

VOLUNTARY CERTIFICATION SCHEME FOR MEDICINAL PLANT PRODUCE

PROCEDURE FOR APPROVAL OF CERTIFICATION BODIES

0. INTRODUCTION

- 0.1 The Certification Bodies (CB), in order to operate under the **Voluntary Certification Scheme for Medicinal Plant Produce**, hereinafter referred to as the Scheme, shall need to primarily comply with the requirements specified in ISO 17065 and the additional requirements prescribed by the Quality Council of India (QCI) as the joint Scheme owners with NMPB.
- 0.2 The CB 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. It is also necessary that provision is kept for new CBs to get into the Scheme.
- 0.3 Further, in order to launch the Scheme, it is necessary that some CB 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 joint 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

This document describes the procedure to be followed by the Quality Council of India (QCI), as joint scheme owners with NMPB, in processing applications from Certification Bodies seeking approval for undertaking certification under the **Voluntary Certification Scheme for Medicinal Plant Produce (VCSMPP)** on behalf of the Scheme owners.

2. ELIGIBILITY FOR APPROVAL

The Certification Bodies desirous of operating under VCSMPP shall meet anyone of the following criterion:

- (i) NABCB accredited for ISO 17065 with the Scope covering VCSMPP.
- (ii) NABCB accredited for ISO 17065 but not for VCSMPP and have applied to NABCB for extension of scope to cover VCSMPP.
- (iii) Not yet accredited by NABCB.

3. CRITERIA FOR APPROVAL

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

4. GENERAL REQUIREMENTS

4.1 **Legal Entity:** 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 certification body 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.

4.2 **Organizational Structure**

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.

4.3 **Integrity:** The CB and its personnel shall maintain integrity at all times. The CB shall implement adequate measures to ensure integrity.

a. **Impartiality**

- i. The Certification Body shall be impartial.
- ii. The Certification Body shall be so structured and managed as to safeguard impartiality.
- iii. The Certification Body and its personnel/ staff shall not engage in any activities that may conflict with their Impartiality.
- iv. The Certification Body shall require personnel involved in the certification process to sign a contract or other document by which they commit themselves to declare any prior and/or present association on their own part, or on the part of their employer, with: a) a supplier or designer of products, or b) a provider or developer of services, or c) an operator or developer of processes.
- v. The Certification Body and any part of the same legal entity and entities under its organizational control shall not: a) be the designer, manufacturer, installer, distributor or maintainer of the certified product; a) be the designer, implementer, operator or maintainer of the certified process; b) be the designer, implementer, provider or maintainer of the certified service; c) offer or provide consultancy to its clients; b) offer or provide management system consultancy or internal auditing to its clients where the certification scheme requires the evaluation of the client's management system.
- vi. The Certification Body shall ensure that activities of separate legal entities, with which the Certification Body or the legal entity of which it forms a part has relationships, do not compromise the impartiality of its certification activities.
- vii. When the separate legal entity in 4.1 need to change offers, or produces the certified product (including products to be certified) or offers or provides consultancy, the Certification Body's management personnel and personnel in the

review and certification decision-making process shall not be involved in the activities of the separate legal entity. The personnel of the separate legal entity shall not be involved in the management of the Certification Body, the review, or the certification decision.

- viii. The Certification Body shall act impartially in relation to its applicants and certified clients.
 - ix. The Certification Body 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. NOTE Sources of threats to impartiality of the Certification 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.
 - x. The Certification Body shall not certify a process on which they have provided consultancy, carried out internal audits or provided training, for a minimum of two years following the completion of consultancy/ internal audits / training.
 - xi. The Certification Body shall not use personnel in audits /inspections /evaluations or other certification / inspection activities if they have been employed by or involved in consultancy /training towards the client, for a minimum of two years following the end of the employment/ consultancy / training.
 - xii. The Certification Body shall not have any relationship with its clients other than third party conformity assessment.
- b. **Liability and financing**
- i. 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.
 - ii. The CB shall be able to demonstrate that it has evaluated the risks arising from its certification/inspection 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.
- c. **Publicly Available Information**
- i. The CB shall maintain a website for providing information about the Scheme and its certification activities under the Scheme.
 - ii. 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.
 - iii. The CB shall make publicly available information about applications registered and certifications granted, suspended or withdrawn.
 - iv. The CB shall make publicly available its processes for handling appeals and complaints.

