BHUTAN FOOD AND DRUG AUTHORITY

CERTIFICATION SERVICES

FOOD PRODUCT CERTIFICATION SCHEME

PRODUCT CERTIFICATION SCHEME (PCS) - TYPE 5

1. INTRODUCTION

1.1 To assist the industries and commerce in Bhutan for trade faciltation and product safety and inline with the mandates conferred by Food Act of Bhutan 2005, Bhutan Food and Drug Authority (BFDA) provides food product certification services.

1.2 Product certification is the provision of inspection and impartial third-party certification that fulfillment of specified requirements has been demonstrated. Product certification is carried out by product certification bodies conforming to ISO/IEC 17065 (*Conformity assessment: General requirements for bodies certifying products, processes and services*). Specified requirements for products are contained in standards (Technical Regulations or National Standards) or Scheme Document. Product certification can facilitate trade, market access, fair competition and consumer acceptance of products on a national, regional and international level. The fundamental objectives of product certification are to address the needs of consumers, users and, more generally, all interested parties by giving confidence regarding fulfillment of specified requirements and to allow suppliers to demonstrate to the market that their product has been certified to fulfill specified requirements by an impartial third party body.

1.3. This product certification scheme is designed for Type 5 scheme (See Box 01) operated by Bhutan Food and Drug Authority Certification Services (BFDA-CS) related to the certification of tangible products currently covered under Product Certification Scheme as described in ISO/IEC 17067:2013 to conform to the requirements of ISO/IEC 17065:2012.

BOX 01

SCHEME TYPE 5

The surveillance part of this scheme allows for the choice between periodically taking samples of the product either from the point of production, or from the market, or from both, and subjecting them to determination activities to check that items produced subsequent to the initial attestation fulfil the specified requirements. The surveillance includes periodic assessment of the production process, or audit of the management system, or both. The extent to which the four surveillance activities are conducted may be varied for a given situation, as defined in the scheme. If the surveillance includes audit of the management system, an initial audit of the management system will be needed.

ISO IEC 17067:2013

2. SCOPE

This Product Certification Scheme covers products certified by BFDA-CS based on national standards, technical regulations or other standards as specified by the clients. It supplements Quality Manual which describes the main product certification scheme. BFDA-CS's Food Product Certification is based on scheme requirement Type 5 and is developed on the guidelines provided in clause 5 of ISO/IEC 17067:2013 and ISO/IEC TR 17026:2015.

- ISO/IEC 17067:2013 Conformity Assessment-Fundamentals of product certification and guidelines for product certification schemes.
- ISO/IEC TR 17026:2015 Conformity assessment - Example of a certification scheme for tangible products.

3. TERMS AND DEFINITIONS

For the purposes of this document, the terms and definitions given in ISO/IEC 17000, ISO/IEC 17067, ISO/IEC 17065 in addition to following shall apply.

3.1 Certification system

Rules, procedures and management for carrying out certification.

3.2 Certification scheme

Certification system (3.1) related to specified products, to which the same specified requirements, specific rules and procedures apply.

Note 1- The rules, procedures and management for implementing product, process and service certification are stipulated by the certification scheme.

3.3 Scheme owner

Person or organization responsible for developing and maintaining a specific certification scheme (3.2)

Note 1- The scheme owner can be the certification body itself, a governmental authority, a trade association, a group of certification bodies or others.

4. GENERAL DESCRIPTION OF THE BFDA-CS SCHEME

4.1 Development and operation of the BFDA-CS product certification scheme

BFDA-CS food product certification scheme has been developed and is being operated on the basis of guidance provided in clause 6 of ISO/IEC 17067:2013 and ISO/IEC TR 17026:2015. This BFDA-CS scheme shows how those general provisions are implemented in a Scheme type 5 product certification operated by BFDA-CS.

4.2 Outline of the BFDA-CS food product certification scheme

The food product certification scheme contained reflects a Scheme type 5 product certification scheme. It includes the following functions, activities and elements, which are further described in this document:

4.2.1 Selection (see Clause 5):

i) Specified requirements for the products covered by the scope of the BFDA-CS scheme can be national standards, technical regulations or other standards as specified by the clients. The standards and Schemes of Testing and Inspection specified by the clients should not be lower than the country's requirements.

ii) Elements of the production process to be assessed and of the management system to be audited based on Management System developed by the company.

iii) Determination activities, and the basis on which those activities be undertaken by BFDA-CS are in accordance with ISO/IEC 17065 for product certification bodies. The services for testing are taken from bodies demonstrating the fulfillment of applicable requirements of ISO/IEC 17025 for testing, ISO/IEC 17020 for inspection and ISO/IEC 17021 for management system auditing.

iv) Sampling methods and frequency have been described in the procedures and guidelines (BFDA- CS-PR7.4-01 and BFDA-CS-GL7.4-01) Product specific sampling details have been given in the respective Schemes of Testing and Inspection (STIs).

v) Requirements which the manufacturer has to fulfill in order to gain and maintain certification of the product (e.g. signing a certification agreement), the ongoing operation of a management system, maintaining control over the use of the mark of conformity (BFDA-CS-GL4.1-02), advising BFDA-CS of changes affecting product conformity, and

vi) BFDA-CS certification requirements include:

- payment of prescribed fees for certification services rendered (if applicable),

- completing the certification agreement,
- providing information about changes to the certified product and
- providing access to certified products for surveillance activities.

4.2.2 Determination (see Clause 6), in which BFDA-CS scheme includes:

i) Evaluation of the product- The Team of competent inspector/auditor is constituted to conduct onsite evaluation in accordance with the laid down procedure where a sample for testing is also taken and witnessing of the sample testing is undertaken at the applicant/certified client's premises (partial or full requirements).

ii) Inspection of the production process and audit of other elements of the client's management system critical to managing product conformity through document review and onsite inspection.

