BHUTAN FOOD AND DRUG AUTHORITY

CERTIFICATION SERVICES

ORGANIC PRODUCT CERTIFICATION SCHEME

ORGANIC PRODUCT CERTIFICATION SCHEME – TYPE 6

1. INTRODUCTION

1.1 To assist the organic farmers, producers, industries and commerce in Bhutan to gain market access and to promote food safety, and inline with the mandates conferred by Food Act of Bhutan 2005, Bhutan Food and Drug Authority (BFDA) provides organic certification services.

1.2 Organic Product certification is the provision of inspection and impartial third-party certification that fulfillment of specified requirements has been demonstrated. Product certification is an established conformity assessment activity that provides confidence to consumers, regulators, industry and other interested parties that products conform to specified requirements, including for example product performance, safety, interoperability and sustainability. Product certification can facilitate trade, market access, fair competition and consumer acceptance of products on a national, regional and international level.

1.3 In Bhutan, the National Organic Guarantee System is developed and managed by the National Centre for Organic Agriculture (NCOA) under the Ministry of Agriculture and Livestock. The Ministry of Agriculture and Livestock is the owner of the Bhutan Organic Mark and Bhutan Organic Standard. It also defines the rules for which conformity assessment systems are acceptable for verification of compliance to the Bhutan Organic Standard. BFDA is also mandated by the Ministry to operate organic certification based on Bhutan Organic Standard 2022 in conformity with the requirements of ISO/IEC 17065 (Conformity assessment: General requirements for bodies certifying products, processes and services). Therefore, BFDA has launched Organic Certification scheme through its Certification Services (BFDA-CS) in conformity with ISO IEC 17065:2012 to provide third party organic certification mark based on Bhutan Organic Standard to the producer/ producer groups. BFDA product certification scheme covering organic products is based on the existing Guideline on Bhutan Organic Certification System (BOCS) which was introduced since January 2013.

1.4 This organic product certification scheme is designed for Type 6 scheme (See Box 01) operated by 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 6

This scheme is mainly applicable to certification of services and processes. Although services are considered as being generally intangible, the determination activities are not limited to the evaluation of intangible elements (e.g. effectiveness of an organization's procedures, delays and responsiveness of the management). In some situations, the tangible elements of a service can support the evidence of conformity indicated by the assessment of processes, resources and controls involved. For example, inspection of the cleanliness of vehicles for the quality of public transportation. As far as processes are concerned, the situation is very similar. For example, the determination activities for welding processes can include testing and inspection of samples of the resultant welds, if applicable. For both services and processes, the surveillance part of this scheme should include periodic audits of the management system and periodic assessment of the service or process.

ISO IEC 17067:2013

2. SCOPE

The Organic Product Certification Scheme covers organic products conforming to BOS 02:2022 Bhutan Organic Standard 2022 certified by Certification Services, Bhutan Food and Drug Authority (BFDA-CS). It supplements Quality Manual which describes the main product certification schemes. BFDA Organic Product Certification is based on scheme requirement Type 6 (See Box 01) and is developed on the guidelines provided in clause 6 of ISO/IEC 17067:2013, ISO/IEC TR 17026:2015 and APAC TEC4-001&002.

- 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.
- APAC TEC4-001 Guidance on description of the scope of accreditation for product certification
- APAC TEC4-002-1 Guidance on the Application of ISO/IEC 17065 to Organic Certification.

3. TERMS AND DEFINITIONS

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

3.1 Buffer zone

It is a clearly defined and identifiable area bordering an organic production site from that of a conventional production unit;

3.2 Certification system

Rules, procedures and management for carrying out certification

3.3 Certification scheme

Certification system 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.

3.4 Conventional farming

It is described as the farming systems dependent on input of artificial fertilizers and/or chemicals and pesticides or which are not in conformity with the basic standards of organic production;

3.5 Conversion

It is the process of changing an agricultural farm from conventional to organic farm. This is sometimes also called transition. Conversion does not apply to handling and processing facilities.

3.6 Conversion period

It is the time between the start of organic management and the certification of crops as organic;

3.7 Parallel production

Means any production where the same unit is growing, breeding, handling or processing products which are indistinguishable both in a certified organic quality and a noncertified organic quality. Similarly a situation with "organic" and "in conversion" production of the same product is also parallel production;

3.8 Process- Set of interrelated or interacting activities which transforms inputs into outputs

Note- It includes food production processes, plant growth processes, Organic production processes, heat treatment processes in engineering etc.

3.9 Product- Is defined as result of a process

NOTE 1 Four generic product categories are noted in ISO 9000:2015:

a) services (e.g. transport),
b) software (e.g. computer program, dictionary),
c) hardware (e.g. engine, mechanical part),
d) processed materials (e.g. food processing).

NOTE 2- Organic products are result of processes.

3.10 Product requirement

Requirement that relates directly to a product, specified in standards or in other normative documents identified by the certification scheme.

NOTE- BOS 02:2022 Bhutan Organic Standard 2022

3.11 Producer

A farmer, company or the person legally responsible for the production and/or processing at farm level

3.12 Producer Group

A group of farmers (more than one farmer) coming together as a single unit for implementation and/or certification against the requirements stipulated in BOS 02:2022 Bhutan Organic Standard 2022.

3.13 Retroactive conversion

Means a recognition by the CB of a period of management before the operator applied for certification. Recognition should be based on production records and/or affidavits that the management during that period complied with the organic standard;

3.14 Scheme owner

Person or organization responsible for developing and maintaining a specific certification scheme. In this case it is Bhutan Food and Drug Authority (BFDA) under the Ministry of Health.

3.15 Split production

Means any production where the same unit is growing, breeding, handling or processing products both in a certified organic quality and a noncertified organic quality. Similarly a situation with "organic" and "in conversion" production of products is also split production;

3.16 Wild collection

It is the collection of wild plants and parts thereof, grown naturally, and without intervention.

