
	<p style="text-align: center;">BHUTAN AGRICULTURE &amp; FOOD REGULATORY AUTHORITY CERTIFICATION SERVICES, THIMPHU BHUTAN</p>	<p style="text-align: center;">GAP CERTIFICATION SCHEME</p>	
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**BHUTAN AGRICULTURE AND FOOD REGULATORY AUTHORITY**

**CERTIFICATION SERVICES**

**BHUTANGAP PRODUCT CERTIFICATION SCHEME**

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## BHUTANGAP PRODUCT CERTIFICATION SCHEME – TYPE 6


### 1. INTRODUCTION

**1.1** To assist the BhutanGAP 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 Agriculture and Food Regulatory Authority (BAFRA) provides BhutanGAP certification services.

**1.2** “BhutanGAP” 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** Department of Agriculture under Ministry of Agriculture and Forests 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. BAFRA 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, BAFRA has launched BhutanGAP 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. BAFRA product certification scheme covering BhutanGAP products is based on the existing Ministry of Agriculture and Forests’ 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 BAFRA 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.

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**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 Good Agriculture Practices (GAP): Fruits and Vegetables certified by Certification Services, Bhutan Agriculture and Food Regulatory Authority (BAFRA-CS). It supplements Quality Manual which describes the main product certification scheme. BAFRA Product Certification is based on scheme requirement Type 6 (See Box01) 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.

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### 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 Good Agriculture Practices: Fruits andVegetables

#### 3.6 Producer

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

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### 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 Bhutan Agriculture & Food Regulatory Authority.

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” 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 BAFRA-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):

Specified requirements for the products covered by the scope of the BAFRA-CS scheme are those given in BTS 30:2017 Bhutan Standard Good Agriculture Practices (GAP): Fruits and Vegetables.or contractual document,

- i) Elements of the production process to be assessed and of the management system to be audited based on Management System developed by the company,
- ii) Determination activities, and the basis on which those activities be undertaken by BAFRA 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 ISO/IEC 17020 requirements and services for auditing are taken from body accredited to ISO/IEC 17021-1.

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- iii) Sampling methods and frequency have been described in the procedures and guidelines (BAFRA- CS-PR7.4-01 and BAFRA-CS-GL7.4-01).
- iv) Requirements which the producer/producer group has to fulfill in order to gain and maintain certification of the product by signing a certification agreement (See BAFRA-CS-PR-4.1-01 FM-01), the ongoing operation of a management system, maintaining control over the use of the mark of conformity (BAFRA-CS-GL4.1-02), advising BAFRA-CS of changes affecting product conformity, and
- v) BAFRA 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 scheme includes:

- i) Evaluation of the product- The Team of competent inspector/auditor is constituted to conduct onsite evaluation in accordance with the laid down procedure where a sample for testing is also taken and
- 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 BAFRA-CS-PR7.4-01 and formats specified in this procedure:

- BAFRA-CS-PR7.4-01 Procedure for processing of application for certification
- BAFRA-CS- PR7.4-01-FM-08 Facility audit checklist (GAP)
- BAFRA-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, and the results of these activities, with regard to fulfillment of specified requirements (BAFRA-CS-PR7.4-01-FM-11, BAFRA-CS-PR 7.4-01-FM-12);

- BAFRA-CS- PR7.4-01-FM-14 Form for review and recommendation for grant of licence

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- BAFRA-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

BAFRA-CS-PR 4.1-01 Procedure for use of license, certificates and marks of conformity  
BAFRA-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,
- ii) inspection of the production process and
- iii) audit of the management system;

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

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

There is provision for the clients to apply for recertification to BAFRA-CS before the expiry of license validity. The details are elaborated in BAFRA-CS-PR 7.9-02.


- BAFRA-CS-PR 7.9-01 Procedure for recertification/renewal
- BAFRA-CS-PR7.9-02 FM-01 Application form for recertification (renewal) of licence
- BAFRA-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 (BAFRA-CS-PR7.11-01).