The evaluation report is given as prescribed in the following procedure and its related formats. BFDA-CS-PR7.4-01 Procedure for processing of application for certification

4.2.3 Review of the evaluation results, decision on certification and certification of conformity (see Clauses 7, 8 and 9)

This review includes verification of the suitability, adequacy and effectiveness of selection and determination activities, and the results of these activities, with regard to fulfillment of specified requirements

- BFDA-CS-PR7.4-01 Procedure for processing of application for certification

4.2.4 Licensing and control of the mark (see Clause 10)

i) mark of conformity,
ii) publicity to clients,
iii) misuse of certification and marks of conformity

The details are elaborated in the followings:

- BFDA-CS-PR4.1-02 Procedure for use of license, certificates and marks of conformity
- BFDA-CS-PR -GL4.1-01 Guidelines for the use of standard mark

4.2.5 Surveillance (see Clause 11)

The surveillance ensures conformity to the standard during the period of validity of license. The surveillance activities include periodic assessment of:

i) testing and inspection of product samples, from the factory
ii) inspection of the production process and
iii) audit of the management system;
iv) drawl/testing of samples from the open market

- The details are elaborated in BFDA-CS-PR7.9-01 Procedure for surveillance of certified clients.

There is provision for the clients to apply for recertification to BFDA-CS before the expiry of license validity.

- The details are elaborated in BFDA-CS-PR 7.9-02 Procedure for recertification/renewal.

4.2.6 Termination, reduction, suspension and withdrawal of certification and license (see 10.6)

When a nonconformity with certification requirements is substantiated, either as a result of surveillance or otherwise, BFDA-CS shall consider and decide upon the appropriate action.

- This aspect is detailed in procedure BFDA-CS-PR 7.11-01 Procedure for termination, reduction, suspension or withdrawal of certification

4.2.7 Managing changes affecting certification (see Clause 12)

The changes affecting certification has been explained in the quality manual Clause 7.10 and elaborated in procedure BFDA-CS-PR7.10-01 Procedure for Managing Changes Affecting Certification

NOTE-These functions are consistent with the requirements specified in ISO/IEC 17065, in which the functions selection and determination are together referred to as "evaluation".

A description of the functions listed above appears in ISO/IEC 17000:2004 (See Fig 01)

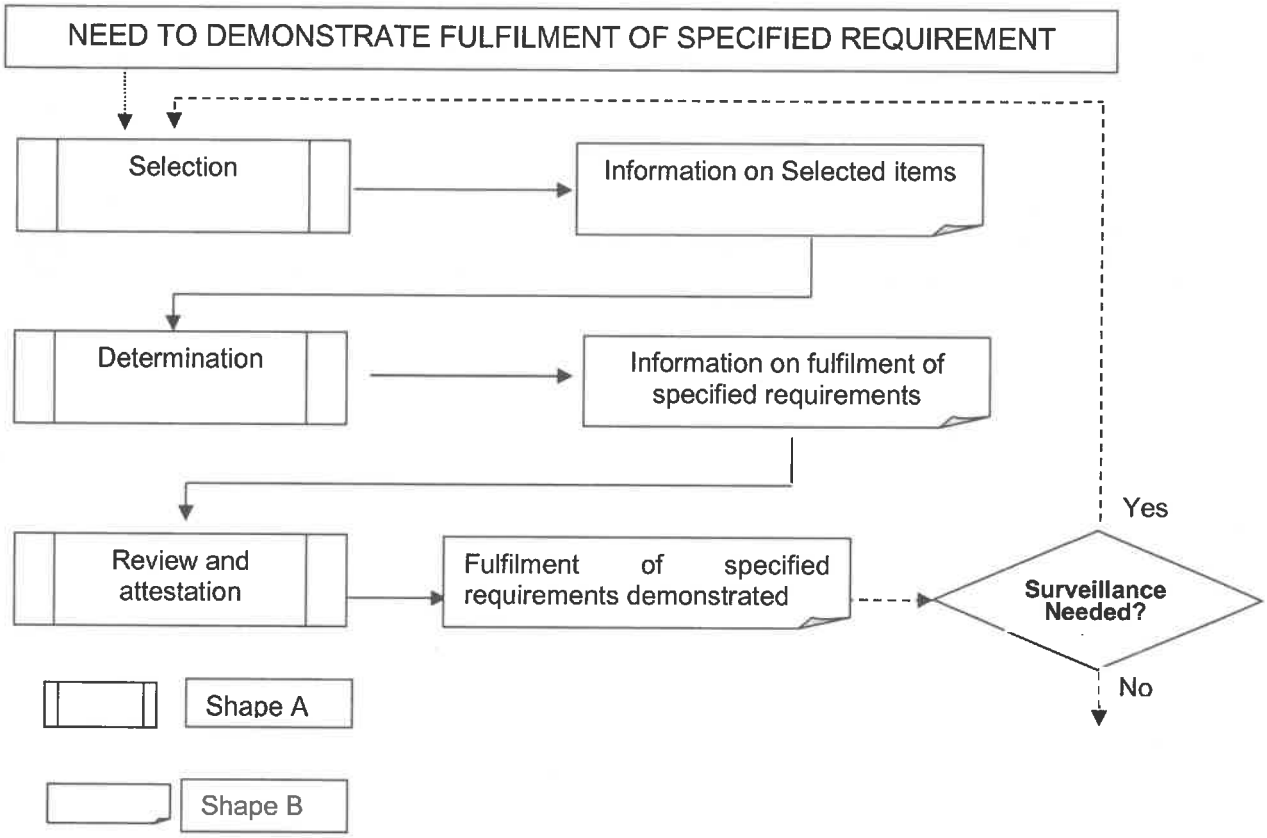


Fig 01 Functional approach to conformity assessment-solid arrows link the conformity assessment functions and their outputs /inputs & broken arrows express the possible needs or demands for conformity assessment. Shape A represents a conformity assessment function& Shape B represents output from a function and is also the input to the next function.

4.3 Scope of the BFDA-CS food product certification scheme

The scope of the BFDA-CS food product certification scheme is defined in terms of the types of products, the certification requirements and the geographical areas within which it operates.