- d. **Confidentiality:** The CB shall ensure confidentiality of information obtained in the course of its certification activities by having a suitable system.
- e. **Certification agreement:** The Certification Body shall have a legally enforceable agreement for the provision of certification activities to its client. In addition, the Certification Body shall ensure its certification agreement requires that the client comply at least, with the specific requirements as prescribed in the relevant accreditation standards (ISO 17065) and the Scheme document.
- f. **Responsibility for decision on certification**
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.
- g. **Use of certificates and marks of conformity**
The certification body shall ensure that the Rules for Use of Certification Mark as described in Section 6 of the VCSMPP Scheme document are adhered to.
- h. **Fee:**
A fee shall be charged to the client for various activities of the scheme, without any discrimination between clients, geographical location, size of the client. 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:** 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.
- 4.2 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 / inspection activities and for selecting technical experts, if needed, as per the requirements of this Scheme.
- 4.3 **Competence:** The Certification Body shall define the competence of the personnel involved in application review, evaluation and review and decision making.
 - 4.3.1 Evaluators – The evaluators shall meet the following requirements:
 - a) **Education** – Degree and/or Post-secondary education in any stream of science relevant to medicinal plants like agriculture, horticulture, soil sciences or agroforestry areas, sufficient to provide knowledge of basic microbiology, agronomy, plant entomology and pathology, and hygienic conditions in the production and processing or collection of medicinal plants as relevant to the species certified.
 - b) **Work Experience** – The evaluator shall have at least 5 years of full time equivalent post qualification experience in forestry/horticulture/agriculture production, including at least two years of work experience in quality assurance within farm management, inspection or enforcement, or the equivalent. The number of years of total work experience may be

reduced by one year if the evaluator has completed appropriate post-secondary education in the education relevant to horticulture and/or agriculture sector.

- c) **Training** – Successful completion of training in audit techniques based on ISO 17021/ISO19011. Appropriate training in respect of agriculture, horticulture, soil sciences or agro forestry areas, agronomy, plant entomology and pathology, and hygienic conditions in the production and processing of horticulture crops. All qualified evaluators shall undergo all the training relevant to the criteria level they will be auditing in as the sector (technical area) experts.
- d) **Evaluation experience** – For initial qualification as an Evaluator for VCSMPP scheme at least 12 man-days of evaluations in farm sector in at least 4 different organizations, as an observer/trainee, under the leadership of a qualified evaluator, in the last 3-year period shall be required. The time spent by the observer/trainee shall not count towards time spent on evaluation. Additional evaluation experience of 6 man-days as trainee team leader, under the supervision of a qualified team leader shall be essential for qualification of an evaluator as team leader. In this case the time spent by the trainee team leader as well as the qualified team leader may be counted.

4.3.2 Selection of evaluation team - The evaluation team may consist of one or more members. The certification body shall ensure the competence of the evaluation team as stated below:

- a) The certification body may include evaluators who do not have the requisite qualifications as prescribed above, as part of evaluation team, provided they are supported by technical experts (TEs) who meet the qualifications at 4.1.3.1 a) and b) above.
- b) The time spent by the TE on an evaluation shall be in addition to the evaluation time which the CB is expected to spend.
- c) In case of an evaluation team having more than one member, one of the evaluators shall be designated as team leader.

4.4 Personnel records: 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.

4.5 Outsourcing/subcontracting: The certification body operating the VCSMPP Certification Scheme shall not outsource any activity other than testing. Sending of samples to the CB's own laboratory shall also be considered as sub-contracting.

4.6 Test Laboratory: If required, the certification body shall test all samples of farm produce or semi-finished produce drawn for independent evaluation, in a laboratory accredited to ISO 17025 by NABL with relevant scope of accreditation, for ascertaining conformance to the certification criteria.

4.6.1 The certification body shall maintain a directory of laboratories to which it intends to sub-contract. It shall have a formal contract with the sub-contracted laboratories for provision of competent services and also for ensuring aspects like impartiality and confidentiality as relevant.

4.6.2 If the certification body uses an in-house laboratory (part of the same legal entity), it shall be ensured that there exists an adequate separation, in terms of organization structure and reporting and defined responsibilities. It shall also ensure through above means and policies

and procedures, that there is no possibility of compromising the independence of the lab personnel by bringing undue pressure over them.

4.6.3 The certification criteria against which the product is to be tested or if in case of complaint shall be clearly mentioned and communicated to the testing laboratory. The sample(s) shall be so dispatched that they do not get damaged and or contaminated, undergo deterioration, and the product integrity is maintained. The certification body shall have a documented procedure for drawl of samples and their subsequent handling and dispatch to the laboratories. The procedure shall also include aspects like receipt of test reports and their evaluation.

