scheme means auditing for compliance to Regulations relating to Food safety, which is a part of the Certification Criteria (normative document).

3.6 Conducting the audit

3.6.1 The CB shall conduct the audits (stage 1, stage 2,surveillance and renewal audits) in accordance with the process described in clause 9.4 of ISO 17021..The process includes conducting the opening meeting, communication during the audit, obtaining and verifying information through interviews, observation of processes and activities and review of documentation and records, identifying and recording audit findings, preparing audit conclusions and conducting the closing meeting.

3.6.2 Audit Findings - Any nonconformities observed during Stage 2 audit, with respect to the certification criteria shall be informed in writing to the applicant for taking necessary action. The nonconformities shall be classified as Major or Minor depending on how they affect the capability of the organization to achieve the intended results and shall not be recorded as opportunities for improvement .

a) **Major Nonconformity** – A nonconformity shall be classified as Major when a finding affects the capability of the organization's IndiaHACCP system to achieve the intended results.

b) **Minor Nonconformity** – A nonconformity shall be classified as a Minor when a finding does not affect the capability of the organization's IndiaHACCP system to achieve the intended results.

3.6.2.1 Opportunities for improvement may be identified and recorded..

3.6.2.2 When the audit findings indicate that compliance to specific **regulatory requirement(s)** is not established or is not effective , the audit findings shall be identified, **categorized as major non conformities** and the management / top management of the Organization shall be notified of the same.

3.6.2.3 The CB shall seek a root cause analysis along with correction and corrective actions to address the major non conformity within a period of one month and minor nonconformities within a period of 3 months.

3.6.2.4 All Major nonconformities are required to be closed before initial certification through verification of adequacy of the correction and corrective actions, while for minor nonconformities the CB shall review and accept the organization's plan for correction and corrective action. All Major nonconformities, shall require a follow-up audit.

3.7 The audit report

3.7.1 The audit reports for stage 1 and stage 2 shall clearly provide evidence and conclusions about the fulfilment of the audit objectives as described above and shall contain sufficient detailed information regarding conformity with all the relevant certification requirements, including the Certification Criteria, a conclusion on the appropriateness of the certification scope and a recommendation from the audit team. The CB shall develop appropriate report format(s) that provides adequate and complete details for ensuring appropriate review and decision in respect of grant of certification. The audit report shall include the results and the conclusions of the audit with respect to the IndiaHACCP Criteria and the additional requirements of this Scheme. The audit of the IndiaGHP Criteria and the applicable Regulatory requirements pertaining to food safety shall be reported separately and attached to the audit report.

3.8 Certification Decision

3.8.1 The CB shall carry out an independent review of the audit reports and the non conformities prior to making a decision for granting certification for ensuring that;

a) the information provided by the audit team is sufficient with respect to the certification requirements of the certification criteria, the requirements of the India HACCP certification Scheme as given in this document, and the scope for certification;
b) major non conformities have been reviewed and accepted, corrections and corrective actions verified and closed out; and that
c) minor nonconformities have been reviewed and organization's plan for correction and corrective action has been accepted .

3.8.2 This review shall be carried out by a person(s) or a committee having the relevant competence, duly authorised for this function. The responsibility for review and decision making function, shall however be that of the CB.

3.8.3 Certification decision shall be the sole responsibility of the CB and the persons taking certification decisions shall have the relevant competence. Review and the certification decision may be completed concurrently by the same person(s).

3.8.4 The CB shall grant certification after ensuring complete compliance to the Certification Criteria, certification scheme and certification process requirements and all nonconformities have been addressed. There shall be no conditional grant of certification.

3.8.5 When based on the audit report and its recommendations and the results of the review and certification decision, the CB decides, not to grant certification then the same along with the reasons for not granting the certification, shall be communicated to the applicant organization. If the organization expresses interest in continuing the certification process, the CB can resume the process for certification as described above.

3.9 Certification Documentation

3.9.1 On grant of certification, the CB shall inform the organization and issue a Certificate, uniquely identified, which shall be in accordance with the requirements of clause 8.2 of ISO 17021 and clause 8 of ISO 22003.

3.9.2 When defining the scope, the CB shall indicate for each location the name of the food chain category and the specific sector as specified in Annex A of ISO/TS 22003.

3.9.3 Formal certification documentation shall only be issued after, or concurrent with, the following:

a) the decision to grant or extend the scope of certification has been made;
b) certification requirements have been fulfilled;
c) the certification agreement has been completed/signed.

3.10 Surveillance Activities

3.10.1 The CB shall conduct first surveillance within 12 months of the grant of certification and subsequently once a year.

3.10.2 The man-days required for conducting a surveillance audit shall be determined as per requirements stipulated in ISO/TS 22003 clause 9.1.4 and its Annex B and Clause 3.3.11 mentioned above.