Parties involved in the BFDA-CS scheme

The main parties involved in the operation of the BFDA-CS scheme are:

a) The scheme owner - the Certification Services of Bhutan Food and Drug Authority (BFDA-CS) under the Ministry of Health,
b) the organization that has a certification agreement with the BFDA-CS, or that has applied for one; this organization is referred to as 'the client'.

The prospective clients for food product certification can be cottage and small industries, as well as well-established food processing units.

The food product certification scheme owner is the BFDA-CS who is also the certification body. The scheme owner is responsible for the rules, procedures, management and integrity of the BFDA-CS food product certification scheme.

BFDA-CS as the Scheme owner may involve other parties such as accreditation bodies [see ISO/IEC 17067:2013, 6.5.1 f)] or sub-contractors (see ISO/IEC 17067:2013, 6.5.10) to assist them. Further information for the scheme owner and the development of the scheme can be found in ISO/IEC 17067:2013, 6.3 and 6.4.

BFDA-CS may outsource some activities to other organizations but always retains responsibility for the outcome. The review, decision and certification cannot be outsourced.

The client is often the manufacturer, who may use sub-contractors for some of the production operations, but sometimes the manufacturer's agent or another organization in the supply chain (e.g. a distributor) can act as the client and seek certification. In such cases, the client normally has no control of the manufacturing processes and no access to the production facilities. Before signing a certification agreement, the client needs to be able to ensure that the BFDA-CS can perform all necessary inspection activities of the production processes and the manufacturer's quality management system.

5. SELECTION

5.1 Specified requirements

Selection of elements in the BFDA-CS scheme within the declared scope (see 4.3) specifies the requirements that the products are intended to fulfill the product requirements. These requirements are specified by reference to national and international standards, technical specifications or scheme documents that have been developed in accordance with ISO/IEC 17007:2009.

In addition, there are further requirements for the client to fulfill (i.e. certification requirements), including the following:

- payment of prescribed fees for certification services rendered (if applicable),
- completing the certification agreement,
- providing information about changes to the certified product and
- providing access to certified products for surveillance activities.

5.2 Determination procedures

This BFDA-CS scheme provides details of the procedures to be used for determination activities, such as:

a) sampling, testing and other evaluation activities where these have not been adequately specified in the product requirements or scheme documents;
b) assessing the production process; and
c) auditing those elements of the client's management system which are identified as critical to ongoing product conformity.

5.3 Sampling processes

This BFDA-CS scheme specifies the sampling methods to be used for evaluation. Samples need to be:

a) statistically representative of the population of products to be certified;
b) made using components and sub-assemblies identical to those used in production; and
c) made using production tools and assembled using methods established for the production run.

Where evaluation is performed on prototype samples, further evaluation of subsequent production samples is necessary.

BFDA-CS-GL7.4-01 Guidelines for drawal, coding, sealing and dispatch of samples

5. 4 Application for certification and certification contract

5.4.1 Sequence of a certification cycle and involved activities

BFDA-CS provides the potential client with necessary information in the form of a brochure or informative documents to understand and follow the rules for the specific certification scheme. These rules are publicly available and provided on demand.

BFDA-CS-GL7.2-01 – Guidance for clients enquiring about product certification

BFDA-CS-GL7.2-02 – Guidelines for applicants for product certification

The client makes an application to BFDA-CS for certification of its specified products. The application provides the BFDA-CS with all necessary information as prescribed in 7.2 of ISO IEC 17065:2012 and elaborated in clause 7.2 of the Quality Manual to enable it to plan the evaluation and certification process.

Once the application is received from the client, BFDA-CS checks that the information provided by the client is clear and sufficient and, if it is not, asks the client for the necessary clarification or additional information.

- BFDA-CS-PR 7.2-01 Procedure for receipt, review and registration of application
- BFDA-CS-PR 7.4-01 Procedure for processing of application for certification

