

	BHUTAN FOOD AND DRUG AUTHORITY CERTIFICATION SERVICES		QUALITY PROCEDURE
	DOC. BFDA-CS-PR-7.2-01	ISSUE 04	REVISION 00
			01 MARCH 2023

PROCEDURE FOR RECEIPT, REVIEW AND REGISTRATION OF APPLICATION

1. PURPOSE

To ensure uniform receipt, review and registration of applications for product certification.

2. SCOPE

This includes all applications received for product certification under the following three schemes:

- a) product certification scheme covering general food products.
- b) product certification scheme covering organic products; and
- c) product certification scheme covering GAP products.

3. RESPONSIBILITY

3.1 The Head, BFDA is responsible for defining criteria for application and application review for taking rational decision for grant of certification.

3.2 Certification Manager is responsible for developing procedures for application receipt, review and registration.

3.3 Certification Officer is responsible for ensuring completeness of applications, registration of application, appointment of application reviewer and inspection team.

4. PROCEDURE

4.1 Receipt of Application

4.1.1 The prospective applicants for product certification avail application from BFDA and apply together with relevant supplementary information as under:

- a) BFDA-CS-PR7.2-01-FM-01 along with BFDA-CS-PR7.2-01-FM-02 for product certification scheme covering general food product.
- b) BFDA-CS-PR7.2-01-FM-03 along with BFDA-CS-PR7.2-01-FM-04 for product certification scheme covering BhutanGAP products.
- c) BFDA-CS-PR7.2-01-FM-05 along with BFDA-CS-PR7.2-01-FM-06 for product certification scheme covering organic products.

4.1.2 The prospective applicants for organic and BhutanGAP certification can be any one of the two options:

- a. Individual Producer /Farmer
- b. Group producer

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4.1.3 The prospective applicants for food product certification can be any one of the two options:

- a. Cottage and small industries
- b. Well established food processing plants/food establishments

4.1.4 It is ensured that all the necessary information provided to complete the certification process according to the requirements of the relevant certification schemes. As a minimum the applicant should provide the following information:

- a) the product(s)/produce(s) to be certified,
- b) the standard(s) for which seeking certification,
- c) name and the address of its physical location(s), significant aspects of its process and operations,
- d) the applicable legal obligations,
- e) list of test facilities used for quality control of the product/produce to be certified.
- f) information relevant for the field of certification applied for, concerning the applicant, such as its activities, human and technical resources including laboratory testing facilities, list of available equipments and /or inspection facilities, functions, and relationship in a larger corporation, if any.
- g) Commitment to comply with the requirements of the standard.
- h) information concerning all outsourced processes used by the applicant that will affect conformity to requirements,
- i) BFDA-CS can establish appropriate contractual controls over that legal entity (ies). If such contractual controls are needed they can be established prior to providing formal certification documentation.

4.1.5 The process of Product Certification starts with the receipt of application in the prescribed application form (See Fig 01) with information covering the above aspects by the applicant organization, along with an application fee, if applicable.

4.1.6 The BFDA-CS also uses a variety of media and mechanisms to collect this information at various times, including an application form. Such information gathering may be in conjunction with or separate from the completion of the legally binding Certification Agreement described in BFDA-CS -PR4.1-01.

4.2 Review of Application

4.2.1 The BFDA-CS assigns the responsibility to one of its officers to conducts a review of the information obtained with the application to ensure that:

- a) the information about the applicant and the product is sufficient for the conduct of the application review and subsequent certification process.
- b) the differences, if any, in understanding between BFDA-CS and the client is resolved including agreement regarding standard.

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- c) the scope of certification sought is defined.
- d) To verify that all the information sought are submitted along with the proof.
- e) the competent personnel to perform all evaluation activities are available.
- f) the competence and capability to undertake the certification activity such as review and decision-making process.

4.2.2 When a new application is received, BFDA-CS identifies product, processes and services, national standards and certification scheme if the BFDA-CS has no prior experience. BFDA- CS starts the process of developing national standards and certification scheme for such areas.

4.2.3 BFDA-CS has a process of identifying products requiring the same type of knowledge of the requirements and having similar characteristics and technology of another product for grouping them for the development of certification scheme and human resources.

4.2.4 BFDA-CS assesses from its pool of technical auditor (inspectors) and technical experts if it has available to it all the necessary competence and capability to perform the evaluation, review and certification activities in respect of the certification scheme and the scope of certification asked for and ensures that it has the competence and capability for all certification activities it undertakes and maintain a record of the justification for the decision to undertake certification.

4.2.5 When BFDA-CS lacks any competence or capability for the certification activities applied for it either declines or adds additional resource to undertake certification in such areas.

4.2.4 Review of applications shall be done by a competent person and the records of review shall be maintained.

4.2.7 BFDA- CS shall not review applications from applicants who have earlier either misused the certification/certification mark, or whose earlier certificate was cancelled because of violation of terms and conditions, for at least one year.

4.3 Registration of application

4.3.1 The applications found to be complete and supported with all documents sought shall be accepted and registered in order of receipt with a unique identification number, acknowledged.

4.3.2 The unique number will be alpha numeric such as BFDA-CS-A-001 will be the number for first application. An application register format of which is given in BFDA-CS-PR7.2-01-FM-03 is opened to record applications in a chronological order.

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4.3.3 Registration should be done within seven working days of receipt and records shall be maintained.

4.3.4 If producer or producers found to be misusing the Certification/certification Mark while their application is being processed for grant of certificate, shall not be processed any further, and shall be rejected after giving a due notice of 15 days.

4.3.5 The request from the ex-applicant for the grant of certificate shall be treated as fresh application and the entire procedure for grant of certificate shall be adhered.

4.4 Closure of application

If an application does not progress for grant of license within 6 months, it should be considered for closure in accordance with BFDA-CS -GL7.2-04.

REFERENCES

- ISO/IEC 17030:2003 CA-General Requirements for Third-Party Marks of Conformity
- ISO/IEC 17067:2013 Conformity Assessment-Fundamentals of Product Certification and Guidelines for Product Certification Schemes
- BFDA-CS-PR4.1-01 Procedure for legally enforceable certification agreement
- BFDA-CS-GL7.2-01 Guidance for clients enquiring about product Certification.
- BFDA-CS-GL7.2-02 Guidance for the applicants for product certification
- BFDA-CS-GL7.2-03 Guidelines for closure of applications
- BFDA-CS-PR7.2-01-FM-01 Form: Application for food product certification
- BFDA-CS-PR7.2-01-FM-02 Form: Initial questionnaire for factory assessment
- BFDA-CS-PR7.2-01-FM-03 Form: Application for BhutanGAP certification
- BFDA-CS-PR7.2-01-FM-04 Form: Initial questionnaire for farm assessment for BhutanGAP certification
- BFDA-CS-PR7.2-01-FM-05 Form: Application for organic certification
- BFDA-CS-PR7.2-01-FM-06 Form: Initial questionnaire for farm assessment for organic certification
- BFDA-CS-PR7.2-01-FM-07 Form: Application register
- BFDA- CS-PR7.2-01-FM-08 Form: Review of application
- BFDA-CS-PR7.2-01-FM-09 Form: Acknowledgement of application

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Fig. 01 - Operation of Product Certification System