4. GENERAL DESCRIPTION OF THE ORGANIC CERTIFICATION SCHEME

4.1 Development and operation of the Organic product certification scheme

The organic certification scheme has been developed and is being operated on the basis of guidance provided in clause 6 of ISO/IEC 17067:2013, ISO/IEC TR 17026:2015 and APAC TEC4-002-1 Guidance on the Application of ISO/IEC 17065 to Organic Certification.

This organic product scheme shows how those general provisions are implemented in a Scheme type 6 organic product certification scheme operated by BFDA-CS.

4.2 Outline of the Organic product certification scheme

The organic product certification scheme reflects a Scheme type 6 product certification scheme (See Box 01). 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 organic products covered by the scope of the scheme are those given in BOS 02:2022 Bhutan Organic Standard 2022 or contractual document,

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

iii) Determination activities, and the basis on which those activities be undertaken by BFDA are in accordance with ISO/IEC 17065 for product certification bodies. The services for testing are taken from bodies complying with the requirements of ISO/IEC 17025 for testing, services of inspection are taken when necessary from bodies complying to ISO/IEC 17020 requirements and services for auditing are taken from body accredited to ISO/IEC 17021-1.

iv) Sampling methods and frequency have been described in the procedures and guidelines (BFDA- CS-PR 7.4-01 and BFDA-CS-GL 7.4-01)

v) Requirements which the producer/producer group has to fulfill in order to gain and maintain certification of the product (e.g. signing a certification agreement (See **BFDA-CS-PR4.1-01-FM-03)** , 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 organic certification requirements includes:

- 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), which is BFDA-CS Organic 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 (BFDA-CS-PR7.4-01) where a sample for testing is also taken when necessary, and

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 BFDA-CS-PR 7.4-01 and formats specified in this procedure:

- BFDA-CS-PR7.4-01 Procedure for processing of application for certification
- BFDA-CS- PR7.4-01-FM-09 Facility audit checklist (organic)
- BFDA-CS- PR7.4-01-FM-11 Farm technical audit/inspection report

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 stated above and the results of these activities, with regard to fulfillment of specified requirements (BFDA-CS-PR7.4-01-FM-11, BFDA-CS-PR 7.4-01-FM-12)

- BFDA-CS- PR7.4-01-FM-14 Form for review and recommendation for grant of licence
- BFDA-CS- PR7.4-01-FM-15 Product certification marks decision form

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

- BFDA-CS-PR 4.1-01 Procedure for use of license, certificates and marks of conformity
- BFDA -CS-PR -GL7.1-01 Guidelines for the use of standard mark

4.2.5 Surveillance (see Clause 5.10)

The surveillance activities include:

i) testing and inspection of product samples (where necessary),
ii) inspection of the production process and
iii) audit of the management system.

The details are elaborated in BFDA-CS-PR 7.9-01.

- BFDA-CS-PR 7.9-01 Procedure for surveillance
- BFDA-CS-PR7.9-01-FM-02 Report of periodic farm surveillance audit

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.

- BFDA-CS-PR 7.9-01 Procedure for recertification/renewal
- BFDA-CS-PR7.9-02 –FM-01 Application form for recertification (renewal) of licence
- BFDA-CS-PR7.9-02- FM-03 Renewal inspection checklist

4.2.6 Termination, reduction, Suspension and withdrawal of certification and license (see 5.9.5)

The termination, reduction, suspension and withdrawal of certification and license has been explained in the quality manual Clause 7.11 and elaborated in procedure (BFDA-CS-PR7.11-01).

- BFDA-CS-PR7.11-01 Procedure for termination, reduction, suspension and withdrawal of certification

4.2.7 Managing changes affecting certification (see Clause 7)

The changes affecting certification has been explained in the quality manual Clause 7.10 and elaborated in procedure (BFDA-CS-PR 7.10-01).

- BFDA-CS-PR 7.10-01 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)