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

#### 4.2.7 Managing changes affecting certification (see Clause 7)

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The changes affecting certification has been explained in the quality manual Clause 7.10 and elaborated in procedure BAFRA-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)

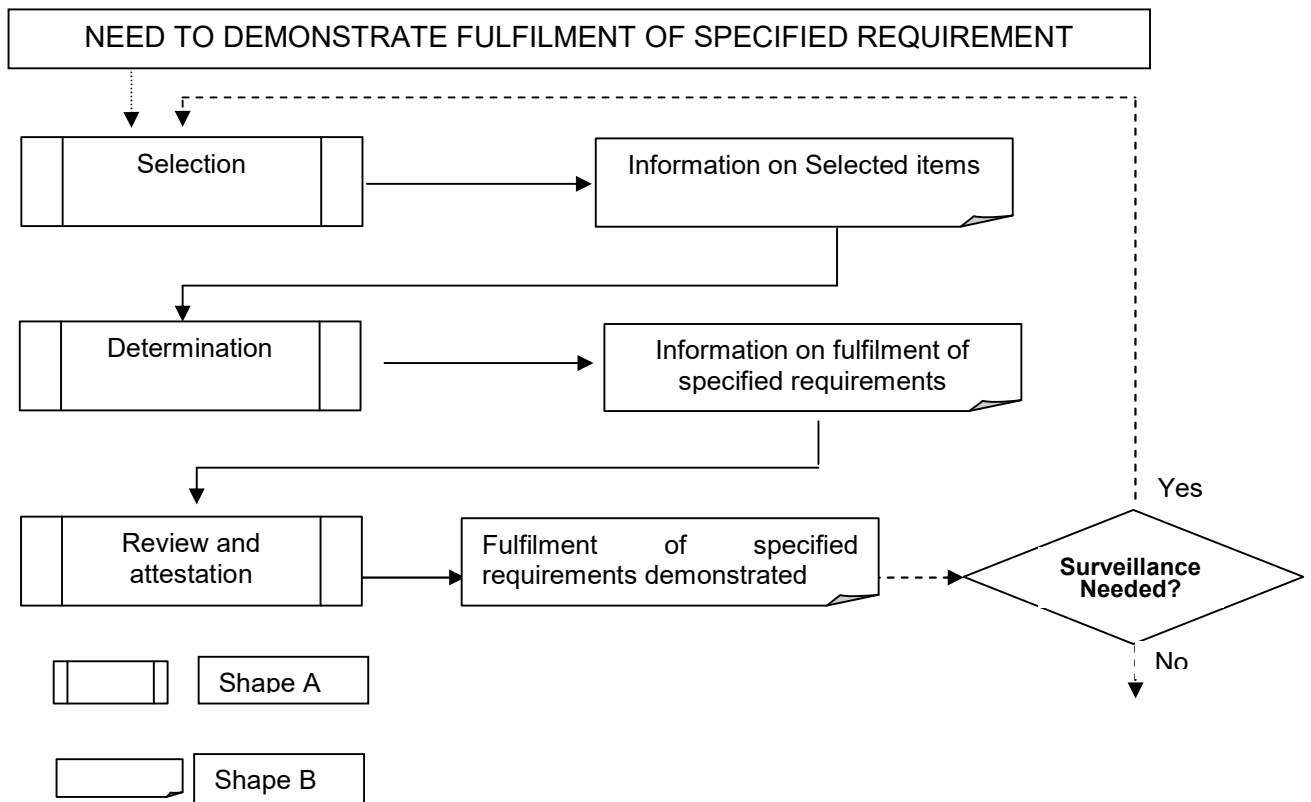



Fig 01 Functional approach to conformity assessment-solid arrows link the conformity assessment functions and their outputs /inputs & broken arrows express the possible needs or demands for conformity assessment.Shape A represents a conformity assessment function& Shape B represents output from a function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

### 4.3 Scope of the BAFRA-CS scheme

The scope of the “BhutanGAP” scheme is defined in terms of the types of product, the certification requirements and the geographical areas within which it operates conforming to



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

#### 4.4 Parties involved in the “BhutanGAP” scheme.

**The main parties involved in the operation of the “BhutanGAP” scheme are:**


- a) The scheme owner i.e. the Bhutan Agriculture and Food Regulatory Authority,
- b) BAFRA-CS for third party certification and
- c) the client organizations that have a certification agreement with the BAFRA-CS or that have applied for one.