3.10.3 The surveillance audit shall be carried out onsite at the organization's certified premises. The surveillance audits shall be conducted as per audit process for a stage 2 audit for evaluating the continuing conformance to the IndiaHACCP Criteria and the requirements mentioned in this document, except that the scope of the audit does not include auditing of the full system .

3.10.4 During each surveillance audit, the audit team shall as a minimum audit and report on the following;

a) internal audits and management review;
b) a review of actions taken on nonconformities identified during the previous audit;
c) complaints handling;
d) effectiveness of the management system with regard to achieving the certified client's objectives and the intended results of the respective management system (s);
e) progress of planned activities aimed at continual improvement;
f) continuing operational control;
g) review of any changes;
h) use of marks and/or any other reference to certification.

3.10.5 Nonconformities, if any, observed shall be categorized as Major or Minor as per the description given above. The nonconformity report shall be provided to the certified organization in writing, generally on site, for root cause analysis, correction and corrective action. Details of the same shall be reported in the Surveillance audit report.

3.10.6 The Nonconformities shall be handled as described in clause 3.6.2 above.

3.11 Suspension and Withdrawal of certification

3.11.1 The CB shall suspend certification when :

a) the client's certified system has persistently or seriously failed to meet the requirements of the IndiaHACCP certification criteria and those stipulated under this Scheme, including requirements for the effectiveness of the system;
b) the certified client does not allow surveillance or recertification audits to be conducted at the required frequencies;
c) the certified client has voluntarily requested a suspension or withdrawal.

3.11.2 The certified organization shall be informed that the certification has been suspended and while under suspension, the certified organization's system certification is temporarily invalid. The certified organization shall be advised to suspend operation of certification and not to make any misleading claims during the period of suspension.

3.11.3 The CB shall revoke suspension only when corrective actions have been taken and verified by the CB.

3.11.4 Suspension shall not exceed a period of six months. The organizations inability to resolve issues relating to suspension within this period shall lead to withdrawal of certification.

3.11.5 The CB shall withdraw the certificate at the request of the certified organization, if the operation(s) in the certified orgnaization's premises can no longer be carried due to reasons of natural calamities such as flood, fire, earthquake etc, lock out declared by the management, or closure of business operations etc.

3.11.6 The information about the suspension and withdrawal of certification shall be made publicly available by the CB on its website.

3.12 Recertification

3.12.1 The certification shall be renewed at the expiry of 3 years validity period. However the recertification process and the recertification certification decision shall be taken on or before the certificate expiry date. In order to achieve the same the CB shall send the Recertification notice to the certified organization at least four months prior to expiry of certificate validity period.

3.12.2 The certified organization shall apply for recertification in the prescribed format provided by the CB along with fee, if any prescribed by the CB at least 3 months before expiry of the certification.

3.12.3 The recertification audit shall be planned and conducted to evaluate the continued fulfillment of all of the requirements of the Scheme. This shall be planned and conducted in due time to enable for timely renewal before the certificate expiry date

3.12.4 The CB shall conduct the recertification audit onsite like a stage 2 audit for an initial certification. However if there are significant changes in the organizations system, certification criteria etc, the CB shall also carry out a stage 1 audit onsite. All process steps from Application to Certification decision and issuance of certification document, as followed for the initial certification audit, as mentioned above in this document, shall be followed.

3.12.5 The CB shall not decide for recertification with conditions for compliance to be verified subsequently. There shall be no conditional recertification.

3.12.6 When performance of the certified organization is not satisfactory, the CB shall withhold the recertification of the certified organization clearly stating the reasons and give time for effecting corrective actions. The verification and decision on recertification should be taken before the certificate expiry date.

3.12.7 The corrective actions shall be verified generally on site unless the CB can verify the same off site prior to considering for renewal of certificate. The justification for offsite review shall be recorded.

3.12.8 On the satisfactory completion of the recertification activity prior to certificate expiry date, the recertification shall be effected from the date of the expiry of the previous certificate. and the intervening period shall be treated as period of suspension and clearly stated on the Certificate. The certified organization shall not claim certification during this period.

3.12.9 However when the organization is unable to complete the recertification audit or the CB is unable to verify the effectiveness of the corrective action, in case of major non conformities, before the certification expiry date, the recertification shall not be recommended and the validity of the certification shall not be extended, and the client shall be informed of the same along with the related consequences.

3.12.10 When a certificate is not renewed, it shall expire at the end of validity period.

3.13 Changes affecting certification

3.13.1 When the certification scheme introduces new or revised requirements both in Certification criteria and Certification process requirements that affect the applicants and the certified organizations, the CB shall ensure these changes are communicated to them. The

CB shall verify the implementation of the changes by the applicants and the organization certified under this Scheme and shall take actions required by the scheme.