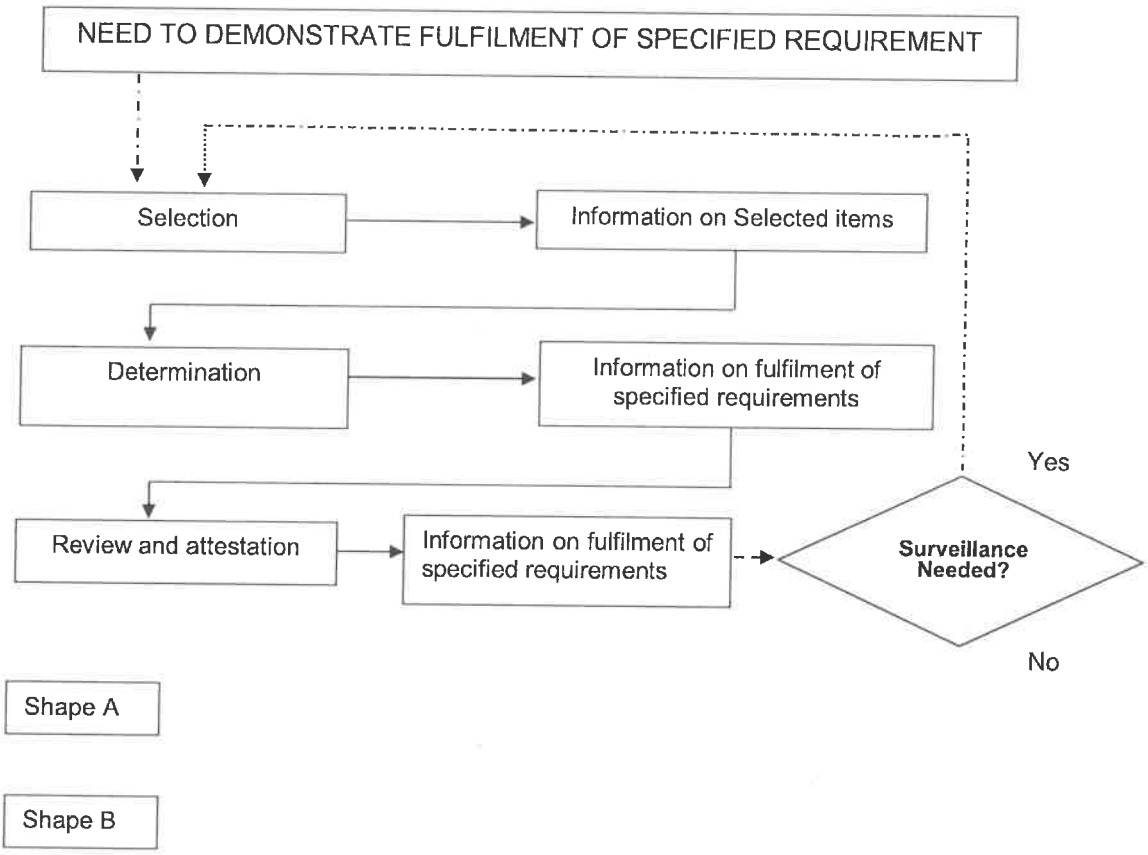

Fig.01 Functional approach to conformity assessment-solid arrows link the conformity assessment functions and their outputs /inputs & broken arrows express the possible needs or demands for conformity assessment. Shape A represents a conformity assessment function & Shape B represents output from a function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

4.3 Scope of the organic scheme

The scope of the organic certification scheme is defined in clause 2 above which is affected by the types of product, the certification requirements and the geographical areas within which it operates.

4.4 Parties involved in the organic scheme

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

a) the scheme owner - Bhutan Food and Drug Authority under the Ministry of Health,
b) BFDA-CS for third party certification, and
c) the client that has a certification agreement with the BFDA-CS, or that has applied for one.

This organic product certification scheme is owned by Bhutan Food and Drug Authority under the Ministry of Health. BFDA CS is the certification body. The scheme owner is responsible for the rules, procedures, management and integrity of the scheme.

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 the producer/producer group, who may use sub-contractors for some of the production operations, but sometimes the producer'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 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 producer's quality management system.

5. SELECTION

5.1 Specified requirements

Selection of elements in the organic 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 Bhutan Organic standards, technical specifications or contractual documents that have been developed in accordance with ISO/IEC 17007. For this Scheme the product requirements are based on BOS 02:2022 Bhutan Organic Standard 2022.

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 organic 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 contractual 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 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 & dispatch of samples

5. 4 Application for certification and certification contract

5.4.1 At the time of application, 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 along with updated version of Bhutan Organic Standard. These rules are publicly available and provided on demand.

BFDA-CS requires the applications to provide all necessary information as prescribed in 7.2 of ISO IEC 17065:2012 together with APAC TEC4-002 and elaborated in clause 7.2 of the Quality Manual to enable it to plan the evaluation and certification process.

BFDA-CS certification scheme requires inspection of additional areas given below, based on the information received from the applicants for certification:

a) access to all relevant facilities of organic production, including accounts and sales related records and other relevant documentation to provide adequate audit trails and traceability of organic certified produce and products,

b) access to record keeping system adapted to the type of production to enable BFDA-CS to retrieve necessary information and to seek verification of the production, storage, processing, purchase and sales,

c) access to inspect non-organic production units or units associated by ownership or management to the applicant client,

d) Access to units conducting repackaging or storage on behalf of the applicants as well as all outsourced activities and processes.

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, BFDA-CS-PR 7.4-01).

Flow diagram of sequence of organic product certification is given in Fig. 02.

