BHUTAN FOOD AND DRUG AUTHORITY

CERTIFICATION SERVICES

BHUTANGAP PRODUCT CERTIFICATION SCHEME

BHUTANGAP PRODUCT CERTIFICATION SCHEME – TYPE 6

1. INTRODUCTION

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

1.2 BhutanGAP Product certification is the provision of inspection and impartial third-party certification that fulfilment 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 Department of Agriculture under Ministry of Agriculture and Livestock is promoting Good Agricultural Practices through BhutanGAP Standard (BTS 30:2017) implementation by the farmers to produce safe food. GAP with its holistic approach is gaining widespread acceptance for ensuring safe and quality production at the primary production level. BFDA is also mandated by the Ministry to operate Third-Party Product Certification for BhutanGAP in conformity with the requirements of ISO/IEC 17065 (Conformity assessment: General requirements for bodies certifying products, processes and services). Therefore, BFDA has launched BhutanGAP Product Certification scheme through its Certification Services in conformity with ISO IEC 17065:2012 to provide third party GAP certification mark based on BhutanGAP Standard to the producer/ producer groups. BFDA product certification scheme covering BhutanGAP products is based on the existing Ministry of Agriculture and Livestock's scheme, which was introduced since March 30, 2017.

1.4 This product certification scheme is designed for Type 6 scheme (See Box 01) operated by BFDA- CS related to the certification of tangible GAP 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

This "BhutanGAP" Product Certification Scheme covers products conforming to BTS 30:2017 Bhutan Standard for Good Agriculture Practices (GAP): Fruits and Vegetables certified by Certification Services, Bhutan Food and Drug Authority (BFDA-CS). It supplements Quality Manual which describes the main product certification scheme. BFDA Product Certification is based on scheme requirement Type 6 (See Box 01) 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, and 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 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 Product- Result of a process

NOTE 1 Four generic product categories (see ISO 9000:2015):

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

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

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

3.5 Product requirement

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

NOTE - BTS 30:2017 Bhutan Standard for Good Agriculture Practices: Fruits and Vegetables

3.6 Producer

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

3.7 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 the BhutanGAP standard.

3.8 Scheme owner

Person or organization responsible for developing and maintaining a specific certification scheme. In this case, it is Certification Services of Bhutan Food and Drug Authority (BFDA-CS)

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 "BhutanGAP" PRODUCT CERTIFICATION SCHEME

4.1 Development and operation of the "BhutanGAP" product certification scheme

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

4.2 Outline of the "BhutanGAP" Product Certification scheme

The product certification scheme contained reflects a Scheme Type 6 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 are those given in BTS 30:2017 Bhutan Standard for Good Agriculture Practices (GAP): Fruits and Vegetables 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 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 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 bodies complying to the requirements of ISO/IEC 17021-1.

iv) Sampling methods and frequency have been described in BFDA- CS-PR 7.4-01 Procedure for processing of application for certification BFDA-CS-GL 7.4-01 Guideline for drawl, coding, sealing and dispatch of samples).

v) Requirements which the producer/producer group has to fulfil in order to gain and 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 as per BFDA-CS-PR4.1-01 Procedure for legally enforceable certification agreement), the ongoing operation of a management system, maintaining control over the use of the mark of conformity (BFDA-CS-GL4.1-01 Guideline for use of standard marks), advising BFDA-CS of changes affecting product conformity, and

vi) BFDA CS certification requirements includes:

- payment of prescribed fees for certification services rendered,
- 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 in the BhutanGAP Product scheme includes:

Evaluation of the product- The Team of competent inspector/auditor is constituted to conduct onsite evaluation in accordance with the BFDA-CS-PR7.4-01 Procedure for processing of application for certification) where sample(s) for testing are also drawn. During evaluation, sampling and testing may be eliminated under the following circumstances:

- The product has already undergone testing and certification to a recognized, equivalent or higher standard, with authentic verifiable documentation.

- The product has already undergone testing from a lab fulfilling the applicable requirements of ISO/IEC 17025 and verifiable test reports are available.