The owner of “BhutanGAP” product certification scheme is the BAFRA Certification Services (BAFRA CS) which is also the certification body. The scheme owner is responsible for the rules, procedures, management and integrity of the “BhutanGAP” scheme.

BAFRA 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.

BAFRA-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 BAFRA-CS can perform all necessary inspection activities of the production processes and the producers' quality management system.

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## 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 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.

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

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

#### **5. 4 Application for certification and certification contract**

At the time of application, BAFRA-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” certification scheme along with updated version of BhutanGAP Standard. These rules are publicly available and provided on demand.


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

Once the application is received from the client, BAFRA-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.

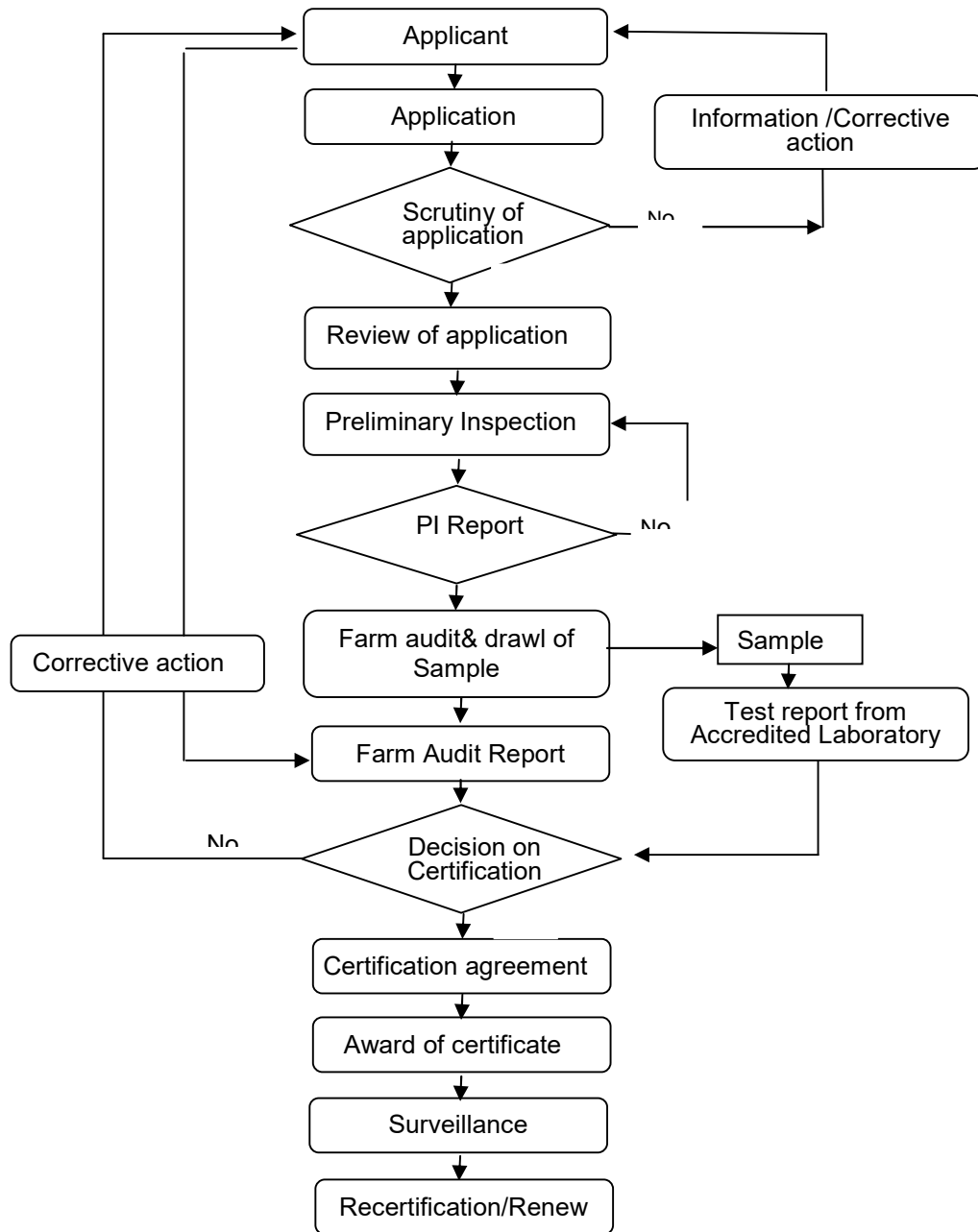
A typical Flow diagram of “BhutanGAP” product certification is given in Fig 02