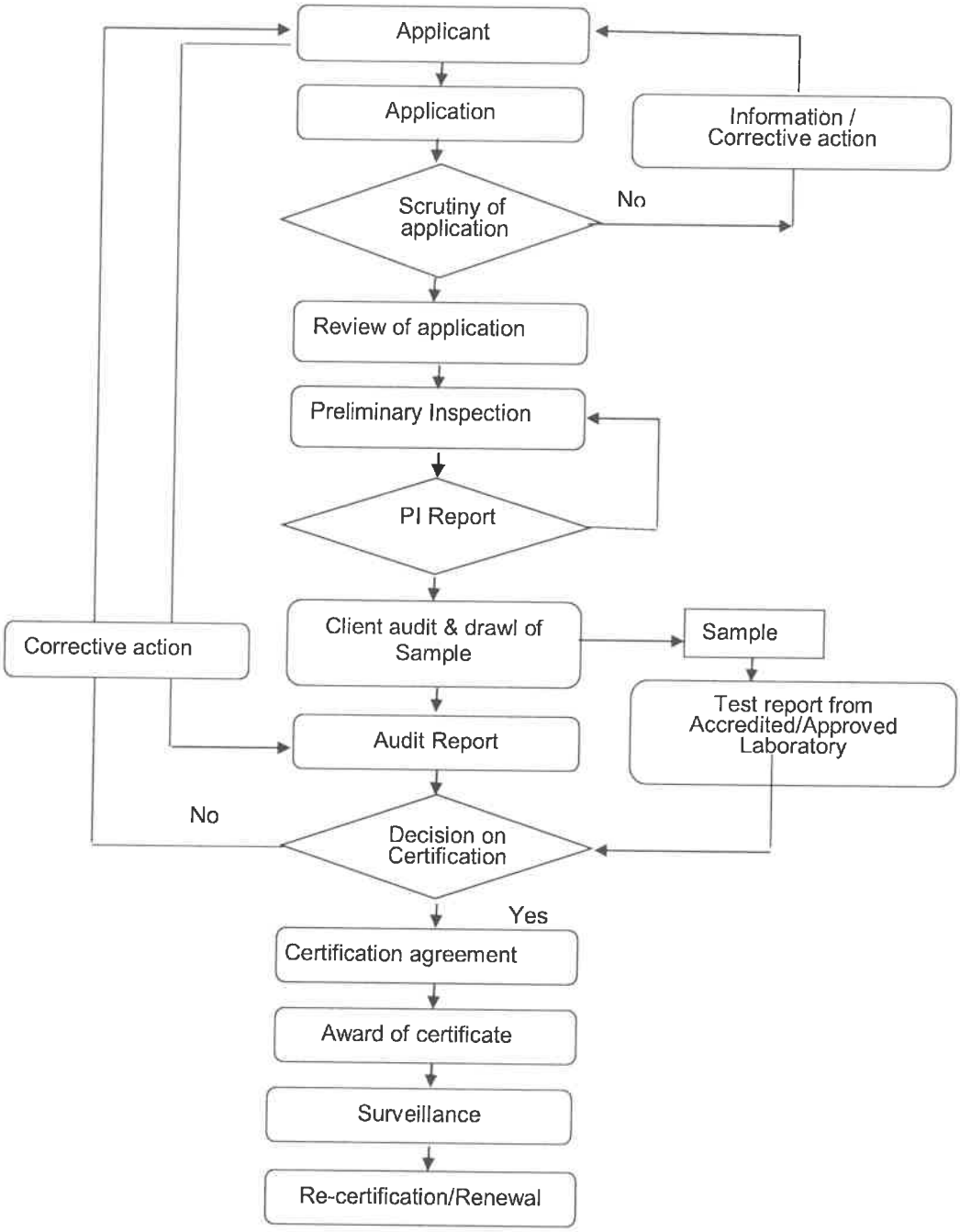

Fig.02 Flow diagram for organic product certification

BFDA-CS Organic certification scheme addresses the aspects, such as retrospective recognition of conversion period, separation and inspection of conventional production units, parallel/split production, group certification and wild collection, etc., in accordance with the relevant organic standard and certification requirements.

Procedures for aspects of risk assessment methodology and risk-based inspections, procedure for estimation of minimum inspection time, policy and procedure for sampling, surveillance assessments including provisions for unannounced inspections, categorization of non-conformities and corrective actions.

BFDA-CS certification process developed has provisions for residue testing, testing of genetically modified organisms, input materials and others as relevant to establish organic integrity in accordance with Bhutan Organic standard.

- 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
- BFDA-CS-PR7.1-01 Procedure for organic risk-based inspection
- APAC TEC4-002 (version 1)- Guidance on the Application of ISO/IEC 17065 to Organic Certification

6. DETERMINATION

6.1 General

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

From the information provided in the application, the BFDA CS ascertains that it has the competence and capability to undertake the certification work. BFDA-CS employs certification personnel competent for the functions they perform, including making required technical judgments, defining policies and implementing them.

BFDA-CS ensures that the identified Evaluators meet the educational and experience requirements established in BFDA-CS-PR6.1-01 and 02.

i) Education: Diploma or degree and/or Post-secondary education in any stream of science relevant to agriculture, horticulture, soil sciences or agro forestry areas sufficient to provide knowledge of basic agronomy, plant entomology, microbiology and pathology, and hygienic conditions in the production and processing of horticulture crops as relevant to the crops certified.

ii) Experience:

1. The evaluator shall have at least one year of full-time work experience in horticulture/ or agriculture production or agricultural inspection or regulatory enforcement, or the equivalent. For those joining BFDA with prior experiences either in auditing or

inspection, evidences in the form of log of work undertaken or certificate from the previous employer.

2. Successful completion of in-house training on ISO ISO 22000 or ISO 17021 or ISO 19001, appropriate training in respect of agriculture, organic farming, horticulture, soil sciences or agro forestry areas, agronomy, plant entomology and pathology, and hygienic conditions in the production and processing of horticulture crops.
3. All qualified evaluators shall undergo all the training relevant on audit criteria: Organic Standard
4. For initial qualification as an evaluator, atleast 10 man-days of inspections/audits in the agriculture sector which may include inspections done in regulatory capacity; successfully completed atleast 5 man-days of evaluations in organic farm sector in at least 2 different organizations, as an observer/trainee, under the leadership of a qualified evaluator.

BFDA-CS while assigning evaluators/inspectors/auditors for the purpose of evaluation should ensure that the same evaluator is not assigned to one client on a continuous basis. Normally change after one certification cycle or 3 years is considered appropriate.

The operators shall have the right to be informed about the identity of the inspector before the inspection visit, and to raise objections related to any potential conflict of interest.

The team nominated for the purpose of evaluation/inspection of the applicant should carry out an offsite review of the relevant information received through application process and ask for any additional information if necessary.

BFDA-CS-PR6.1-01: Procedure for management of competence of certification personnel
BFDA-CS-PR6.1-02: Procedure for selection and registration of certification personnel

6.1.1 Evaluation plan

Based on the application and organic certification scheme, the BFDA-CS prepares an evaluation plan setting out:

a) the organic product type 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 organic certification evaluation activities under this scheme. But sometime an individual plan for BFDA-CS

advises the client of the plan, including any financial and timescale aspects required by the 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 organic 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.

