

	BHUTAN FOOD DRUG AUTHORITY CERTIFICATION SERVICES	QUALITY PROCEDURE	
DOC. BFDA-CS-PR-7.11-01	ISSUE 07	REVISION 00	01 MARCH 2023

PROCEDURE FOR TERMINATION, REDUCTION, SUSPENSION OR WITHDRAWAL OF CERTIFICATION

1. PURPOSE

To ensure an organized and uniform certification process for termination, reduction, extension, suspension or withdrawal of certification, upon substantiating a nonconformity with any certification requirement.

2. SCOPE

This covers termination, reduction, suspension or withdrawal of certification.

3. DEFINITIONS

3.1 Suspension- Temporary invalidation of the statement of conformity for all or part of the specified scope of attestation

3.2 Withdrawal- The Revocation or cancellation of the statement of conformity. Failure to resolve the issues that have resulted in the suspension within the time established by MSCS results in withdrawal of certification.

3.3 Reduced scope of certification- Exclusion of that part of the scope of certification not meeting the requirements or when the client has persistently or seriously failed to meet the certification requirements.

3.4 Termination

If certification is terminated by request of the client.

3. RESPONSIBILITY

3.1 Head, BFDA is responsible for taking decisions for suspension, withdrawal and reduction in scope of certification.

3.2 Certification Manager is responsible for making recommendations on suspension, withdrawal and reduction in scope of certification as per 4.2 of this procedure.

PROCEDURE

4.1 BFDA-CS considers and decides on reduction, extension, suspension and/or withdrawal of certification upon substantiating nonconformity with any certification/scheme requirements. The non-conformities are categorized based on the following:

Minor - a deficiency that do not affect the integrity of the organic system in the implementation of the standard requirements prescribed in BOS. 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;

	BHUTAN FOOD DRUG AUTHORITY CERTIFICATION SERVICES	QUALITY PROCEDURE	
DOC. BFDA-CS-PR-7.11-01	ISSUE 07	REVISION 00	01 MARCH 2023

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

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

- When a critical nonconformity is issued at a certified site the certificate shall be immediately suspended for a maximum period of six (6) months.
- When a critical nonconformity is issued during an audit, the client must provide BFDA-CS with objective evidence of an investigation into causative factors, exposed risks and the proposed corrective action plan. This shall be provided to BFDA-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.

4.2 The Certification Manager (who is not involved in any audit activities) carries out review to continue, reduce/extend the scope, suspend or withdraw certification based on substantiated nonconformities with product requirements that arise outside surveillance or supervisory activities on the basis of all information available regarding the substantiated nonconformity.

4.3 The Head, BFDA makes the decision to continue, reduce/extend the scope, suspend or withdraw, or terminate; certification based on the recommendation of Certification Manager.

4.4 The Certification Manager, and the Head of BFDA involved in making these reviews and decisions shall neither be assigned nor performed any evaluation tasks related to substantiating the nonconformity.

4.5 If certification is cancelled/terminated (by request of the client), suspended or withdrawn, BFDA-CS shall take actions specified by the certification scheme and shall make all needed modifications to formal certification documents, public information, authorizations for use of marks, etc. to ensure it provides no indication that the product continues to be certified.

4.6 If a scope of certification is reduced/extended, BFDA-CS shall take actions specified by the certification scheme and shall make all needed modifications to formal certification documents, public information, authorizations for use of marks, etc. to ensure the reduced/extended scope of certification is clearly communicated to the client and clearly described in certification documentation and public information.

4.7 If certification is suspended, BFDA-CS assigns one or more persons to formulate and communicate to the client:

	BHUTAN FOOD DRUG AUTHORITY CERTIFICATION SERVICES	QUALITY PROCEDURE	
DOC. BFDA-CS-PR-7.11-01	ISSUE 07	REVISION 00	01 MARCH 2023

- actions needed to end suspension and restore certification for the product(s) in accordance with the certification scheme; and
- any other actions required by the certification scheme.