BAFRA-CS-PR 7.2-01 Procedure for receipt, review and registration of application


BAFRA-CS-PR 7.4-01 Procedure for processing of application for certification

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STEPS INVOLVED IN “BhutanGAP” PRODUCT CERTIFICATION



**Fig.02 Flow diagram for BhutanGAP product certification**

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## 6. DETERMINATION

### 6.1 General


BAFRA-CS gathers information to determine the extent to which the client demonstrates its fulfillment of “BhutanGAP” certification scheme requirements.

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

BAFRA-CS ensures that the identified Evaluators meet the following educational and experience requirements established in BAFRA-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 BAFRA 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 22000 or ISO 17021 or ISO 19001, appropriate training in respect of agriculture, 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: BhutanGAP 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 farm sector in at least 2 different organizations, as an observer/trainee, under the leadership of a qualified evaluator.

The evaluation team may consist of one or more members. BAFRA-CS while assigning evaluators/inspectors/auditors for the purpose of evaluation should ensure that the same

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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.

BAFRA-CS-PR6.1-01: Procedure for management of competence of certification personnel


BAFRA-CS-PR6.1-02: Procedure for selection and registration of certification personnel

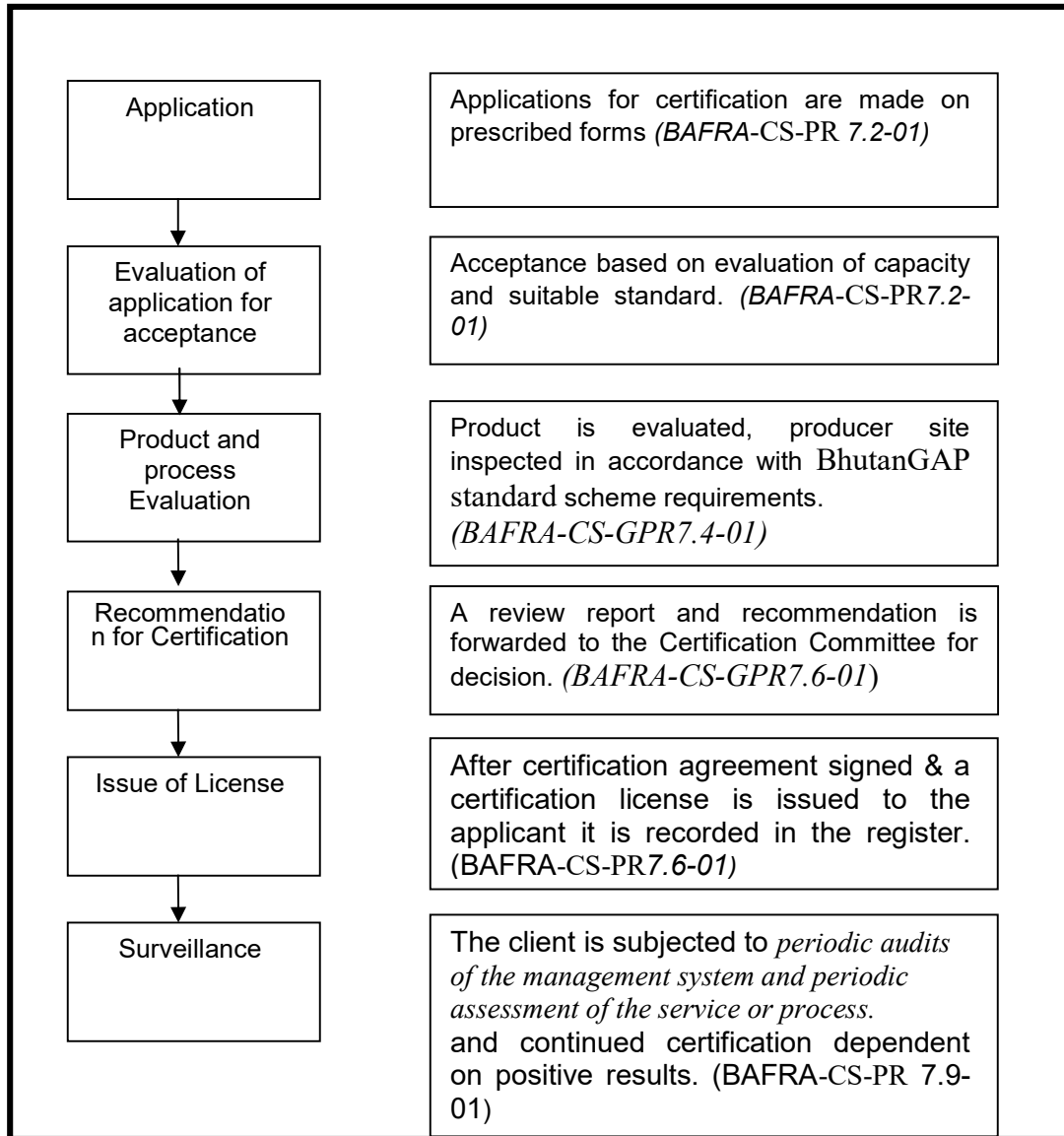
### 6.1.1 Evaluation plan

Based on the application and “BhutanGAP” certification scheme the BAFRA 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.


BAFRA-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

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**Fig.03 Process plan for operations of “BhutanGAP” product certification**

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

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After confirmation of the acceptance of the application, the BAFRA-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.

BAFRA-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 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, BAFRA-CS takes responsibility for these conformity assessment results.

In order to cover this responsibility under this “BhutanGAP” certification scheme the BAFRA 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**



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

Testing facilities used in product evaluation should demonstrate to BAFRA-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 BAFRAP-CS in accordance with BAFRA-CS-PR 6.2-01 approval 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.

BAFRA-CS-PR 6.2-01 BAFRA 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 BAFRA-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

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operation of the site. BAFRA-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 BAFRA-CS process records that demonstrate the effective implementation of the management system.

BAFRA-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 BAFRA-CS that is accredited and/or peer assessed in accordance with relevant International Standards (e.g. ISO/IEC 17021 and/or ISO/IEC 17040).

BAFRA 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**

BAFRA-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,

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- 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, BAFRA-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, BAFRA-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 BAFRA-CS documented procedures BAFRA-CS-PR7.4-01 and checklist BAFRA-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 BAFRA-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 BAFRA-CS;
- e) quality control of the product through the production process in accordance with "BhutanGAP" certification requirements, from the receipt of inputs, through all

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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” certification requirement.

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


**6.3.3.4 Elements of the management system critical for product conformity**

BAFRA-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.