- A risk assessment for BhutanGAP integrity concludes that sampling and testing do not play a critical role in verifying compliance with the specified requirements.

- The product is consistently produced under a certified management system, ensuring consistent quality and conformance to the specified requirements.

i) 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

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 fulfilment 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 (see Clause 4.2.2 for conditions where sampling and testing can be eliminated during evaluation)
ii) inspection of the production process and
iii) audit of the management system.

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

- 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 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 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)

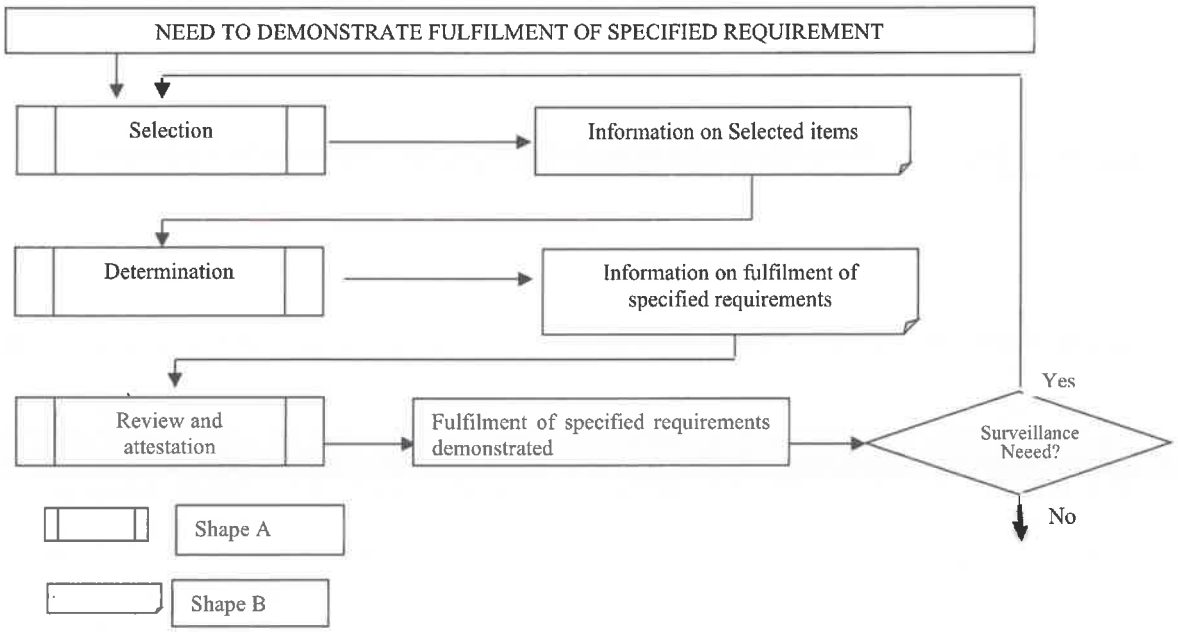


Fig 01 Functional approach to conformity assessment-solid arrows link the conformity assessment functions and their outputs /inputs & broken arrows express the possible needs or demands for conformity assessment. Shape A represents a conformity assessment function & Shape B represents output from a function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

4.3 Scope of the BFDA-CS BhutanGAP Product Certification scheme

The scope of the "BhutanGAP" scheme is defined in terms of the types of products, the certification requirements and the geographical areas within which it operates conforming to BTS

30:2017 Bhutan Standard for Good Agriculture Practices: Fruits and Vegetables (List of certified products See Annex A).

4.4 Parties involved in the BhutanGAP product certification scheme

The main parties involved in the operation of the BhutanGAP product certification 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 BhutanGAP certification can be individual producer, group producer or processors.

The "BhutanGAP" product certification scheme is owned by Certification Services of BFDA (BFDA-CS), Ministry of Health. BFDA-CS is responsible for the rules, procedures, management and integrity of the "BhutanGAP" scheme.

BFDA 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 producer, 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 producers' quality management system.