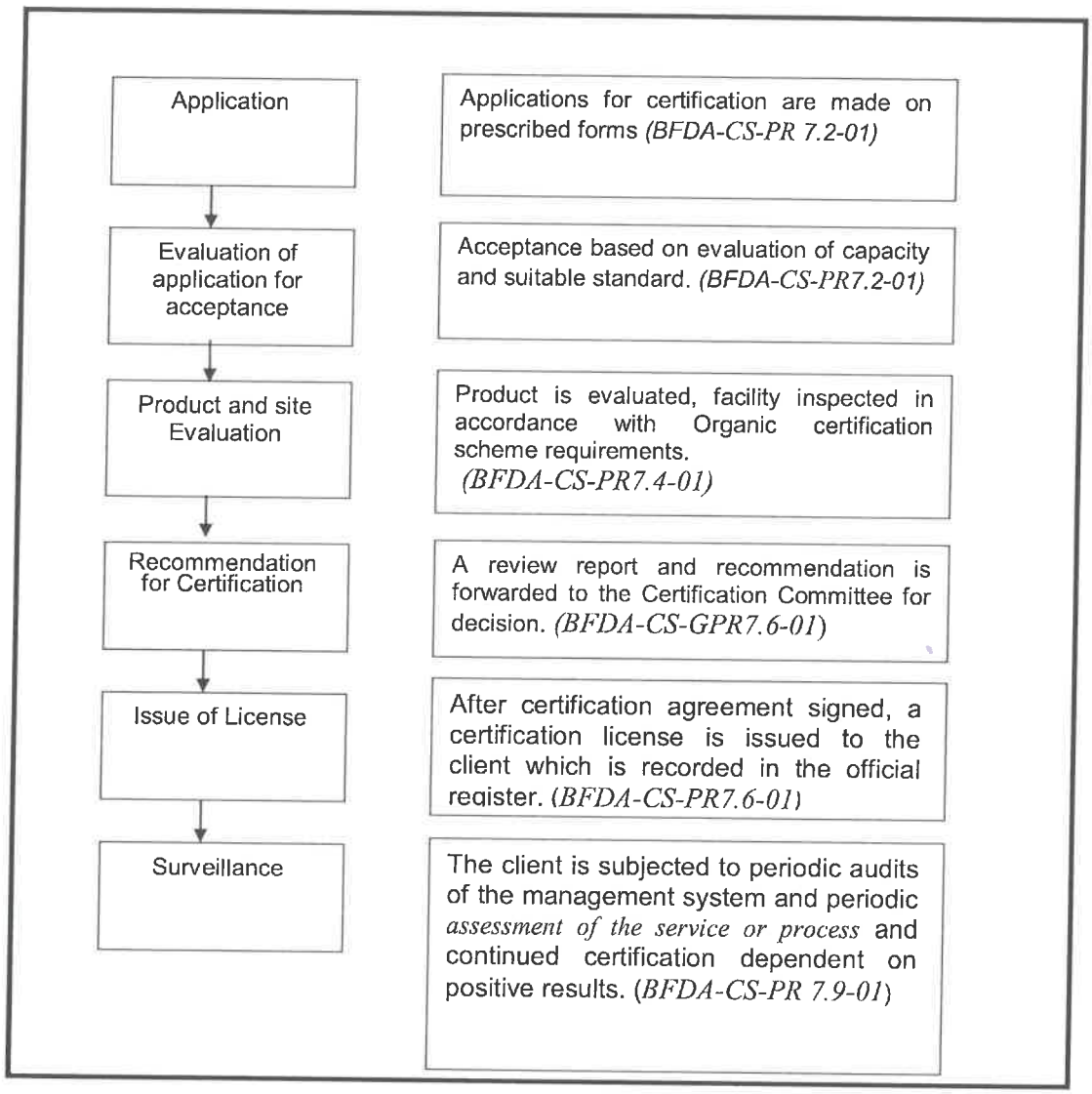

Fig.03 Process plan for operations of organic product certification

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

This 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, the BFDA-CS takes responsibility for these conformity assessment results.

In order to cover this responsibility under this organic scheme the 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 or ISO/IEC 17021 or ISO/IEC 17025, or are accredited to these standards with an accreditation scope relevant to the certification requirements.

Note- This is not in practice in the current operation of the product certification but it is kept here as an enabling provision.

6.2 Initial testing and examination

6.2.1 Conduct of initial testing and examination

The organic product evaluation is carried out in accordance with the methods specified in the BOS 02:2022 Bhutan Organic Standard 2022 and the procedures specified by the BFDA-CS organic 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-PR6.2-01 BFDA 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.

6.2.2 For organic products, the auditors shall take and analyze samples in each case if the auditors suspect possible contamination through the use of products or techniques not authorised for organic production.

- BFDA-CS-PR 6.2-01 BFDA Laboratory Recognition Scheme
- BFDA-CS-PR7.1-01 Procedure for organic risk-based inspection
- BFDA-CS-GL-7.4-01 Guidelines for Drawl, Coding, Sealing and Dispatch of Samples

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

6.3.1 General

Evaluation of the client's organic production process and audit of the elements of the management system critical to product conformity (See Box 02) forms part of the initial inspection in accordance with this organic 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 organic 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 also given to the extent that the management system certification is mutually recognized, through it originating from BFDA-CS that is accredited and/or peer assessed in accordance with relevant International Standards such as ISO/IEC 17021-1 and/or ISO/IEC 17040.

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 organic product is produced and constitutes an inspection/audit team that includes persons competent in:

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

6.3.3.2 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) visits of facilities, storage units, fields/farms to include visits to non-organic areas when necessary),
c) inspection of the production process,
d) audit of the elements of the management system critical to product conformity.
e) identification and investigation of areas of risk to organic integrity,
f) review of records, accounts, sales figures, etc.,
g) sampling and analysis, when necessary,
h) calculation and confirmation of input/output norms, production estimates, etc.,
i) interview not only with designated responsible persons on the farm/production units, but also with other levels of employees like farm workers, production staff, etc.,
j) verification that changes to the standards and to requirements, when necessary; and
k) verification that corrective actions of nonconformities

6.3.3.3 BFDA-CS carries out the following inspections:

a) Announced annual Inspections

a) Inspection of certified operators shall take place at least once annually.
b) Inspection of sub-contracted operators or units shall take place at least once annually.
c) Timing of inspections shall not be so regular as to become predictable.
d) There shall be provisions for more inspections based on the non-conformities.

b) Unannounced Inspections

BFDA-CS also selects the certified operators for unannounced inspection based on risk assessment, wherein all operators falling under high risk category is subjected to atleast one unannounced inspections in a year.

6.3.3.4 Risk assessment

In addition, the BFDA-CS follows procedure for conducting risk assessment (See BFDA-CS-PR7.1-01) of its certified operators covering all scope of activities.

The risk assessment procedure covers the criteria for determining the risk category as high, medium or low. The system for risk analysis also determines the number of announced and unannounced inspections. Depending on the risks identified, BFDA-CS decides whether it is appropriate to increase the frequency of inspections, than those planned in accordance with generic scheme requirements. BFDA-CS also includes the following:

a) additional visits to the certified client's premises on the basis of a risk based system and
b) end product testing for residues and GMOs based on the results of risk assessment.

6.3.3.5 For individual farmers, BFDA-CS inspection/audit team evaluates the proper functioning of the farm and checks whether the requirements of this scheme and the Bhutan Organic Standard are fulfilled by the farmers.

6.3.3.6 For producer groups, BFDA-CS inspection/audit team should evaluate the proper functioning of the group's internal control (quality management) system, manual and documentation as described in Organic standard.