Flow diagram of product certification is given in Fig. 02

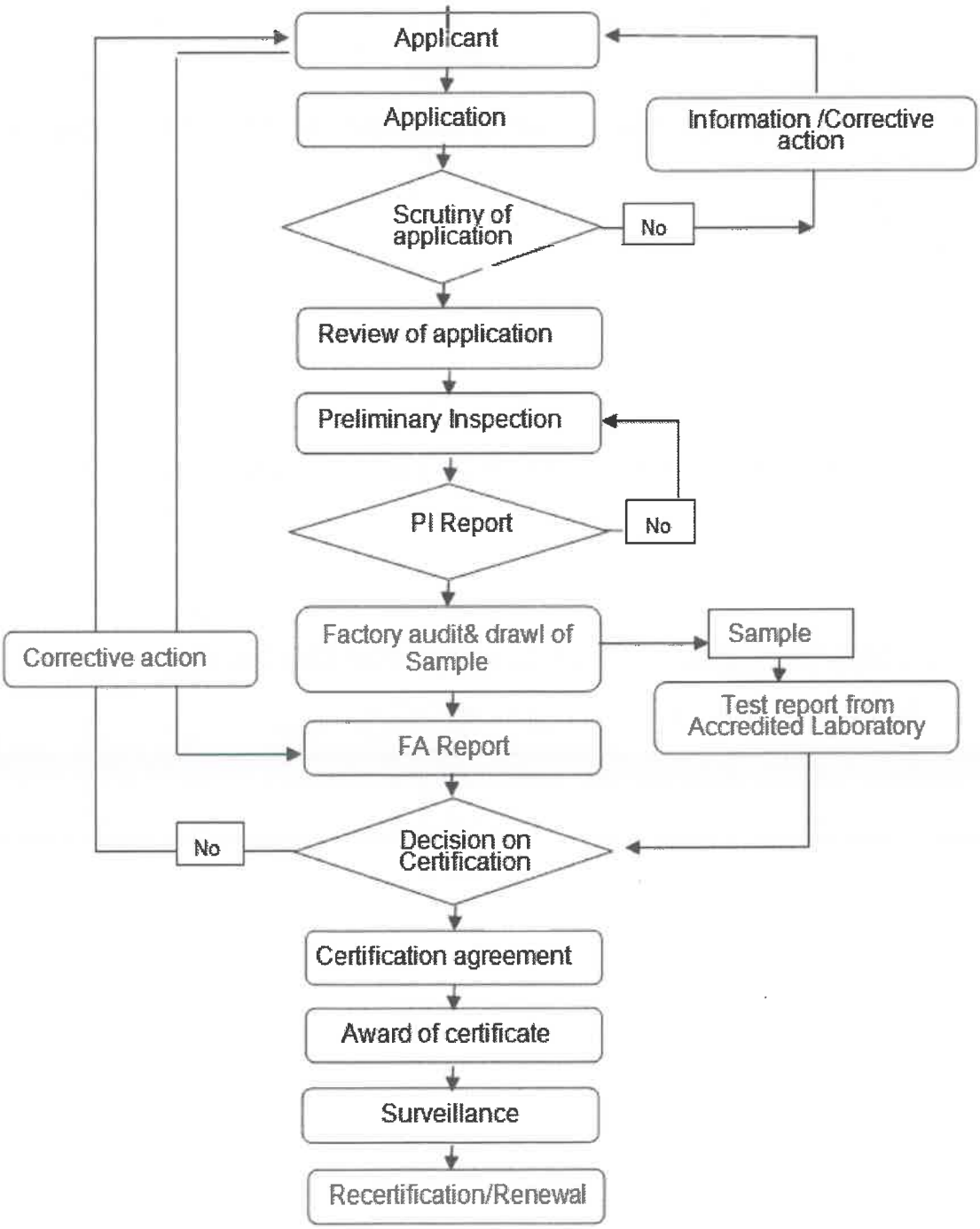


Fig.02 Flow diagram for Food Product Certification

6. DETERMINATION

6.1 General

The BFDA-CS gathers information to determine the extent to which the client demonstrates its fulfillment of product certification requirements.

6.1.1 Evaluation plan

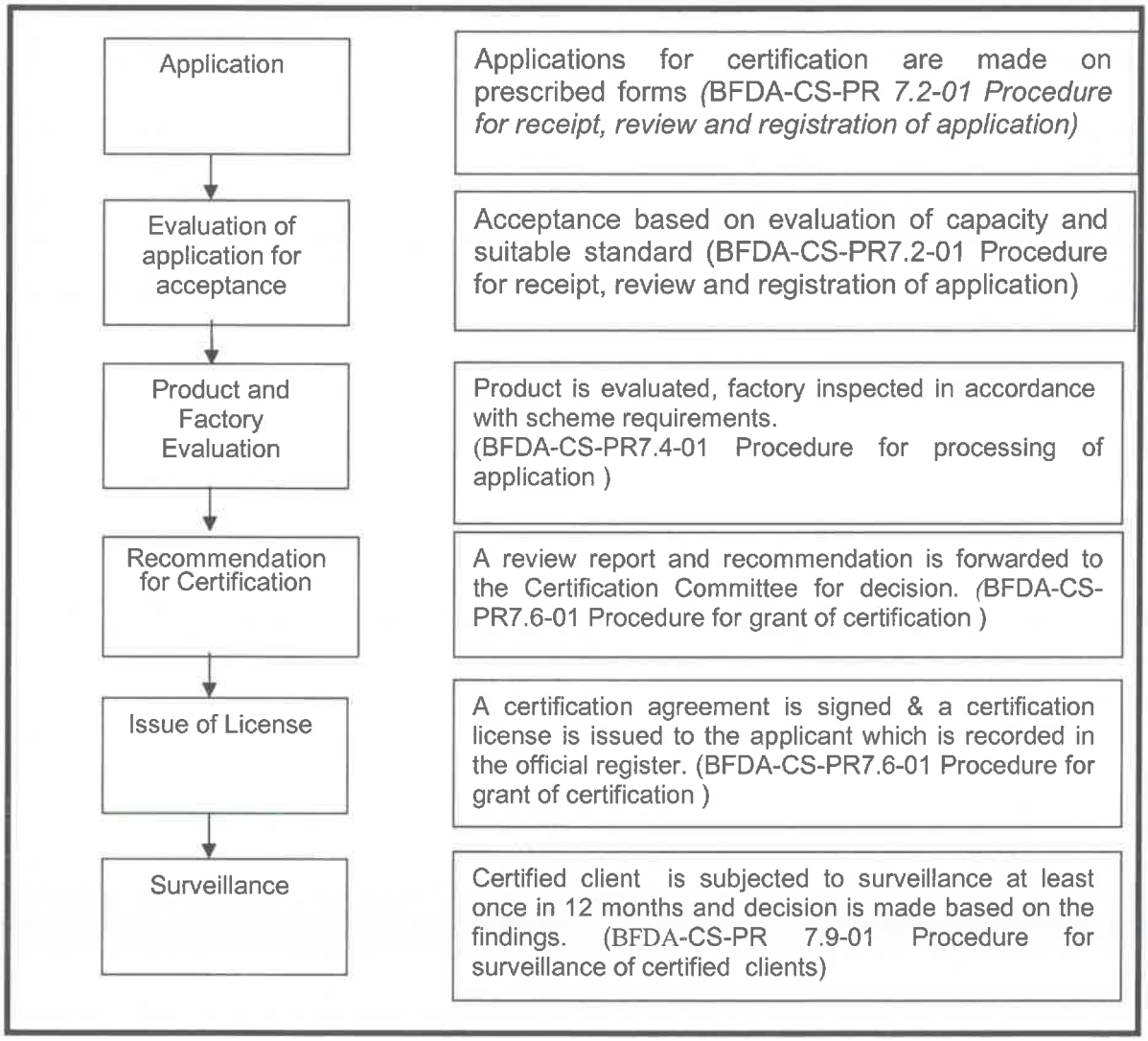
From the information provided in the application, the BFDA-CS ascertains that it has the competence and capability to undertake the work.