5. SELECTION

5.1 Specified requirements- Information on Selected items

Selection of elements in this 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 in BhutanGAP standard, technical specifications or contractual documents that have been

developed in accordance with ISO/IEC 17007. For this Scheme the product requirements are based on BTS 30:2017: Bhutan Standard for Good Agriculture Practices: Fruits and Vegetables.

In addition, there are further requirements for the client to fulfill certification requirements as given in Quality Manual including the following:

- payment of prescribed fees for certification services rendered,
- 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 scheme provides details of the procedures describing Information on fulfilment of specified requirements 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-GL7.4-01Guidelines for drawal, coding, sealing and dispatch of samples

a. 5. 4 Application for certification and certification contract

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 "BhutanGAP" Product certification scheme along with updated version of BhutanGAP Standard. 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

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 BhutanGAP production, including accounts and sales related records and other relevant documentation to provide adequate audit trails and traceability of BhutanGAP 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-BhutanGAP 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 Procedure for receipt, review and registration of application
BFDA-CS-PR 7.4-01 Procedure for processing of application for certification

A typical Flow diagram of "BhutanGAP" product certification is given in Fig 02

STEPS INVOLVED IN "BhutanGAP" PRODUCT CERTIFICATION

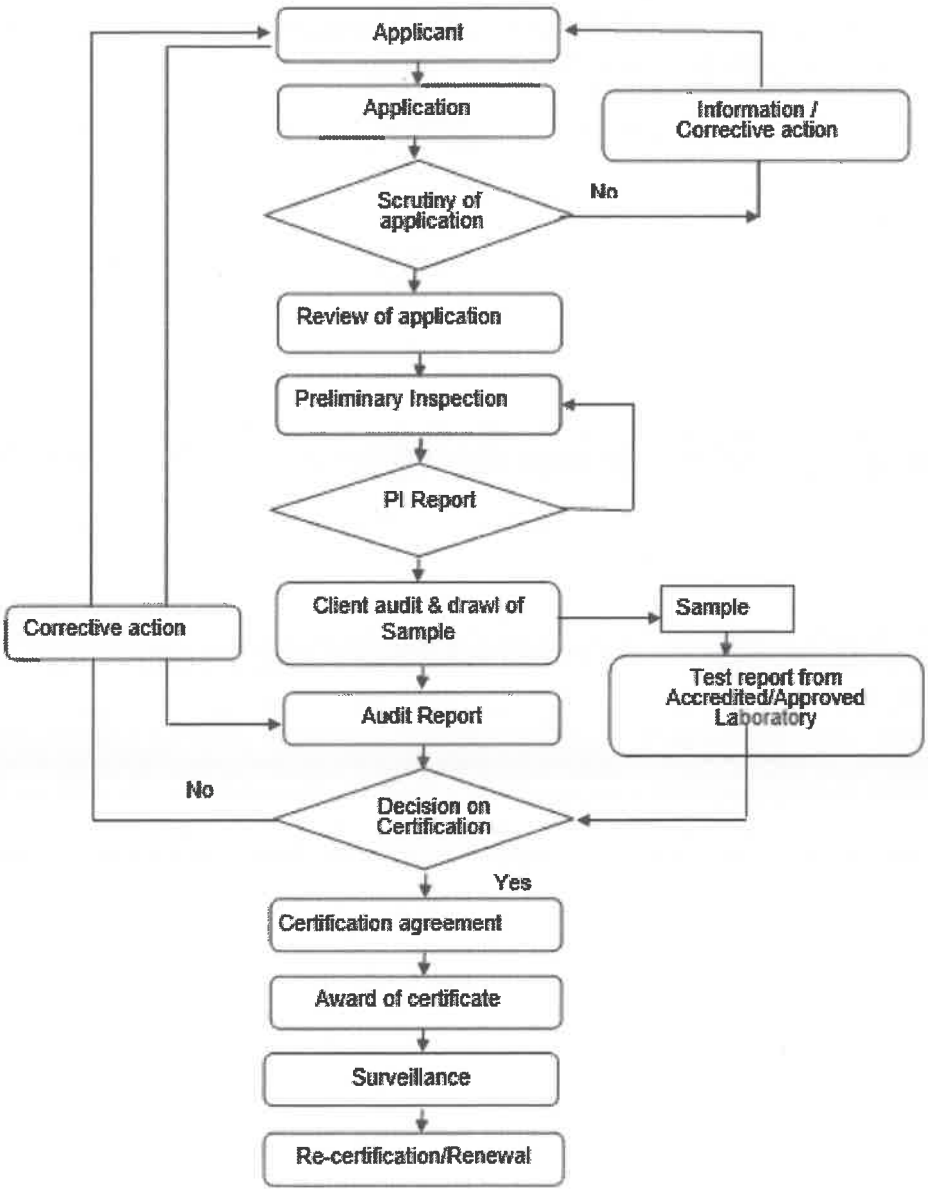


Fig.02 Flow diagram for BhutanGAP product certification

6. DETERMINATION

6.1 General

BFDA-CS gathers information to determine the extent to which the client demonstrates its fulfillment of "BhutanGAP" product 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 BFDA-CS ensures that the identified Evaluators meets the competence procedure requirements.