6.3.4 Production process

The organic production process is inspected to assess the client through direct observation and examination of the production process and communicating with production personnel in accordance with BFDA-CS-PR7.4-01 documented procedures and format BFDA-CS-PR7.4-01.FM-09 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 BOS 02:2022 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 BOS 02:2022 Bhutan Organic Standard 2022 used in the BFDA-CS scheme,

c) the client organic product sampling and testing is undertaken where necessary in accordance with the certification requirements 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 organic product certification scheme and

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

6.3.4.1 Inspection of parallel production of farms

If a farm is engaged in parallel production, the BFDA-CS shall ensure, in addition to the requirements for part conversion, the following: -

- Buffer zones are maintained for demarcation
- Crops are visually distinguishable
- Inspections are carried out at critical times
- Inspection is done in a timely manner
- Accurate production estimates are available
- The crops are harvested in such a way that there are reliable methods to verify the actual harvest of the respective crops
- Appropriate storage capacity exists to ensure separate handling
- The documentation regarding the production is well managed and makes a clear distinction between certified and non certified production

6.3.4.2 Inspections of grower groups

BFDA-CS inspection/audit team should evaluate the proper functioning of the group's internal control (quality management) system, manual and documentation as described in the Organic Internal Control System Manual of the National Centre for Organic Agriculture.

(i) The external inspection by the BFDA-CS shall be planned after internal inspections of all the farmers are carried out by the Internal Control System (ICS)

(ii) The inspectors shall use the standardized format: BFDA-CS-PR7.2-01-FM-06 for sourcing the information from the grower groups.

(iii) The inspector shall verify that new farmers are included in the group only after the internal inspections are completed

(iv) The inspector shall carry out the risk assessment of the ICS

(v) The inspector shall draw a sample of farms for visiting the farmers in the ICS

(vii) The inspection shall include a witness audit of the internal inspector for assessing his knowledge and inspection procedures.

(viii) The inspector shall verify the documentation of the ICS that adequate records of inspections are maintained.

(ix) Instances of non-compliance and the active measures taken by the ICS with special reference to sanctions shall be assessed from the documentation.

(xi) The inspector shall interview the farmers, ICS manager to assess the knowledge of operator on Bhutan Organic Standard.

(xii) The inspector shall verify the collected information from the ICS with the submitted information by the grower group during registration/renewal.

6.3.4.3 Inspection of wild product collection

BFDA-CS shall at least include the following for inspection of wild product collection;

(i) To verify that the area of collection is properly identified on appropriate maps issued by the concerned Government Authorities. The map shall be large and distinct enough to reduce the risk of mixing up with non-certified production.

(ii) Verification of records of all collectors and the quantities bought from each collector.

(iii) Visit to an appropriate portion of the certified area.

(iv) Visits and/or interviews of the concerned in the supply chain such as collectors, local agents, landowners and other parties (environment agencies, NGOs, etc.)

6.3.4.4 Inspection of all stages in handling

The following applies to inspection of the whole production chain.

(i) Each step in the handling of a product shall be inspected, at least once annually (storage units, packaging, shipment, etc).

(ii) Any person who sells a product (raises invoice) shall be registered and certified. This requirement applies until the product is in its final package/has its final label.

6.3.4.5 Inspection of processing units

During the inspection of the processing units, the following shall be taken care

(i) The inspector shall verify that sufficient quantities of organic ingredients are used and that organic integrity is maintained through all stages of processing.

(ii) The inspector shall review all ingredients and their sources to ensure that the ingredients meet organic standards.

(iii) The inspector shall also review product formulation to determine if they meet labelling standards.

(iv) Inspectors shall verify the existing record keeping system and evaluate whether it is adequate of tracking organic products.

(v) The inspector shall conduct an audit trail to track the product from receipt of raw material/ingredients, ingredient storage, through all stages of processing, packaging, labelling, warehousing, shipping and sales of the finished product.

(vi) The inspector shall conduct a sample audit review, which consists of randomly choosing a finished product(s) either from a sales invoice, a product purchased or a product seen in the warehouse. The inspector shall record the Package/Lot Number on the finished product and follow the product back through the record keeping system to the receipt of incoming

ingredients. The inspector shall point out the deficiencies if any in the product tracking system.

(vii) The inspector shall inspect all the subcontracted units annually.

6.3.4.6 Inspection of Packed Products

BFDA-CS is not obliged to have a system for inspection of products that are further handled after being packed in the final consumer package.

BFDA-CS however, are obliged to take action where there is reason to believe that the standards have been or may be violated at such later stages.

6.3.4.7 Inspection of Storage Facilities

Depending on the kind of storage, the product, packing, prevailing storage practices and the time of storage, inspections shall be required.

6.3.4.8 Inspection of Transport Facilities

Transport is not certified as such, but remains under the responsibility of the operator owning the product during the transport to maintain organic integrity along the entire transportation chain.

6.3.4.9 Inspection for detection of use of Genetically Engineered Products

BFDA-CS shall not grant certification if of Genetically Engineered Products are used. The Inspectors shall carry out inspection to assess potential use of genetically engineered products. When there is a risk of contamination of genetically engineered products, the following samples shall be tested in identified approved laboratories.

- seeds and planting stock
- production inputs
- ingredients

6.3.4.10 Elements of the management system critical for product conformity

BFDA-CS audit the elements of the management system critical for product conformity 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 for 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.

BOX 02

Management system elements critical for operation of organic 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

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.

6.4. Nonconformities

BFDA-CS has specified in the organic 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, non conformities have been categorized as follows:

Minor - a deficiency that do not affect the integrity of the organic system in the implementation of the standard requirements prescribed in Bhutan Organic Standard. Certification may be granted with unresolved minor conformities if the client provides objective evidence of planned corrective action within 3 months of the audit and corrective action is implemented within 12 months after the audit;

Major - severe violations that affect the integrity of the organic system in the implementation of the standardrequirements prescribed in Bhutan Organic Standard. Certification is not granted unless the client provides objective evidence of planned corrective action within 14 days and all major nonconformities are resolved within 1 month after BFDA-CS accepts planned corrective action.