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NOTE- BAFRA-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

BAFRA-CS has specified in the “BhutanGAP” certification scheme how situations of nonconformity with certification requirements are managed. If BAFRA-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** - a deficiency in the requirements to be met with respect to BhutanGAP, which are important but not essential depending upon the produce category. 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** - a deficiency in the requirements to be met with respect to BhutanGAP, which are mandatory and must be followed. 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 BAFRA-CS accepts planned corrective action.

**Critical** – a deficiency in the requirements to be met with respect to BhutanGAP, which are required to maintain 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 product 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 BAFRA-CS with objective evidence of an investigation into causative factors, exposed risks and the proposed corrective action plan. This shall be provided to BAFRA-CS within 14 days after the audit.
- A follow-up audit shall be conducted by the CB 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.

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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, BAFRA-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 “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 BAFRA-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.


- BAFRA-CS-PR7.4-01 Procedure for processing of application
- BAFRA-CS- PR7.4-01-FM-11 Farm audit report
- BAFRA-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 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

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decision is made not to grant certification, the client is informed with the reasons for the negative decision.

**8.2** BAFRA-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 BAFRA-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 Accredited Certification Body 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, BAFRA-CS issues a statement of conformity in the form of a license on the BAFRA-CS Prescribed format after Certification Agreement has been signed. Subsequently the license is uploaded on the Bhutan Agriculture and Food Regulatory Authority Product Certification Services’s (BAFRA-CS) website.

After the license has been granted, the certified client may place the BAFRA-CS “BhutanGAP” scheme’s certification mark on the product subject to conformity of the product to the requirements.

BAFRA-CS-PR4.1-01 Procedure for Legally Enforceable Certification Agreement


## **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 BAFRA 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.

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In all cases, the client ensures that BAFRA-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** BAFRA-CS has developed BAFRA-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 Ministry of Agriculture and Forests only as authorized by BAFRA-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 BAFRA-CS. In such advertisement the standards pertaining to the products or process for which a licence has been granted is to be stated.

BAFRA-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 BAFRA-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

BAFRA-CS submits a Certification agreement (See BAFRA-CS-PR 4.2-01- FM 01) to the licensee for signature. When the licence agreement has been signed, BAFRA-CS issues a license.



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The manner in which the licensee proposes to place or use the Certification Mark, must be approved by BAFRA-CS. The licensing agreement addresses conditions under which the mark or certificate will be used, and establishes rules in the case of misuse as is elaborated in the BAFRA-CS-PR 4.1-02 BAFRA-CS-PR 4.1-02 Procedure for use of license, certificates and marks of conformity

### **10.5 Misuse of the mark**

BAFRA-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 BAFRA-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 Suspending or withdrawing a licence**

#### **10.6.1 Suspension**

BAFRA-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 BAFRA-CS.

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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 BAFRA-CS and the client for a limited period of non-production or for other reasons.

- BAFRA-CS follows the BAFRA-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 (BAFRA-CS 01),
- 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, BAFRA-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 BAFRA-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 BAFRA-CS on its official website.

### 10.7 Publicity by clients

The client has the right to publish the fact:

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- 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 BAFRA-CS, if so required by the product certification scheme.


## 11. SURVEILLANCE

BAFRA-CS carries out surveillance of BhutanGAP certified clients (See BAFRA-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 BAFRA-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.

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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 BAFRA Product Certification (BAFRA 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 BAFRA-CS on request. If non-conforming products have been released onto the market, the client informs BAFRA-CS so that it can agree on the action to be taken.

BAFRA-CS-PR 7.9-02 Procedure for surveillance of certified clients

## 12. CHANGES AFFECTING CERTIFICATION

### 12.1 Changes 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-BAFRA-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 BAFRA-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 BAFRA-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,

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- 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 BAFRA-CS.

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## 12.2 Changes to other BAFRA-CS “BhutanGAP” scheme requirements

BAFRA which is both owner of scheme and certification body informs its clients if necessary, of other changes to the BAFRA-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 BAFRA-CS scheme

## 12.3 Changes by client

The client informs BAFRA-CS about any intended modification to the product, production process or management system which may affect the conformity of the product. BAFRA-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 BAFRA-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 BAFRA-CS using prescribed application form. In such cases BAFRA-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.