4.7 Certification Process

4.7.1 The Certification Body shall assign at least one person to review all information and results related to the evaluation. The review shall be carried out by person(s) who have not been involved in the evaluation process.

4.7.2 Recommendations for a certification decision based on the review shall be documented, unless the review and the certification decision are completed concurrently by the same person.

4.7.3 The CB shall manage the process of certification / inspection as per the documented Certification Process prescribed under the Scheme.

4.7.4 The CB shall maintain records to demonstrate that the certification / inspection process is effectively fulfilled.

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

4.7.6 The CB shall certify only under the Scheme and shall use the logo of the Scheme in the certificates issued to the certified organization.

4.7.7 The CB shall have written agreement with the certified organization on the use of the certificate and the Scheme logo.

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

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

5. APPLICATION

5.1 Any CB interested in the approval of the QCI for the purpose of medicinal plant produce certification may apply to QCI along with information in the format enclosed vide **Annex A**. The applicant shall also enclose the required documents as specified in the application form.

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

5.3 On receipt of the application form, it shall be scrutinized by the secretariat at QCI and those found complete in all respect shall be processed further.

6. ASSESSMENT

6.1 In case the CB is accredited by NABCB for the scope covering VCSMPP (see (i) above), it shall be approved by review of application and there shall be no assessment, unless specifically required for any reason.

6.2 In case the CB is accredited by NABCB but not for VCSMPP, it shall be subject to an assessment by QCI or would have an option to produce an office assessment report of NABCB covering VCSMPP with all issues closed.

6.2.1 A one man day document review shall be conducted by QCI for the documentation relating to VCSMPP.

6.2.2 Based on the information supplied in the application and document review report, an assessment team consisting of a team leader and member(s)/technical expert(s), as needed, will be nominated by QCI for the purpose of assessment at the certification body's head office and other locations, if required. Under normal circumstances, the assessment at head office will be for a total of one manday for CBs accredited for ISO 17065 (please see (ii) above) but not covering VCSMPP and two mandays for CBs not accredited to ISO 17065 (please see (iii) above). The technical expert's man-day/s would be charged extra, as applicable. This however is subject to change based on information in the application and document review, if applicable.

6.2.3 The names of the members of the assessment team along with their CVs will be communicated to the applicant body giving them 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/experts nominated by QCI have signed undertakings regarding confidentiality and conflict of interest.

6.2.4 The dates of the office assessment shall be decided as per mutual convenience of the assessment team and the applicant body. The certification body shall be informed of the assessment plan by the team leader. In case information collected during the office assessment requires inclusion of any key locations in the assessment programme, the applicant shall be informed and the assessment programme shall be modified to cover such locations. The sub-contractors shall also be included in the assessment programme depending on the nature of activities carried out by them and the extent of control demonstrated by the applicant certification body.

6.2.5 In case recommended by the assessment team or otherwise felt necessary, QCI may decide to witness assessments for either or both of following sub scopes:

Good Agricultural Practices for Medicinal Plants
Good Field Collection Practices for Medicinal Plants

6.3 The certification body may request for approval of any one sub scope.

6.4 The team shall submit its assessment report(s) to QCI, who would review it and take a decision on approval. The approval or otherwise shall be duly communicated to the applicant.

7. VALIDITY OF APPROVAL

7.1 In case the CB is not accredited by NABCB for the scope of VCSMPP, the approval shall be provisional and valid for a period of one year during which the certification body shall be required to obtain formal accreditation from NABCB.

7.2 In case it is decided to extend the period of validity, the Certification body shall be liable for an assessment covering office and witnessing prior to such an extension.

7.3 in case the CB is accredited by NABCB for the scope of VCSMPP, the approval shall be valid as long as accreditation is valid.

8. SURVEILLANCE

QCI at its discretion may conduct a short notice assessment and/or witness actual audit during the period of approval.

9. SUSPENSION/WITHDRAWAL

9.1 The approval of QCI may be suspended/withdrawn during the period of validity if the certification body is found not complying with the criteria of approval with due notice of 15 days.

9.2 The certification body may appeal against the decision to suspend/withdraw approval to the Chairman of the Certification Committee who would get the appeal examined independently and take a decision. His decision shall be final and binding.

10. FEE

The following fee shall apply:

- Application fee: Rs. 5000/-
- Assessment fee: Rs. 20000/- per man-day for document review, if applicable, as well as onsite assessment with travel and stay of the assessment team at actuals.