Critical – a deficiency in the requirements to be met with respect to Bhutan Organic Standard which are required to maintain organic integrity of the produce and failing to adhere to the same may result in a serious food safety incidence due to breach in food safety and organic integrity. The following applies:

- When a critical nonconformity is issued at a certified site the certificate shall be immediately suspended for a maximum period of six (6) months.
- When a critical nonconformity is issued during an audit, the client must provide BFDA-CS with objective evidence of an investigation into causative factors, BFDA-CS within 14 days after the audit.
- A follow-up audit shall be conducted by the BFDA-CS within the six (6) month timeframe to verify the closure of the critical nonconformity.
- The certificate shall be withdrawn when the critical nonconformity is not effectively solved within the six (6) month timeframe.

If the client undertakes corrective actions and these have to be completed within a specified time limit set by the Inspection team, within the above specified timeframe, 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 off site.

6.5 Evaluation report

6.5.1 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.

6.5.2 The report should follow a format (BFDA-CS-PR7.4-01-FM-11) appropriate to the type of organic operations inspected/evaluated. Likewise, the report should cover all relevant aspects of the organic standards and certification process and adequately validate the information provided by the client, including:

a) Date and time of inspection
b) Persons interviewed
c) Crops/products requested for certification
d) Fields and facilities visited
e) Documents reviewed
f) Buffer zones
g) Risk of contamination
h) Inspector's observations
i) Calculation of input/output norms, production estimates etc.
j) Assessment of production system of operator
k) Assessment of the use of logos/ approvals
l) Product reconciliation and verification of stock
m) Interview with responsible persons
n) Evaluation of compliance to standards as well as non-conformities and
o) Certification requirements.

6.5.3 Reports should be designed to allow for elaboration and analysis by the inspector/auditor on areas where compliance might be partial, standards might not be clear, etc. for ensuring appropriate decision with respect to scope of organic certification. The report and accompanying documentation should provide sufficient information to allow verification that the relevant standards have been complied with.

6.5.4 The team shall sign the inspection findings, which will have to be countersigned by the operator. A copy of the inspection report relating to the certification of the operator's production should be available with the registered operator.

- BFDA-CS-PR7.4-01 Procedure for processing of application
- BFDA-CS- PR7.4-01-FM-05 Facility technical audit/inspection report
- BFDA-CS- PR7.4-01-FM-07 Facility inspection checklist based on Bhutan Organic Standard 2022

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 fulfil the specified requirements, a review is carried out by a competent officer(s) who has not been involved in the determination activities. If the evidence is sufficient, a recommendation for certification is made.

8. DECISION

8.1 When the outcome of the review is positive, a decision is made to grant certification. The decision is made by the Certification Committee. 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.

8.BFDA-CS may at its discretion refuse to grant a licence or extend its scope or cancel or alter so as to reduce the scope of the licence provided that the refusal, cancellation or alteration is a recommendation of the Inspector of BFDA-CS based on assessment/audit as to which a decision by the Certification committee shall be conclusive. The refusal to renew or cancel a licence for failure to discharge its obligations shall be based on the report of the Inspector of BFDA-CS on assessment/audit during surveillance and regular review. Such decisions shall be communicated to the licensee in writing.

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 signing the Certification Agreement. Subsequently the license is uploaded on the BFDA-CS website. After the license has been granted, the certified client may place the organic certification mark on the product subject to conformity of the product to the requirements. BFDA-CS provides the standard mark together with the license and mode of application of the standard mark on the product.

- BFDA-CS-PR4.1-03 Procedure for Legally Enforceable Certification Agreement

10. LICENSING, USE OF CERTIFICATES AND MARKS OF CONFORMITY

10.1 General

The use of the organic 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 Organic Certification Mark

10.2.1 BFDA-CS has developed BFDA-CS-PR4.1-02 Procedure for use of license, certificates and marks of conformity in accordance with ISO/IEC Guide 23 and ISO/IEC 17030. The certified Licensee may use the Bhutan Organic Certification Mark, which is the property of the Ministry of Agriculture and Livestock only as authorized by BFDA-CS.

10.2.2 The licensee shall inform potential customers, purchasers or purchasing authorities of the full and exact details of the licence;

a. The licensee shall display the licence in his premises;

b. The licensee shall make use of the Certification Trade Mark as authorized;

c. The licensee shall state in documentation brochures or through advertising media that the organization or location to which the licence applies have been assessed and approved by BFDA-CS. In such advertisement the standards pertaining to the products or process for which a licence has been granted is to be stated.

10.2.3 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

10.2.4 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. BFDA-CS-PR 4.1-02 Procedure for use of license, certificates and marks of conformity

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 it cannot be determined from the certificate or mark of conformity used,
b) the name of the product classification where it is not completely obvious, and
c) identification of the relevant standard(s) including date of publication such as BOS 02:2022

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

10.4 Issuing of a licence

10.4.1 BFDA-CS submits a Certification agreement (See BFDA-CS-PR4.1-01-FM 01) to the licensee for signature. When the licence 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 4.1-02.

10.4.2 Obligations of the applicant

An applicant on grant of a licence to use of the Bhutan Organic Certification Mark shall:

a. at all times comply with the requirements of the licence as set out therein
b. only claim that it is holding a licence in respect of the capability which is the subject of the licence and which relates to the products or processes in accordance with the licence requirements;
c. submit to BFDA-CS for approval the form in which it proposes to use its licence or proposes to make references to the licence;
d. upon suspension or termination of the licence, however determined, discontinue its use forthwith and withdraw all promotional and advertising matter which contains any reference thereto;
e. permit access to the Inspector for purposes of assessment, audit or surveillance. The licensee shall give full details of all actions taken in response to field problems arising from allegations of defects in products or processes covered in the licence and allow the Inspector access to all relevant records and documents for the purpose of verifying such details;
f. be required to produce evidence of continuing operations for the products or processes covered by the licence. The licensee shall notify BFDA-CS in writing of discontinuance

in such operations exceeding three months. Discontinuance of a licence in excess of six months or more may lead to cancellation of licence. In such cases, a new application shall be lodged with BFDA-CS and an assessment visit will be necessary prior to grant of a new licence;

g. pay all financial dues to BFDA-CS, even for the period of discontinuance or suspension of licence.