Based on the scheme the BFDA-CS prepares an evaluation plan setting out:

a) the product type (e.g. model identification) for which certification is sought,
b) the Bhutan standards and other normative documents that specify the product requirements,
c) the evaluation methods and procedures to be used,
d) the product samples and/or the sampling procedures required for evaluation,
e) the methods and procedures to be used when assessing the production process,
f) the coverage and the extent of the auditing of the management system,
g) the personnel and other resources, including outsourcing, to be used for the evaluation.

BFDA-CS has prepared a generic plan (See Fig.03) that is used for all certification evaluation activities under this scheme. But some time an individual plan for each client or individual evaluation is also prepared.

Fig.03 Process plan for operations of product certification



BFDA-CS advises the client of the plan, including any financial and timescale aspects required by the BFDA-CS scheme, and ensures that the client has completed, or has undertaken to complete, the certification agreement.

After confirmation of the acceptance of the application, BFDA-CS makes the necessary arrangements with the client for the initial evaluation in accordance with the evaluation plan and inspection plan. The determination activities are:

a) initial testing and examination of the product,
b) inspection of the production processes, and
c) audit of the elements of the management system addressed by the client that are critical to product conformity.

BFDA-CS is responsible for all actions included in the particular certification scheme, including sampling, testing, inspection of the production process, auditing of the management system, and surveillance of the certified product.

6.1.2 Acceptance of conformity results generated prior to the application or provided by the client

This BFDA-CS food product certification scheme accepts conformity assessment results (including such items as test results and management system certification) which are generated prior to the application, or are provided by the client. In accordance with ISO/IEC 17065:2012, 6.2 and 7.4.5, BFDA-CS takes responsibility for these conformity assessment results.

In order to cover this responsibility under this scheme BFDA-CS:

a) Checks that the conformity assessment results relate to the certification requirements; and

b) Identifies whether the conformity assessment results come from a body that fulfils the applicable requirements of ISO/IEC 17020 for inspection, or ISO/IEC 17021-1 for management system or ISO/IEC 17025 for testing, or are accredited to these standards with an accreditation scope relevant to the certification requirements.

6.2 Initial testing and examination

6.2.1 Conduct of initial testing and examination

The product evaluation is carried out in accordance with the methods specified in the applicable standard(s) and the procedures specified by the BFDA-CS food product certification scheme. The objective is to ascertain if the product fulfils the specified requirements.

Testing facilities used in product evaluation should demonstrate to BFDA-CS that they meet the technical requirements of ISO/IEC 17025:2017. This can be demonstrated by:

a) the testing facility having a current accreditation as fulfilling the requirements of ISO/IEC 17025 with a scope of testing covering the test methods established by the normative document for the product being certified, or

b) the assessment of the competence of the testing laboratory, if not accredited, by BFDA-CS in accordance with BFDA-CS-PR 6.2-01 Procedure for Laboratory Recognition Scheme using a suitably competent laboratory assessor, including the witnessing of testing on a periodic basis, or

c) the testing laboratory having a peer assessment recognition by a competent organisation with a scope covering the product being certified.

If test results are accepted, test reports and samples are examined together to ensure that test results are applicable to product samples under consideration.

6.3 Evaluation of the production process and audit of the management system

6.3.1 General

Evaluation of the client's production process and audit of the elements of the management system critical to product conformity forms part of the initial inspection in accordance with this product certification scheme.

The client designates:

a) a responsible person as the main contact with BFDA-CS;

b) a person(s) with management responsibility for the technical performance of the production processes and management system.

6.3.2 Document review

The first stage of undertaking an evaluation of the production process and audit of the management system is a document review. BFDA-CS conducts a document review of the client's management system in order to determine the readiness for the onsite evaluation.

To facilitate the document review, the client provides information on the management system pertinent to the production process. The client makes available to BFDA-CS records that demonstrate the effective implementation of the management system.

BFDA-CS may, at its discretion, take into account the client's current management system certification, provided that the certification covers:

a) the scope of products being considered; and
b) the sites where the activities take place.

Consideration is given to the management system certification that is accredited and/or peer assessed in accordance with relevant International Standards (e.g. ISO/IEC 17021-1 and/or ISO/IEC 17040 General Requirements of peer assessment of conformity assessment bodies and accreditation bodies).

BFDA-CS shall review the list of testing equipment available within the applicant company to assess the capacity of the company to comply with the requirements of the specified Standard and its Scheme of Testing and Inspection.

BFDA-CS evaluates the information provided, requests additional information as needed, and determines whether the application can proceed to the onsite stage of the determination function.

6.3.3 On-site Inspection/Audit

6.3.3.1 General

BFDA-CS arranges a date for a visit to each of the client's site(s) where the certified product is produced and constitutes an inspection/audit team that includes persons competent in:

a) the applicable product requirements;
b) appropriate test and/or inspection procedures and techniques;
c) conformity assessment procedures; and
d) the management system requirements and audit methodologies as included in the BFDA- CS scheme.

The matters to be investigated by the inspection/audit team at the client's facilities include:

a) determine that all information provided in the application is correct and complete;
b) inspection of the production process;
c) audit of the elements of the management system critical to product conformity.

At the Preliminary Inspection Stage, the inspection/audit team thoroughly assess the applicant's readiness for Factory Audit. During this stage, the Scheme of Testing and Inspection (STI) is also prepared (for new Standards)/discussed (for existing STIs), the factory's capacity to comply with the requirements of the STI is assessed and availability of testing equipment for certification against the standard is also inspected. Also, other GHP and GMP related requirements in the factory are assessed.

At the Factory Audit Stage, the inspection/audit team thoroughly carries out process inspection of the products against the requirements and audit of management system. During the Factory Audit, the company's adoption and acceptance of the Standard and STI are established.