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### 13. CONFIDENTIALITY

BAFRA-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.

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

BAFRA-CS-PR 7.13-01 Procedure for handling complaints

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

### 16 FEES

BAFRA CS has prescribed schedule of fees for provision of certification services for each product listed in Annex A.


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**ANNEX A**

**LISTING GAP CERTIFIED PRODUCTS**


Sl.No.	Name of Product	Standard Regulation	License/ Certificate No.	Date of Grant
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				



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### LIST OF REFERRED TO DOCUMENTS

Sl. No	Doc. No.	DOCUMENT TITLE	Issue Status	Issue Date
1.	BAFRA-CS-PR4.1-01	Procedure for legally enforceable certification agreement	03	15 April 2020
2.	BAFRA-CS-PR4.1-02	Procedure for use of license, certificate and mark of conformity	02	15 April 2020
3.	BAFRA-CS-PR4.2-01	Procedure for management of impartiality and conflict of interest	03	15 April 2020
4.	BAFRA-CS-PR4.5-01	Procedure for maintaining confidentiality of data and information	02	15 April 2020
5.	BAFRA-CS-PR4.6-01	Procedure for publically available information	02	15 April 2020
6.	BAFRA-CS-PR5.2-01	Procedure for operation of impartiality committee	03	15 April 2020
7.	BAFRA-CS-PR6.1-01	Procedure for management of competence of certification personnel	04	17 July 2020
8.	BAFRA-CS-PR6.1-02	Procedure for selection and registration of certification personnel	03	15 April 2020
9.	BAFRA-CS-PR6.1-03	Procedure for identification of training needs and providing training	02	15 April 2020
10.	BAFRA-CS-PR6.1-04	Procedure for monitoring and evaluation of competence of certification personnel	02	15 April 2020
11.	BAFRA-CS-PR6.2-01	Procedure for Laboratory recognition scheme	02	15 April 2020
12.	BAFRA-CS-PR7.1-01	Procedure for organic risk based inspection	02	17 July 2020
13.	BAFRA-CS-PR7.2-01	Procedure for receipt, review and registration of application	03	15 April 2020
14.	BAFRA-CS-PR7.4-01	Procedure for processing of application for certification	04	17 July 2020
15.	BAFRA-CS-PR7.4-02	Procedure for calculation of man days for technical audit	04	15 April 2020
16.	BAFRA-CS-PR7.6-01	Procedure for grant of certification	04	17 July 2020
17.	BAFRA-CS-PR7.7-01	Procedure for control of certification documentation	02	15 April 2020
18.	BAFRA-CS-PR7.9-01	Procedure for surveillance of certified clients	03	17 July 2020
19.	BAFRA-CS-PR7.9-02	Procedure for recertification (Renewal)	03	17 July 2020
20.	BAFRA-CS-PR7.10-01	Procedure for managing changes affecting certification	02	15 April 2020
21.	BAFRA-CS-PR7.11-01	Procedure for termination, reduction, suspension and withdrawal of certification	03	17 July 2020
22.	BAFRA-CS-PR7.12-01	Procedure for control of certification records	02	15 April 2020
23.	BAFRA-CS-PR7.13-01	Procedure for handling complaint	02	15 April 2020
24.	BAFRA-CS-PR7.13-02	Procedure for handling appeals	02	15 April 2020
25.	BAFRA-CS-PR8.3-01	Procedure for document control	02	15 April 2020
26.	BAFRA-CS-PR8.4-01	Procedure for control of records	02	15 April 2020
27.	BAFRA-CS-PR8.5-01	Procedure for conducting management reviews	02	15 April 2020

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28.	BAFRA-CS-PR8.6-01	Procedure for conducting internal audits	02	15 April 2020
29.	BAFRA-CS-PR8.7-01	Procedure for corrective and preventive action	02	15 April 2020