10.4.3 The Certification Mark shall be applied in such manner as it may be easily visible as a distinct mark on the products or the packaging relating to articles which cannot be labeled or covered. The Certification Mark shall be applied to only such types, grades, classes, varieties, sizes of the products for which the licence has been granted.

The manner in which the licensee proposes to place or use the Certification Mark, must be approved by BFDA-CS.

When a Certification Mark has been specified in respect of an article or process, no person other than the licensee in possession of a valid licence shall make any public claim, through any advertisement, sales promotion leaflets, pricelists or the like, that his product conforms to the relevant Certification Mark.

Every licensee shall institute and maintain, to the satisfaction of BFDA-CS, a system of control to keep up the quality of his production or process by means of a scheme of testing and inspection, so as to ensure that the articles or process, in respect of which the Certification Mark is being used, comply with the Organic standard.

The licensee shall maintain a complete record of the tests and inspection and such other data as specified in the scheme for testing and inspection, to establish to the satisfaction of the BFDA-CS that the required control of production or process has been and is being satisfactorily maintained. Such records shall, on demand, be made available for inspection to BFDA-CS.

- BFDA-CS-PR 4.1-02 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.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 Suspending or withdrawing a licence

10.6.1Suspension

BFDA-CS may suspend the applicability of the licence 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 licence as applicable to that product. A licence may also be suspended after mutual agreement between BFDA-CS and the licensee for a limited period of non-production or for other reasons.

BFDA-CS follows the BFDA-CS-PR 7.11-01 Procedure for termination, reduction, suspension or withdrawal of certification.

BFDA shall notify the client in writing of Suspension within 15 days. 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.

During the period of suspension, the client shall make no misleading claims and will advise relevant existing and potential purchasers regarding the status of certification, and cease to use the certification mark on the products manufactured since the date of notification of suspension. BFDA shall ensure that the manufacturing unit has procedures in place to ensure that a non-conforming certified product that gave rise to suspension of certification is recalled.

At the end of the suspension period, BFDA-CS investigates whether the indicated conditions for re-instituting the licence have been fulfilled.

The suspension will be restored when:

- the client has closed all the non-conformities to the satisfaction of the audit team.

- the client is ready for onsite audit and successful completion of the audit.

On fulfilment of these conditions, the suspension is removed by notifying the licensee.

If the certified licensee is unable to satisfy the requirement for reinstatement within 180 days or time given by BFDA whichever is less, the License may be cancelled.

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

10.6.2 Withdrawal

Apart from the suspension of a licence, a licence 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,
c) if there is any other contravention of the licensing 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 licence 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 licence.

Prior to withdrawal of a license, BFDA-CS decides upon the consequences in relation to products certified under the licence, 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 licence 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 agreement.

Withdrawal of a licence may be publicized by BFDA-CS on its official website.

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 organic certification scheme has defined surveillance process for organic certified clients (See BFDA-CS-PR 7.9-02) to be conducted at site at least once in 12 months in order to provide confidence that organic products after the initial certification continue to fulfil the specified requirements.

The surveillance activities are selected according to the nature of the product and the consequences and probability of nonconforming products. The frequency is adjusted on the nature of nonconformities in products or the management system and may be carried out more frequently until the necessary level of confidence is restored.

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

a) Inspection of product samples taken either from the point of production, or from the market, or from both for conformity with the certified type,
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.

The client is informed about the results of the surveillance inspection. If surveillance report reveals nonconformity with the certification requirements which cannot be readily corrected by the client, the BFDA-CS considers 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 BFDAA-CS on request. If non-conforming products have been released onto the market, the client informs BFDA-CS so that it can agree on the action to be taken.

- BFDA-CS-PR7.1-01 Procedure for risk-based inspection
- BFDA-CS-PR 7.9-01 Procedure for surveillance of certified client

12. CHANGES AFFECTING CERTIFICATION

12.1 Changes in certification requirements

If BFDA-CS makes any changes in the certification requirements, it should ensure, by any means that it chooses, that the information is immediately transmitted to the certified clients and also inform about the transition period for the client to comply with the changed requirements. The transition period should be decided based on the changed requirements and taking in to account considerations such as the decision regarding the products under production before the changes are made known to the client.

BFDA-CS should determine whether the announced changes require further visits and confirmation. It should inform the certified client of all conditions under which the client should not release the organic certified material to the market before getting confirmation from the CB.

If the certified client outsources parts of production/processing activities to other organic producers, this should be informed to BFDA-CS in advance, allowing BFDA-CS to inspect the same if necessary. In case of outsourcing, BFDA-CS requires the certified client to be held fully responsible for the outsourced activities. This should also be made part of the legally enforceable agreement between BFDA-CS and the client.

12.2 Changes to product requirements

When a standard or another normative document which is part of the certification requirements is changed, there are a number of factors that have to be considered by the scheme owner-BFDA-CS when t fixes the date on which the new product requirements of the changed document will come into force (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) operational constraints of BFDA-CS.

12.3 Changes to the scheme requirements

BFDA-CS which is the certification body informs its clients if necessary, of other changes to the 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 CS scheme

12.4 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 licence 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 licence, it will be necessary to carry out inspection of 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 relevant legal system(s).

15. COMPLAINTS AND APPEALS

BFDA CS has procedure describing how to deal with complaints received from stakeholders such as importers of the certified organic products, competent authorities and regulators regarding the organic products supplied by its certified clients. The client also has a right to complain to BFDA-CS about aspects of the service provided.

BFDA-CS includes response time, responsibilities and the handling procedures including investigation processes. If complaint investigation indicates violation of product integrity,BFDA-CS should decide about undertaking additional or unannounced audits of the client's premises.

BFDA-CS has a system in place that ensures that the clients inform it of any complaints received regarding the quality of an organic product. The clients should also inform BFDA-CS of the measures taken by client to correct the defects, if any, identified based on their investigation of the complaint received. They should also inform of the measures taken to prevent reoccurrences.

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.