6.3.3.2 Production process

The production process is inspected include assessing the client through direct observation and examination of the production line and communicating with production personnel in accordance with BFDA-CS documented procedures to demonstrate:

a) the client has the necessary facilities, equipment, personnel and procedure for carrying out the tasks associated with producing the product in accordance with the product requirements;

b) the client's capability and competence to monitor, measure and test the product during and after production so as to assure conformity with the specific product requirements used in the BFDA-CS scheme;

c) that the client sampling and testing (whether it be in-house or outsourced) is undertaken in accordance with the certification requirements (including the specific product standards

and methods of tests) and the applicable requirements of ISO/IEC 17025 and the certification requirements;

d) taking of samples by BFDA-CS and subsequent verification of test results or inspection reports by BFDA-CS;

e) quality control of the product through the production process in accordance with the certification requirements, from the receipt of inputs, through all transformation processes, through to dispatch of the completed products in accordance with the Scheme of Testing and Inspection (STI) provided by BFDA-CS; and

f) the ability of the client to identify and separate nonconforming product and to maintain product traceability where there is a certification requirement.

6.3.3.3 Elements of the management system critical for product conformity

BFDA-CS audits the elements of the management system critical for product conformity (See Box 02) include reviewing:

a) procedures covering the production processes, including quality control, production resources and personnel competence that can affect product conformity,
b) documents and records control in relation to production processes and product conformity,
c) existing management system certifications and associated audit reports if any,
d) internal audits and management reviews,
e) procedures and records associated with product nonconformance, corrective and preventive actions,
f) the identification, marking, and marketing of conforming products in accordance with certification requirements and license agreements,
g) those management system processes that are carried out by the client as part of the product certification scheme, and that the client has the necessary planned arrangements to ensure that the management system processes will continue to be effectively implemented and maintained.

NOTE- BFDA-CS gives consideration to the amount of audit time when the client's management system is certified by an accredited or peer assessed quality management system certification body.

BOX 02

Management system elements critical for operation of product certification scheme:

a) General management system documentation (e.g., manual, policies, definition of responsibilities,
b) Control of documents,
c) Control of records,
d) Management review,
e) Internal audit,
f) Corrective actions,
g) Preventive actions.

Ref: ISO IEC 17065 Section 8

6.4. Nonconformities

BFDA-CS has specified in the scheme how situations of nonconformity with certification requirements are managed. If BFDA-CS is not satisfied that the client has demonstrated that certification requirements have been fulfilled, it informs the client of those aspects which do not comply with applicable requirements as nonconformities.

Under this scheme, nonconformities have been categorized as follows:

Minor Nonconformity:

- A deficiency in documentation, process control, procedures or test results that, when inspected in relation to other findings, indicates a low risk that the products do not meet the certification requirements.
- Minor nonconformities shall need to be addressed as early as possible but not later than 3 months (90 days) from the date these have been observed by the audit team.
- The client is required to undertake appropriate root cause analysis before deciding the corrective action. The client is required to carry out root cause analysis and propose corrective action(s) within 20 days from the date these have been observed by the audit team.
- When the minor nonconformity is issued to a new client, certification is not granted unless it is resolved within the stipulated time frame.
- When the minor nonconformity issued to a certified client remains unresolved even after the prescribed time frame, the nonconformities are liable to be upgraded to the higher categories, based on the judgement of the audit team.

Major Nonconformity:

- A deficiency in product test results, documentation, process control or a procedure that, when set in relation to other findings indicates a moderate to high risk that the products do not meet the certification requirements.

- Major nonconformities shall need to be addressed as early as possible but not later than 2 months (60 days) from the date these have been observed by the audit team.

- The client is required to undertake appropriate root cause analysis before deciding the corrective action. The client is required to carry out root cause analysis and propose corrective action(s) within 15 days from the date these have been observed by the audit team.

- When the major nonconformity is issued to a new client, certification is not granted unless it is resolved within the stipulated time frame.

- When the major nonconformity issued to a certified client is not resolved within the stipulated time frame, the certification may be liable for partial or complete suspension based on the nature of the nonconformity.

Critical Nonconformity:

- A deficiency when a direct food safety impact without appropriate action by the client is observed during the audit or when legality and/or certification integrity are at stake.

- Critical nonconformities shall call for immediate correction and corrective action based on appropriate root cause analysis. Such actions shall have to be completed and nonconformities resolved within 1 month (30 days) from the date these have been observed by the audit team.

- When the critical nonconformity is issued to a new client, certification is not granted unless it is resolved within the stipulated time frame.

- When the critical nonconformity issued to a certified client is not resolved within the stipulated time frame, the certification may be liable for partial or complete suspension or withdrawal based on the nature of the nonconformity.

For the implementation of the corrective actions based on the nonconformities raised, BFDA-CS may follow up for the necessary parts of the initial product evaluation, inspection and audit to verify the nonconformity has been adequately addressed. Depending on the nature of nonconformities, verification may be on-site or offsite.

6.5 Evaluation report

Following the initial product evaluation, inspection of production process and audit of the elements of the management system, and after satisfactory corrective action on any nonconformity, the Team Leader prepares a report on the evaluation team's findings. The report will be considered as part of the total package of evidence to demonstrate compliance with the certification requirements for making the certification decision.

7. REVIEW

When all determination activities have been completed, the results of initial product evaluation and the on-site inspection are available to ensure that they provide the necessary evidence that the product and the system for managing product quality fulfill the specified requirements.

The BFDA-CS shall assign 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 determination activities. If the evidence is sufficient, a recommendation for certification is made by the Reviewer.

8. DECISION

When the outcome of the review is positive, a decision is made to grant certification. For decision making, a Certification Committee is constituted, chaired by the Head of BFDA. The Head takes the certification decision based on the recommendations of Certification Committee considering the review report and information related to the evaluation, its review, and any other relevant information. When the outcome of the review is negative, a decision is made not to grant certification, the client is informed with the reasons for the negative decision.

9. CERTIFICATION (ATTESTATION)

Following the decision to grant certification, BFDA-CS issues a statement of conformity in the form of a license on the BFDA-CS prescribed format after Certification Agreement has been signed in accordance with BFDA-CS-PR4.1-01 Procedure for Legally Enforceable Certification Agreement. The license is valid for a period of three years, and is subject to at least one surveillance audit in 12 months. Subsequently, the list of certified clients is uploaded on the BFDA-CS website. Along with the Certification Agreement, BFDA-CS ensures that a separate agreement for processing the products in conformity with the specified Standard and its STI is also signed by the client.