3.13.2 The contractual agreement with the organization certified under this Scheme shall have clearly defined clause which shall make it makes mandatory for the certified organization to agree to implement the changes in his processes and product, necessitated by the changes in above requirements.

3.13.3 Following decision on, and publication of, the changed requirements, the CB shall verify that each organization certified under this Scheme makes necessary adjustments within such time as decided under the Scheme. The verification may involve steps like onsite audit, review and decision making followed by issuance of revised formal certification documentation to extend or reduce the scope of certification, etc. In case the changes necessitate changes, then the CB shall also review and approve changes and make necessary revision in the Certification agreement. The records shall provide justification for choice of activities chosen for the purpose verification of changes.

3.13.4 The certified organization shall also be bound by the certification agreement to inform the CB about changes initiated by the certified organization; including changes in process and product design, changes in technology of manufacturing, etc; which have the potential to affect the certification criteria. Based on the nature of changes informed, the CB shall decide the verification activities.

3.13.5 Change of Location/Ownership/Name

3.13.5.1 The certified organization shall inform the CB of any change in the location of its facility.

3.13.5.2 On receipt of such information, the CB shall issue instructions to the certified organization for suspension of certification with immediate effect.

3.13.5.3 The facility at the new location shall be subject to an onsite audit at the new site like an Initial Certification of an applicant.

3.13.5.4 If the audit is satisfactory, the CB shall transfer the Certificate to the new location .

3.13.5.5 The CB shall endorse the change of premises on the Certificate.

3.13.5.6 In the event of change of Ownership, the organization shall provide necessary documentary evidence. The new management of the organization shall submit its acceptance to the agreement for with the CB, and payment of fees. The same process shall be followed as and when an existing applicant undergoes a change in management. Such changes shall not call for a visit to the production site.

3.13.5.7 In case of change of Name, the manufacturer shall inform the change in the name to the CB supported with documentary evidence, and if satisfied the CB shall endorse the Certificate in the new name.

3.14 Extension of scope

3.14.1 When the certified organization request for extension of scope of certification already granted, the CB shall, obtain this request on a prescribed Application form for the purpose for obtaining information on the additional scope of certification, products and processes covered therein, HACCP studies involved, undertake an application review for adequacy and sufficiency of information to enable the conduct of an Application review, and determine the competence of auditors and decision maker required for this, and determine the audit mandays for review of the additional documents and an onsite audit for verifying compliance to decide on extension of scope sought. This may be conducted in conjunction with a surveillance audit.

3.14.2 The process of extension of scope shall undergo the same process steps of receiving an application, application review, auditing , corrective actions on non conformities if any, audit reporting and decision making as in case of initial certification.

3.14.3 The extension of scope shall be clearly mentioned in the certificate document along with its date of inclusion for avoiding any misrepresentation or misinterpretation. Irrespective of the date of inclusion, the validity of the Certificate shall remain unchanged.

3.15 Certification Fees

3.15.1 The CB shall charge a fee to the organization in a non discriminatory manner

3.15.2 The CBs fee structure shall be publically accessible and also be provided on request.

3.15.3 CB shall notify and obtain consent to its fee structure from the organizations prior to grant of certification. As and when the fee undergoes a change, the same shall be communicated to all including applicants and the certified organization operating under this scheme of certification for their acceptance.

3.15.4 Client Records

3.15.4.1 The CB shall have a documented policy and documented procedures in respect of the retention of records to demonstrate that all certification process requirements have been effectively fulfilled.

3.15.4.2 The certification related records shall be retained for two certification cycles. If required by law or any regulation relevant to the products certified, like FSSA, etc, then the records shall be retained for longer period in accordance with the relevant regulation.

3.15.4.3 The CB shall keep records confidential. Records shall be transported, transmitted and transferred in a way that ensures confidentiality is maintained.

3.15.4.4 The certification records shall include records for all organizations, including all organisations that submitted applications, and all organizations audited, certified, or with certifications suspended or withdrawn. The records of certification of organizations shall include the following:

a) Application information and results of application review and man-days estimation and team competence records;
b) Audit planning and preparation records, audit plans and other related records;
c) justification for auditor time determination
d) Records of Stage 1 and stage 2 audit reports and related records;
e) Initial and final evaluation records, Records of verification of correction and corrective actions;
f) Records of review and certification decisions; committee deliberations and decisions, if applicable;
g) Certification agreement;
h) Certification Documentation (certificate, etc), including scope of certification;
i) Records of complaints and appeals, and any subsequent correction or corrective actions;
j) Related records necessary to establish the credibility of the certification, such as evidence of the competence of auditors, technical experts, review personnel, and decision makers, etc, as relevant;
k) Any other records as relevant to the certification process, in order to provide confidence that the certification scheme requirements were complied with.