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

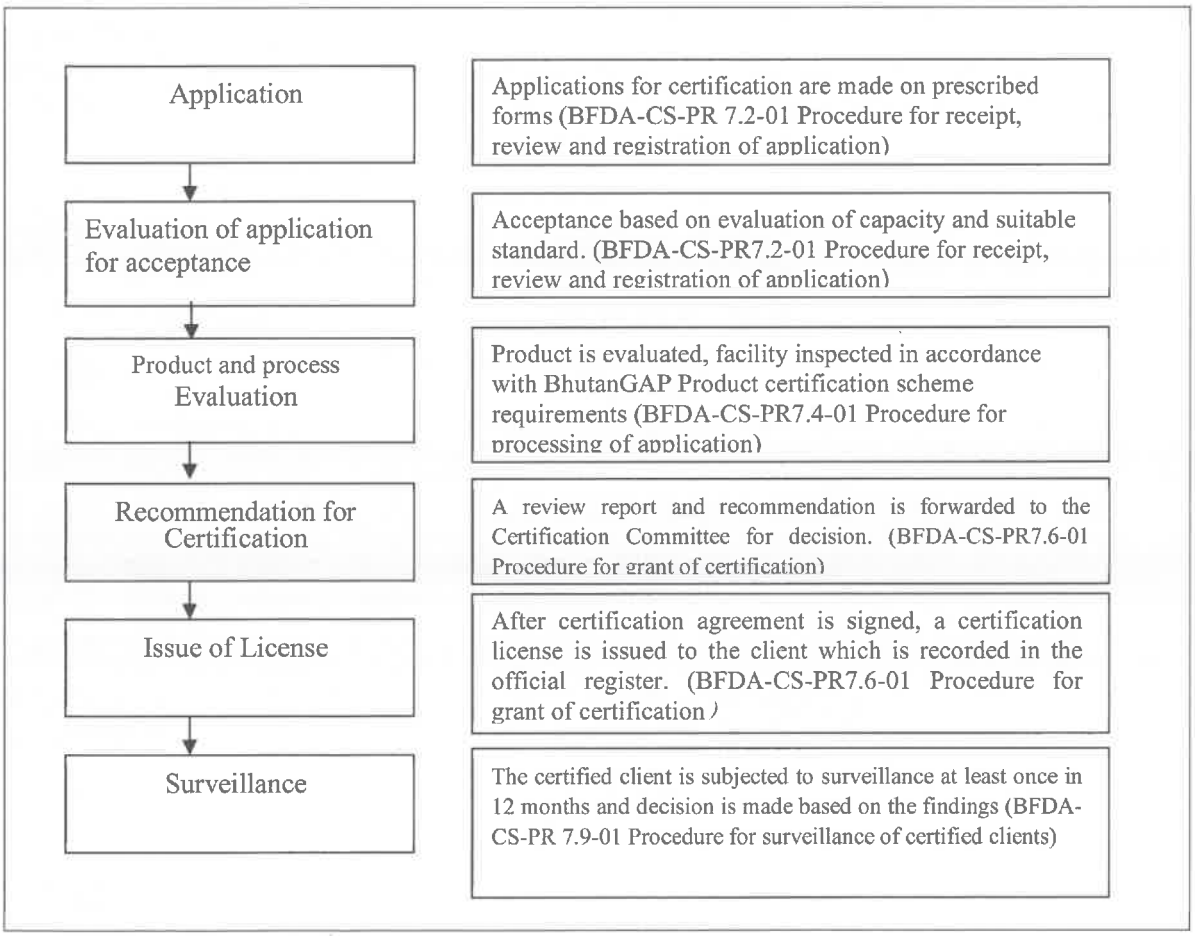
6.1.1 Evaluation plan

Based on the application and "BhutanGAP" certification scheme the BFDA CS prepares an evaluation plan setting out:

a) the "BhutanGAP" 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 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 "BhutanGAP" product certification



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

After confirmation of the acceptance of the application, the 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) inspection of the production processes,
b) initial testing and examination of the product, when necessary 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 "BhutanGAP" 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 BhutanGAP 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 "BhutanGAP" certification scheme the BFDACS:

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 product evaluation is carried out in accordance with the methods specified in the Bhutan GAP standard(s) and the procedures specified by the BFDA-CS 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 17025:2005. 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 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.

BFDA-CS-PR 6.2-01 BFDA Laboratory Recognition Scheme

6.3 Evaluation of the production process and audit

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 Bhutan GAP product certification scheme.

The client designates:

a) a responsible person as the main contact with the 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 of the documents submitted by the producer on the operation of the site. 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 BFDA-CS process 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 (e.g. ISO/IEC 17021 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 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) 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,
c) Inspection of the producer processes,
d) audit of the elements of the management system critical to product conformity.
e) review of records, accounts, sales figures, etc.,
f) sampling and analysis, when necessary,
g) calculation and confirmation of input/output norms, production estimates, etc.,
h) 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.,
i) verification that changes to the standards and to requirements, when necessary; and
j) verification that corrective actions of nonconformities.

6.3.3.3 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 BhutanGAP Standards are fulfilled by the farmers.

6.3.3.4 In addition, for producer groups, BFDA-CS inspection/audit team evaluates the proper functioning of the group's internal control (quality management) system, manual and documentation as described in BhutanGAP standards.