After the license has been granted, the certified client may place the BFDA-CS scheme's certification mark on the product subject to conformity of the product to the requirements. BFDA-CS provides the standard mark together with the license with procedure and mode of application of the standard mark on the product.

10. LICENSING USE OF CERTIFICATES AND MARKS OF CONFORMITY

10.1 General

The use of the certificate mark is controlled through a licence issued by the BFDA-CS to each organization which uses them on, or in conjunction with, certified products.

The licensee may be different from the client to which the certificate was issued. Circumstances under which a different organization might be involved include:

a) The client sub-contracts the manufacture of the product, including the placing of the mark on the product, to another organization- the manufacturer would need to be a licensee;
b) A customer of the client applies its own label, including the mark, to the product under an agreement with the client- the customer would need to be a licensee;
c) Other similar cases.

In all cases, the client ensures that BFDA-CS team has access to the licensee's premises for the purposes of inspection of the production process and audit of the management system, initially and during surveillance.

10.2 Mark of conformity

BFDA-CS has developed BFDA-CS-PR 4.1-02 Procedure for use of license, certificates and marks of conformity in accordance with ISO/IEC Guide 23 and ISO/IEC 17030. The license document and mark of conformity are distinctive and are:

a) proprietary in nature, with legal protection as regards composition and control of use,
b) so coded or otherwise designed as to aid in the detection of counterfeiting or other forms of misuse, and
c) non-transferable from one product to another

The mark of conformity is directly applied to each individual product except where the physical size of the unit or the type of product does not permit this, in which case the mark may be applied to the smallest package in which the unit is marketed.

10.3 Other labeling

In certain circumstances, it may be appropriate to use other labelling in association with the certificate or mark of conformity, such as:

a) the name or logo of BFDA-CS where such cannot be determined from the certificate or mark of conformity used,
b) the name of the product classification where such is not completely obvious, and
c) identification of the relevant standard(s) including date of publication.

The certificate and labeling are used in accordance with the food product certification scheme.

10.4 Issuing of a license

BFDA-CS submits a Certification agreement to the licensee for signature. When the license agreement has been signed, BFDA-CS issues a license.

The licensing agreement addresses conditions under which the mark or certificate will be used, and establishes rules in the case of misuse. In addition, it is elaborated in the BFDA-CS-PR 4.102 Procedure for use of license, certificates and marks of conformity.

10.5 Misuse of the mark

BFDA-CS takes action when unauthorized, incorrect, or misleading use of the certificates or marks of conformity is found in accordance with provisions of Food Rules and Regulations of Bhutan 2017. The same is also covered under BFDA-CS-PR 4.1-02 Procedure for use of license, certificates and marks of conformity

Incorrect references to the certification scheme or misleading use of certificates or the mark found in advertisements, catalogues, etc., are dealt with by suitable actions, which could include legal or corrective action or publication of the transgression.

10.6 Termination, Reduction, Suspension or Withdrawal of license

10.6.1 Termination

BFDA-CS may terminate the license based on the request of the client.

10.6.2 Reduction

BFDA-CS may reduce scope of certification license upon the request of the client or as determined by the BFDA-CS, to exclude that part of the scope of certification not meeting the certification requirements.

10.6.3 Suspension

BFDA-CS may suspend the applicability of the license to a specific product for a limited period in the following cases:

a) if the surveillance shows nonconformity with the requirements of such a nature that immediate withdrawal is not necessary;

b) if a case of improper use of the certificate or the mark (e.g. misleading publications or advertisement) is not solved by suitable retractions and appropriate corrective actions by the licensee;

c) product not conforming to specified product standard (2 consecutive samples, from the factory or market, as determined by date of manufacture, fail to conform to the requirements of the product requirements),

d) if there has been any other contravention of the product certification scheme or the procedures of BFDA-CS.

The licensee is prohibited from identifying as certified any product that has been produced under a suspension of the license as applicable to that product.

A license may also be suspended after mutual agreement between BFDA-CS and the licensee for a limited period of non-production or for other reasons.

An official suspension of a license is confirmed by BFDA-CS in a registered letter to the licensee specifying the conditions of suspension (or by equivalent means). In this letter BFDA-CS shall also indicate the conditions to be fulfilled for considering lifting of suspension.

The licensee may give notice of appeal in accordance with BFDA-CS-PR 7.13-02 Procedure for appeals handling and BFDA-CS when considering the appeal may or may not (depending on the nature of the case) decide to proceed with its decision to suspend the license.

At the end of the suspension period, BFDA-CS investigates whether the indicated conditions for re-instituting the license have been fulfilled. On fulfilment of these conditions, the suspension is removed by notifying the licensee.

10.6.4 Withdrawal

Apart from the suspension of a license, a license is withdrawn in the following cases:

a) if the surveillance shows that the nonconformity is of a serious nature and no action has been taken as per the timeline given in the Certification Agreement,
b) if the licensee fails to comply with the due settlement of financial obligations (if applicable),
c) if there is any other contravention of the licensing/certification agreement,
d) if inadequate measures are taken by the licensee in the case of suspension.

In the above cases, BFDA-CS has the right to withdraw the license by informing the licensee in writing concerning the specification of a time limit.

The licensee may give notice of appeal, and BFDA-CS when considering the appeal may or may not (depending on the nature of the case) decide to proceed with its decision to withdraw the license.

Prior to withdrawal of a license, BFDA-CS decides upon the consequences in relation to products certified under the license, whether the mark of conformity needs to be removed from all products in stock, and if practicable, from products already sold, or whether a clearance of the stock of marked products is permissible within a short period of time. BFDA-CS decides if other actions are required, including, if necessary, in cases of a serious nature - informing the clients of the licensee, by the licensee or by BFDA-CS.

Furthermore, the license may be withdrawn in the following cases:

a) if the licensee does not wish to maintain the license,
b) if the standard or rules are changed and the licensee either will not or cannot ensure conformity with the new requirements (see 7.1),
c) if the product is no longer made or the licensee goes out of business,
d) on the grounds of other provisions specified in the licensing/certification agreement.