These persons shall be competent in their knowledge and understanding of all aspects of the handling of suspended certifications.

4.8 Any evaluations, reviews or decisions needed to resolve the suspension or that is required by the certification scheme shall be completed in accordance with specified procedures.

4.9 If certification is reinstated after suspension BFDA-SC shall make all needed modifications to formal certification documents, public information, authorizations for use of marks, etc. to ensure all appropriate indications exist that the product continues to be certified.

4.10 If a decision to reduce the scope of certification is made as a condition of reinstatement, BFDA-CS shall make all needed modifications to formal certification documents, public information, authorizations for use of marks, etc. to ensure the reduced scope of certification is clearly communicated to the client and clearly described in certification documentation and public information.

5 SUSPENSION OF LICENCE

5.1 Action is initiated for suspension of license when the normal operation of a license is not feasible on account of following reasons:

- 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) If the surveillance shows non conformity with the requirements of such a nature that immediate withdrawal is not necessary.
- e) The client is unwilling or unable to make changes in response to BFDA’s procedure changes
- f) Improper use of the logo, symbol, registration, registration document or misrepresentation of registration
- g) 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.
- h) Failure to meet their financial obligations to BFDA

	BHUTAN FOOD DRUG AUTHORITY CERTIFICATION SERVICES	QUALITY PROCEDURE	
DOC. BFDA-CS-PR-7.11-01	ISSUE 07	REVISION 00	01 MARCH 2023

- i) Any other violation of the requirements within the certification agreement with BFDA.
- j) 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.
- k) 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.
- l) 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 certified licensee is unable to satisfy the requirement for reinstatement within 180 days or time given by BFDA whichever is less, the License may be cancelled.

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.

6 WITHDRAWAL OF LICENSE

6.1 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-CS'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-CS 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.

	BHUTAN FOOD DRUG AUTHORITY CERTIFICATION SERVICES	QUALITY PROCEDURE	
DOC. BFDA-CS-PR-7.11-01	ISSUE 07	REVISION 00	01 MARCH 2023

- 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-CS certified product is found to be genuine, cancellation of the license may be considered depending upon the seriousness of the complaint.
- g) if the licensee fails to comply with the due settlement of financial obligations,
- h) if there is any other contravention of the licensing agreement,
- i) if inadequate measures are taken by the licensee in the case of suspension, resulting in non-closure of non-conformities raised during the suspension of the License even after 180 days.

6.2 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.

6.3 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.

6.4 Prior to withdrawal of a license, BFDA-CS decides upon the consequences in relation to products certified under the licence, whether the mark of conformity needs to be removed from all products in stock, and if practicable, from products already sold, or whether a clearance of the stock of marked products is permissible within a short period of time.

6.5 BFDA-CS decides if other actions are required, including if necessary in cases of a serious nature - informing the clients of the licensee, by the licensee or by BFDA-CS. Furthermore, the licence may be withdrawn in the following cases:

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

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

7. EXTENSION

Upon the request of the client at any point of certification cycle, the scope of certification can be extended after the verifications conducted as per BFDA-CS's certification process.

	BHUTAN FOOD DRUG AUTHORITY CERTIFICATION SERVICES	QUALITY PROCEDURE	
DOC. BFDA-CS-PR-7.11-01	ISSUE 07	REVISION 00	01 MARCH 2023

8. REDUCTION

Upon the request of the client or during the surveillance audit as identified/verified by the audit team, the scope of certification can be reduced after the verifications conducted as per BFDA-CS's certification process.

5. REFERENCES

- BFDA-CS -PR7.4-01 Procedure for processing of application for certification
- BFDA-CS -PR8.7-01 Procedure for corrective and preventive action
- BFDA-CS -PR7.6-01 Procedure for grant of certification
- BFDA-CS -PR7.9-01 Procedure for surveillance
- BFDA-CS -PR7.9-02 Procedure for recertification (renewal)