6.3.3.2 Production process

The production process is inspected to assess the client through direct observation and examination of the production line and communicating with production personnel in accordance with BFDA-CS documented procedures BFDA-*CS-PR7.4-01* and checklist BFDA-*CS-PR7.4-01.FM-08* 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 BTS 30:2017 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 "BhutanGAP" 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 "BhutanGAP" certification requirements;
d) taking of samples by inspector/auditors 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 "BhutanGAP" certification requirements, from the receipt of inputs, through all transformation processes, through to dispatch of the completed products in accordance with the "BhutanGAP" certification Scheme, and
f) the ability of the client to identify and separate nonconforming product and to maintain product traceability where there is a "BhutanGAP" product certification requirement.

6.3.3.3 The Inspector shall carry out inspection based on the BhutanGAP Standard and checklist BFDA-CS-PR7.4-01-FM-08 -Audit checklist for BhutanGAP.

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 BhutanGAP Internal Control System Manual of the Department of Agriculture

To ensure the proper functioning of the group's internal control system, BFDA-CS undertakes risk assessment of the group through random selection of a minimum sample size of the members in the group.

(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 of BFDA-CS shall use the prescribed formats 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 BhutanGAP Standards.
(xii) The inspector shall verify the collected information from the ICS with the submitted information by the grower group during registration/renewal.

6.3.3.4 Elements of the management system critical for product conformity

BFDA-CS technical auditors audit the elements of the management system critical for "BhutanGAP" 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 in relation to 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.

The Quality Manual conforming to ISOIEC 17065 under section 8 has identified following management system elements as essential for operation of the BhutanGAP 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.

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 "BhutanGAP" certification 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 meeting the certification requirements that do not significantly affect the integrity of the BhutanGAP product certification system. 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 meeting the certification requirements that poses a moderate to high risk to the integrity of the BhutanGAP product certification system.