Withdrawal of a license may be publicized by BFDA-CS.

Termination, reduction, suspension or withdrawal of certification is detailed in BFDA-CS-PR 7.11-01 Procedure for termination, reduction, suspension or withdrawal of certification

10.7 Publicity by clients

The client has the right to publish the fact:

a) that an identified product has been certified,
b) that the client has been authorized to issue:
   i) use a certificate of conformity, or and
   ii) apply a mark of conformity for products to which the licence applies.

In every case, the client takes sufficient care of its publications and advertising that no confusion arises between certified and non-certified products.

The client does not specify any function or make any claim or the like in user information that could lead purchasers to believe that performance of the product or its use is covered by the certification when in fact they are not.

Instruction books manuals or other user information accompanying the product and related to the certification scheme are approved by BFDA-CS, if so required by the product certification scheme.

11. SURVEILLANCE

BFDA-CS food product certification scheme has defined surveillance process for certified clients (See BFDA-CS-PR 7.9-01 Procedure for surveillance of certified clients) to be conducted at site at least once in 12 months in order to provide confidence that products manufactured after the initial certification continue to fulfill the specified requirements.

The surveillance activities are selected according to the nature of the product and the consequences and probability of non-conforming products. The frequency with which the activities are carried out is specified in the BFDA-CS procedures and guidelines and can be

adjusted in the light of the results of previous surveillance cycles. For example, if nonconformities in products or the management system have been found, surveillance may be carried out more frequently until the necessary level of confidence is restored.

Surveillance activities cover all sites where manufacturing takes place and include one or more of the following:

a) Inspection of product samples shall be taken from the point of production and from the market for conformity with the standard requirements,

b) Testing of product samples taken either from the point of production, or from the market, or from both to check that they fulfil the specified requirements,

c) Inspection of the production process and auditing of the management system, including examination of the client's quality records relating to the production process.

It may not be necessary to repeat all of the elements of the initial product evaluation and such tests are classified as 'Type Tests'. In such cases, the surveillance may be based on examination only, or combined with more simple tests which ensure that the product is in conformity with the standard requirements. The client is informed about the results of the surveillance.

If surveillance reveals nonconformity with the certification requirements which cannot be readily remedied by the client, BFDA-CS decides what action to take.

The client keeps a record of any complaints relating to compliance with the certification requirements and documents the remedial actions taken. The client makes the records available to BFDA-CS on demand. If the client detects that non-conforming products have been released onto the market, recall process shall be initiated as per existing food recall procedure of BFDA and BFDA-CS shall be informed about the measures adopted.

12. CHANGES AFFECTING CERTIFICATION

12.1 Changes to product requirements

When applicable standards or other normative documents which are part of the certification requirements are changed, BFDA-CS shall fix the date on which the revised requirements of the documents will come into force keeping in view the other factors influencing the implementation (effective date reflecting the transition period).

The effective date of obsolescence of a standard or other normative document is communicated by BFDA-CS to all applicable clients to allow them adequate time to take appropriate action.

In those cases when the standard development organization responsible for the standard or other normative document defines the transition period until which the superseded document is valid, this date defines the obsolescence of the superseded document unless otherwise stated by law or by the BFDA- CS scheme.

Further factors that are considered when choosing the effective date include, but are not necessarily restricted to, the following:

a) Compliance with regulations or contractual obligations,
b) the urgency of complying with revised health, safety, or environmental requirements,
c) the length of time and financial costs for retooling and manufacturing a product complying with the revised requirements,
d) the extent of stock on hand and whether it can be reworked to meet the revised requirements,
e) avoidance of unintentional commercial advantage given to a particular manufacture or design;
f) operation constraints of BFDA-CS.

12.2 Changes to other BFDA-CS scheme requirements

BFDA-CS which is both owner of scheme and certification body informs its clients, if necessary, of other changes to the BFDA-CS scheme requirements such as:

a) Test and examination procedures where these are not contained in the standards or other normative documents that specify the product requirements,

b) Criteria and procedures for inspection of production processes and audit of management systems,

c) Conditions for licensing of the certification mark

d) Qualification criteria and procedures for conformity assessment bodies participating in the BFDA-CS scheme

12.3 Changes by client

The client informs BFDA-CS about any intended modification to the product, production process or management system which may affect the conformity of the product. BFDA-CS determines whether the announced changes require another initial testing and inspection or other further investigations. In such cases, the client is not permitted to release products under the certificate resulting from such changes until BFDA-CS has notified the client accordingly.

A client wishing to extend the scope of certification to additional types or models of products, to the same specified requirements as the products for which a certification is already granted, applies to BFDA-CS using prescribed application form. In such cases BFDA-CS

may decide not to carry out an inspection of production process or management system but to require or select test samples of the additional types of products to determine that they comply with the specified requirements. If the tests are successful, the scope of certification is extended and the license agreement may be modified.

If the client wishes to apply the certification to additional types of products, but to different specified requirements, or if the client wishes to apply for an extension of the certification to cover an additional facility that is not covered by the earlier license, it will be necessary to carry out those parts of the original application procedure which do not cover the new circumstances.

13. CONFIDENTIALITY

BFDA-CS is responsible for ensuring that confidentiality of information is maintained by its employees and those of its subcontractors concerning all information obtained as a result of their contacts with the client; this applies also to information obtained at the application stage. BFDA-CS-PR 4.7-01 Procedure for maintaining confidentiality of data and information.

14. PRODUCT LIABILITY

All questions related to product liability need to be dealt with on the basis of the national legal system.

15. COMPLAINTS AND APPEALS

The client has a right to complain to BFDA-CS about aspects of the service provided. The client may also appeal to BFDA-CS against its decisions on issuing, maintaining, extending, suspending, withdrawing or terminating certification. In all of these cases, BFDA-CS deals them in accordance with procedures for complaints and appeals process.

BFDA-CS-PR 7.13-01 Procedure for handling complaints
BFDA-CS-PR 7.13-02 Procedure for handling appeals

16 FEES

The certification services provided by BFDA-CS is on gratis.