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|  | <b>BHUTAN FOOD AND DRUG AUTHORITY<br/>CERTIFICATION SERVICES</b> |          |             | <b>GUIDELINES</b> |
|  | DOC. BFDA-CS-GL-7.2-01   | ISSUE 03 | REVISION 00 | 01 MARCH 2023     |

## **GUIDANCE FOR CLIENTS ENQUIRING ABOUT PRODUCT CERTIFICATION**

### **1. PURPOSE**

To provide uniform guidance for clients enquiring about product certification.

### **2. SCOPE**

This Guidance provides general information to the clients enquiring about the product certification schemes operated by BFDA-CS.

### **3. DEFINITION**

3. Product Certification is the provision of inspection and impartial third party certification that fulfillment of specified requirements for products, often contained in Standards has been demonstrated.

### **4. RESPONSIBILITIES**

4.1 Certification Manager is responsible for developing guidance for clients enquiring about product certification.

4.2 Certification Officer is responsible for making available of this general guidance to the clients enquiring about product certification, through print, webpage or various other means.

### **5. GUIDELINES**

#### **5.1 General requirements**


5.1.1. The prospective applicant for product certification may avail the form for Application and other relevant supplementary information as under, from our website [www.bafra.gov.bt](http://www.bafra.gov.bt) or from the Certification Services at the BFDA head office:

- 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

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

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

5.1.3 Applicants who are group producers for organic and BhutanGAP certification should have the registration certificate from the Department of Agriculture Marketing and Cooperatives.

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5.1.4 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

5.1.5. Applicants for food product certification should have:

- a. valid trade license from the Ministry of Economic Affairs.
- b. valid food safety license from BFDA.

5.1.6. Applicants are required to provide a Scheme of Testing and Inspection (STI) including a Flow Chart and/or records of routine inspection and testing based on the requirements of the specified Standard during the pilot phase and where these had not been recorded because production had not started, the applicant should provide plans in the form of Quality Control (QC) sheets, etc. to record such data.

5.1.7. Applicants are required to submit copies of relevant documents demonstrating conformance to the legal and statutory requirements.

5.1.8. The license shall be renewed every three years.

#### **5.1.9. License Fee**


Currently, the product certification services offered by BFDA-CS is on gratis and therefore, the license fee is not applicable.

### **5.2 Requirements for the Quality Manual/ Quality Plan/Internal Control System of a product**

5.2.1 The Quality Plan of a product shall be developed by the client and a copy of it shall be submitted together with the completed application form and other relevant supplementary information for Product Certification. The Quality Plan shall conform to this Scheme.

5.2.2 The Quality Plan should as a minimum have the following information in the order listed:

- a) A Title Page bearing
  - i) Company Name
  - ii) Title of document- including name of product (Generic and Brand)
  - iii) Effective date of document
  - iv) Authorization; Name and Signature of Head of Company
- b) Table of Contents
- c) A factory/farm layout showing:
  - i) Processing equipment

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- ii) Warehouse or Storage Area (for raw materials, packaging materials and finished product)
  - iii) Hygienic facilities (Hand washing facilities, Staff toilet(s), changing room(s) etc)
  - iv) Production/harvesting areas and conventional areas
  - v) Production/harvesting areas and conventional areas
- d) An organogram showing designations and lines of communication of personnel in the factory/farm establishment.
- e) Descriptions and specifications data (information) on raw materials, finished product, processing, processing equipment, contact surfaces and measuring devices.
- f) Process flow diagram for product indicating all control points
- g) Standard operating procedures (SOP), Plans and Policies:
- i) SOP for Assessing quality of raw materials, processing and finished product
  - ii) SOP for Cleaning Equipment, Contact surfaces, Processing area and General factory premises.
  - iii) SOP for Handling Customer Complaints
  - iv) SOP for Product Recall
  - v) Staff Training Plan
  - vi) Staff Health and Hygiene Plan
  - vii) Pest Prevention and Control Plan
  - viii) Waste Management Plan
- h) Monitoring Forms (MF) for Quality Control Activities
- i) MF for the quality of raw materials, packaging materials, processing and finished product.
  - ii) MF for Corrective Action
  - iii) MF for Cleaning and General Housekeeping Activities
  - iv) Customer Complaint Record Forms
  - v) Staff Training Record Forms

## 6. 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