- 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 in meeting the certification requirements that poses a threat to BhutanGAP certification integrity and failing to adhere to the same may result in a serious food safety incidence due to breach in food safety and BhutanGAP certification integrity.

- 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 off site.

6.5 Evaluation report

6.5.1 Following the initial product evaluation, inspection of the 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 "BhutanGAP" certification requirements for making the certification decision.

6.5.2 The report should follow a format appropriate to the type of farm operations inspected/evaluated. Likewise, the report should cover all relevant aspects of the BhutanGAP standards and certification process and adequately validate the information provided by the client, as per the format BFDA-CS-PR7.4-01-FM-11 – Farm audit report.

6.5.3 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-11 Farm audit report
- BFDA-CS- PR7.4-01-FM-08 Audit checklist based on BhutanGAP Standard.

7. REVIEW

When all determination/evaluation 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, 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.

8.2 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 the 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 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 surveillance audit at least once 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 on the acceptance for producing the products in conformity with the specified BhutanGAP Standard and maintaining records in the BhutanGAP farm diary and/or ICS manual is also signed by the client.

After the license has been granted, the certified client may place the BFDA-CS "BhutanGAP" scheme's certification mark on the product subject to conformity of the product to the requirements.

10. LICENSING USE OF CERTIFICATES AND MARKS OF CONFORMITY

10.1 General

The use of the certification mark is controlled through a licence issued by the BFDA CS to each client 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 processing of the product, including the placing of the mark on the product, to another organization- the producer 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 BhutanGAP 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 BhutanGAP Certification Mark, which is the property of the Department of Agriculture 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.

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

10.3 Other labelling

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 such as BTS 30:2017.

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 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 4.1-02 Procedure for use of license, certificates and marks of conformity.

10.4.2 Obligations of the applicant

An applicant on grant of a licence to use of the BhutanGAP 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 license. (If Applicable)

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 BhutanGAP 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. 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 "BhutanGAP" 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 licence10.6.1 Termination

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 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 client is prohibited from identifying as certified any product that has been produced under a suspension of the license as applicable to that product. A licence may also be suspended after mutual agreement between BFDA-CS and the client for a limited period of non-production or for other reasons.

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

10.6.4. 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 (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 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.

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.

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

10.6 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 "BhutanGAP" products to which the license applies.

In every case, the client must take 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 "BhutanGAP" certification when in fact they are not.

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

11. SURVEILLANCE

BFDA-CS carries out surveillance of BhutanGAP certified clients (See BFDA-CS-PR 7.9-02) at least once in 12 months in order to provide confidence that GAP certified products after the initial certification continue to fulfil the specified requirements.

The surveillance activities are selected according to the nature of the "BhutanGAP" 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 quality Manual 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 processing takes place and include one or more of the following:

a) Inspection of "BhutanGAP"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.

It may not be necessary to repeat all of the elements of the initial evaluation. This could be the case with custom-made products and could be applied to cases where the initial testing is very complicated or where the samples are very expensive. In such cases, the surveillance may be based on examination only, or combined with more simple identification tests which ensure that the product is in conformity with the certified type. Such identification tests are described in the product certification scheme. The client is informed about the results of the surveillance.

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

The certified 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 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-PR 7.9-02 Procedure for surveillance of certified clients

12. CHANGES AFFECTING CERTIFICATION

12.1Changes to product requirements

When a standard or another normative document which is part of the "BhutanGAP"certification requirements is changed, there are a number of factors that have to be considered by the scheme owner, BFDA-CS when it fixes the date on which the new product requirements of the changed document will come into force reflecting effective date of transition period.

The effective date of obsolescence of a standard or other normative document is communicated by BFDA-CS to all concerned 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 "BhutanGAP" certification 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 processing 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 producer or design,
f) operational constraints of BFDA-CS.

12.2 Changes to other BFDA-CS "BhutanGAP" 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 "BhutanGAP "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 licence agreement may be modified.

If the client wishes to apply for the certification of 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 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

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
BFDAA-CS-PR 7.13-02 Procedure for handling appeals

16. FEES

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