	<b>BHUTAN FOOD AND DRUG AUTHORITY CERTIFICATION SERVICES</b>	<b>QUALITY PROCEDURE</b>	
DOC. BFDA-CS-PR-7.9-02	ISSUE 05	REVISION 00	01 MARCH 2023

## **PROCEDURE FOR RECERTIFICATION (RENEWAL) OF LICENSE**

### **1 PURPOSE**

To assess the effectiveness of the BFDA Product Certification Marks Scheme operated by licensee to consider continuation.

### **2. SCOPE**

This procedure covers all licenses coming for renewal under BFDA-CS.

### **3. RESPOSIBILITY**

**3.1** Head, BFDA is responsible for renewal of licenses granted under BFDA-CS.

**3.2** Certification Manager and Certification Officers are responsible for implementation of this procedure for continuing suitability of product certification.

### **4. PROCEDURE**

**4.1** A renewal notice as per prescribed format is issued to the licensee three months before the date of expiry of the license in the current operative period.

**4.2** The licensee shall submit the renewal application at least one month in advance of the expiry of the license, in the prescribed form.


#### **4.3 Review of application**

**4.3.1** All information regarding the surveillance visits carried out during the operative period and the factory and market samples drawn and tested during the period should be given. The information about pending actions, and samples under test at the time of previous renewal shall also be included. Information about samples withdrawn may also be incorporated in the renewal Form giving the reasons.

**4.3.2** The position regarding complaints received in respect of the license and the actions taken thereof shall also be given. Under 'Any Other Information' the follow-up action taken on the lapses and failures observed, and the corrective actions taken by the licensee should be given. Also the performance of the licensee during the period including suspension of marking, inclusion of additional varieties, changes permitted in the licensee's premises, personnel, etc. should also be given.

**4.3.3** If the required information is not provided in the application or BFDA-CS establishes the need for renewal inspection at the client's location, BFDA-CS shall institute an audit team to carry out renewal inspection and make use of the checklist during the visit.

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#### 4.4 Renewal of License

**4.4.1** License is considered for renewal when the renewal application is received before the date of expiry, performance is satisfactory upon document review and dues stand cleared.

**4.4.2** Renewal case should be put up in the format preferably two weeks in advance of the validity date to the Head, BFDA for orders, by the dealing officer with recommendations clearly giving the period recommended for renewal so that the decisions are taken and implemented well before the validity period ends.

**4.4.5** After the renewal orders, necessary endorsements shall be prepared for signatures of the renewing authority on the original license document submitted by the licensee within one month.

**4.4.6** Licenses are recertified normally for a period of one year. However, a license may be recertified for a period of three years at the request of the licensee, provided advance marking fee and License fee has been paid for the period of renewal.

**4.4.7** BFDA-CS shall accept written request for deferment of renewal period if the client agrees to refrain from using the Certification Mark during the deferment period. The deferment period will be for a maximum of 3 months after which they are required to apply for renewal.

#### 4.5 Refusal of Renewal of License

License is not considered for renewal when;

- the application is not received even after one month of the validity date,
- when the application is received and overall assessment of performance is unsatisfactory and there exist no or little possibility of effecting an improvement (requiring a considerable time beyond 6 months for implementation);


#### 4.5 Deferment of Renewal of License is deferred if:

- a) renewal application is not received within the validity period or before the expiry date, renewal application is received in an incomplete form.
- b) the license is under suspension of marking at the end of validity period, the renewal may be deferred for a period of six months.
- c) renewal application has been received but overall performance needs improvement which may require not more than two months from the date of validity.

#### 5. 1 SUSPENSION OF LICENCE

BFDA reserves the right to suspend a license for the following conditions:

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- a) 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),
- b) Major non-conformity (s) indicating a failure of the client’s product certification system.
- c) Client’s failure to take corrective actions to identified non-conformity (s) within targeted date.
- d) The client is unwilling or unable to make changes in response to BFDA’s procedure changes
- e) Improper use of the logo, symbol, registration, registration document or misrepresentation of registration
- f) Client violates the intent of the certification in such a way as to do damage to the image of the registration process and its certified management system has persistently failed to meet certification requirements.
- g) Failure to meet their financial obligations to BFDA
- h) Any other violation of the requirements within the certification agreement with BFDA.
- i) Client may be placed on Suspension and subsequent cancellation for not undertaking surveillance audit according to the stipulated dates as defined in individual scheme procedure requirements.
- j) at the request of the certified client, if the operation(s) in the certified premises can no longer be carried due to reasons of natural calamities such as flood, fire, earthquake etc, lock out declared by the management, or closure of business operations etc.
- k) Any other reason that may be intimated from time to time.


**5.2** BFDA shall notify the client in writing of Suspension within 15 days. The Suspension letter requires satisfactory closure of all issues communicated by BFDA.

**5.3** The suspension will be restored when:

- the client has closed all the Non Conformities to the satisfaction of the audit team.
- the client is ready for onsite audit and successful completion of the audit.

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

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

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### 5.3 WITHDRAWAL OF LICENSE

**5.3.1** Action is initiated for withdrawal of license when the normal operation of a license is not feasible due to violation and also on account of following reasons:

- a) Nonconformity of serious nature affecting health and safety observed during inspection or independent testing and that the corrective actions required would take considerable time for effective implementation.
- b) Certified unit contravenes the terms and conditions of certification and provisions of BFDA's certification scheme or the STI, considered serious in nature, for example non-settlement of financial dues, repeated failures of samples, suspension of certificate, inadequate corrective actions, lack of compliance to internal quality protocol, misuse of BFDA Certification Mark(s), non settlement of complaints, not allowing technical auditor access during working hours for the purposes of assessment, using Mark for types/varieties not included in the scope of the license, etc.
- c) The measures taken towards correcting the discrepancies/nonconformities are found inadequate or the proposed plan for corrective actions will take a considerable time beyond 6 months for implementation.
- d) If the licensee does not wish to prolong the license and send a communication to that effect.
- e) If the standard is amended/revised and implemented and the licensee either will not or cannot ensure compliance to the new requirements.
- f) If a complaint against BFDA certified product is found to be genuine, cancellation of the license may be considered depending upon the seriousness of the complaint.
- g) Non-closure of Non-conformities during the Suspension of License is an interim measure that may lead to cancellation if it lasts more than 180 days.

**5.3.2** In case of any of the situations as mentioned above, BFDA will communicate the decision of withdrawal to the client within fifteen days from the date it is noticed by BFDA.

### 6. REFERENCES

- BFDA-CS-PR7.11-01 Procedure for reduction, extension suspension or cancellation of certification  
 BFDA-CS -PR7.9-02 -FM-01 Form: Application for recertification (renewal) of licence  
 BFDA-CS -PR7.9-02-FM-02 Form: Letter intimating renewal of licence to the licensee  
 BFDA-CS -PR7.9-02- FM-03 Form: Renewal inspection checklist

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