GUIDELINES FOR APPLICANTS FOR PRODUCT CERTIFICATION

1. PURPOSE

To provide guidelines on what prospective applicant to product certification needs to know before filing the application taking certification.

2. SCOPE

This Guideline provides general information to the applicants on the grant of product certification license under the product certification schemes operated by BFDA-CS.

3. DEFINITION

3.1 Applicant is an organization that applies for a license under the Product Certification Schemes operated by BFDA-CS.

3.2 Application is the request for grant of license under the Product Certification Schemes operated by BFDA-CS.

4. RESPONSIBILITIES

4.1 Certification Manager is responsible for developing the guideline for applicants for product certification.

4.2 Certification Officer is responsible for making available of the general information to prospective applicants and the general public, through print, webpage or various other means.

5. GUIDELINES FOR APPLICANTS

5.1. The Product Certification Schemes operated by BFDA-CS is governed by the Food Act of Bhutan, 2005 and the Food Rules and Regulations of Bhutan, 2017, which gives BFDA-CS powers to grant licenses to producers to use the Standard Marks on their products which conforms to the requirements of the corresponding Bhutan Standard/Regulation. The Act also provides for penalties for violation of the Act.

5.2 Application

5.2.1 To get product certification, the prospective applicant applies in duplicate in the prescribed application forms together with the relevant supplementary information as under, along with an application fee, if applicable:

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

5.2.2 The applicant must ensure that the form for application and relevant supplementary information is complete and accompanied with all documents sought. If the application is found incomplete in providing adequate information, it is returned to the applicant with advice to submit the same duly completed. Every complete application is registered and acknowledged. The applicant is also requested to indicate convenient date for preliminary visit.

5.3 Evaluation

5.3.1 License to use the Standard Mark on a product is accorded only after BFDA-CS has ensured the capability of the client to manufacture/produce the product continuously in accordance with the relevant Bhutan Standard. This is ensured through factory/farm evaluation to ascertain the capability of the manufacturer/producer to produce products according to the relevant Bhutan Standard especially with respect to raw materials, process of manufacture, manufacturing capability and quality control facilities including testing equipment and supervisory staff.

Samples are tested in the factory/farm, where feasible, in order to bring out any deficiencies in test equipment /testing procedures and testing personnel as well as for spot establishment of quality of product. Simultaneously, samples are also drawn for testing in the independent laboratories for assessing conformity to the relevant standard.

5.4 Grant of license

5.4.1 The manufacturer is required to agree to operate a well-defined certification Scheme as approved by BFDA-CS from time to time, which inter alia prescribes the specific tests and the frequency for conducting them. In order to meet the expenditure incurred by BFDA-CS in operating the license, the client also has to agree to pay a marking fee fixed by BFDA-CS for the product, if applicable. License is granted only after the client agrees to these conditions and if the factory/farm inspection and test reports are satisfactory and the client signs the certification agreement.

5.4.2 Pre-requisites for grant of license

The basic requisites for the grant of license to use the Standard Mark by the client are:

a) The availability of manufacturing and processing equipment,

b) A test laboratory equipped to check quality characteristics of the product strictly in accordance with the test procedure detailed in the specification and should be manned by competent and qualified personnel,

c) The conformance of the product and raw material to quality characteristics as given in the relevant Bhutan Standard.

d) The applicant confirming acceptance to follow the Scheme of Testing and Inspection (STI) or set conditions and, to pay the marking fee (if applicable).

e) Documentation authenticating the premises of manufacture such as Certificates/ documentary evidence from relevant competent authorities indicating ownership of the premises by the applicant firm.

5.4.3 It shall be ensured that the licenses are granted within a maximum period of sixty working days from the date of registration of the application.

5.4.4 The requisites detailed above are satisfied before a license is granted to the client. Any deviation from prerequisites requires prior sanction of BFDA-CS who may, based on the merit of the case, permit relaxation in the in-house testing facilities.

5.5 Surveillance after the grant of license

5.5.1 After the grant of license, BFDA-CS carries out surprise periodic surveillance visits through technical auditors. During these surveillance visits, technical auditors check that the client is following the prescribed STI or standard requirements and all other relevant requirements. Sample(s) are also drawn and tested in the factory/farm to ascertain whether the product conforms to the requirements of the relevant Bhutan standard. Further, samples(s) are tested in independent laboratories recognized by BFDA-CS to ensure that the products are in conformity with the relevant Bhutan Standard.

5.5.2 In addition, samples are also drawn from open market for testing in recognized laboratories. It is ensured that the products bearing Standard Mark conform to the relevant Bhutan Standard, when manufactured and tested on continuous basis according to the relevant Scheme of Testing and Inspection.

5.6 Operation of license

5.6.1 License is considered for renewal when the renewal application is received before the date of expiry, performance is satisfactory and dues stand cleared.

5.6.2 License is not considered for renewal when the application is not received in time, received but performance is unsatisfactory and there exist no or little possibility of effecting an improvement

5.6.3 The license is cancelled when nonconformity of serious nature affecting health and safety is observed during inspection or independent testing. Any contravention of the licensing provisions or the STI considered serious in nature, for example, non settlement of complaints, not allowing technical auditor access during working hours for the purpose of inspection, using the Mark for types /varieties not included in the scope of the licence etc.

5.7 The scheme of testing and inspection (STI)

5.7.1 The STI document is a tool for in-process control in production for a given article /process. In order to ensure consistency in the evaluation of product conformity to specification, the licensee has to follow an agreed Scheme of Testing and Inspection (STI) while exercising self marking rights and maintain records of the test results.

5.7.2 An applicant applying for Certification license is required to accept and implement the STI after grant of license.

5.8 Certification marking fees

5.8.1 The Certification marking fee is levied to meet administrative and surveillance expenses incurred by BFDA-CS for rendering the necessary services in relation to certification of product.

5.8.2 With a view to encourage certification activities in the small scale sector, and to reduce the burden on account of low volumes of production a lump sum concession is given to small scale industries. The applicant is required to give his acceptance of marking fees prior to the grant of license.

5.9. Obligation of licensees

a) Nominate responsible person(s) to deal with all matters concerning product certification schemes operated by BFDA-CS Certification to keep the firm's top Management informed and to coordinate audits with BFDA-CS.

b) Pay minimum marking fee in advance. If it is not received in time, your license may be allowed to expire.

c) Supply one copy each of the up-to-date Bhutan Standard(s) and the Scheme of Testing and Inspection/set conditions attached to the license to all concerned especially to the personnel of Quality Control Department.

d) Inform BFDA-CS immediately if there are any changes in the name of the organization, status, factory/farm premises, management, process, design and brand names.

e) Apply for renewal (along with the license and fees) one month in advance of the expiry date of the validity period of your license.

f) Comply with all instructions of BFDA-CS immediately, especially when a license is under suspension or is cancelled /deferred/expired.

g) Get prior approval from BFDA-CS of the design, proportions and manner of applying the Standard Mark.

h) Apply Standard mark only on those varieties and batches/lots of production which conform to the relevant Bhutan Standard and for which firm holds a valid license.

i) Maintain records of inspection and testing indicated in the Scheme of Testing and Inspection (STI)/set conditions attached to license.

j) Extend all possible co-operations to the Technical Auditors of BFDA-CS coming for checking production line and records, testing in the factory premises and drawl of samples for independent testing.

k) Dispatch the sample(s) expeditiously to the Laboratory as instructed by the Technical Auditor with advice to the concerned Certification Officer of BFDA-CS

Note – See Certification agreement for details

5.10 Privileges of licensees

The privileges enjoyed by BFDA-CS licensees include:

a) Use certification mark on letterheads, in advertisements, Brochures, compliments and for other promotional purposes.

REFERENCES:

BFDA-CS-PR7.2-01 Procedure for receipt, review and registration of application
BFDA-CS-PR7.4-01 Procedure for processing of application for certification
BFDA-CS-PR7.6-01 Procedure for grant of certification
BFDA-CS-PR7.9-01 Procedure for surveillance of certified clients
BFDA-CS-PR7.9-02 Procedure for recertification (renewal)