



དཔལ་ལྷན་འབྲུག་གཞུང་། གསོ་བ་ལྷན་ཁག་འབྲུག་བཟའ་ཆས་དང་སྒྲིན་རིགས་དབང་འཛིན།

ROYAL GOVERNMENT OF BHUTAN
MINISTRY OF HEALTH
BHUTAN FOOD AND DRUG AUTHORITY



INSPECTION SERVICES PROCEDURE FOR HANDLING COMPLAINTS

1. PURPOSE

To ensure that all complaints received on the services and decisions of BFDA-IS are addressed in timely and satisfactory manner.

2. SCOPE

This covers all services and decision related complaints received by BFDA-IS.

3. RESPONSIBILITY

Complaints Committee is responsible for handling complaints and satisfactorily resolving them.

Complaint Handling Officer is responsible for providing secretariat for the Complaints Committee and be a member secretary to the Committee.

The respective Chiefs-PABD/ FQSD are overall responsible for resolving the complaints and are Chair of the Committee depending on the nature of the complaint.

4. PROCEDURE

4.1 Complaints committee

4.1.1 BFDA-IS has constituted a complaints committee with the following composition to oversee complaint handling process:

1. Chief, PABD
2. Chief, FQSD
3. Complaint Focal
4. Technical Focal officer - Food/Livestock/Plant (depending on the nature of the complaint)

4.2 Terms of Reference

4.2.1 This committee provides:

- a) Receive and review complaints received in any form (e.g. Phone, letter, online report (BBFSS), etc.)
- b) Conduct thorough investigations, ensuring confidentiality and impartiality.
- c) Make recommendations for resolution and preventative measures to address systemic issues.
- d) Maintain records of complaints, investigations, and resolutions, ensuring confidentiality and compliance with applicable rules and regulations.

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4.3.1 BFDA-IS may receive the complaint in any form e.g., phone no. (1555), text to BFDA officials, letter, e-mail, online report (BBFSS), etc.

Upon receipt of the complaint BFDA-IS records the detail in BFDA-IS-FM-17 Complaint Register and acknowledges the receipt of the complaint to complainant vide form BFDA-IS-FM-16 (Letter Acknowledging Complaint) including complaint number or just provide the complaint number over phone in cases where complete contact information is not available.

4.3.2 Upon receipt of a complaint BFDA-IS shall evaluate and confirm whether the complaint relates to inspection activities, for which it is responsible, and if so, complaint processing form is used for further action.

4.3.3 BFDA-IS is responsible for gathering and verifying all necessary information (to the extent possible) to progress the complaint to a decision. Investigation is conducted and details of the investigation are recorded BFDA-IS-FM-37 (Complaint processing form).

4.3.4 The decision resolving the complaint shall be made by, or reviewed and approved by, person(s) not involved in the inspection activities related to the complaint.

4.3.5 Committee/ team is formed for taking the decision on complaint. Complaint related observation, recommendation and order are documented in the complaint processing form.

4.3.6 Whenever possible, BFDA-IS gives formal documented notice of the outcome and end of the complaint process to the complainant using BFDA-IS-FM-38 (Letter informing closure of complaint).

4.3.7 BFDA-IS takes any needed subsequent action in order mentioned below (correction and corrective action) also conducts a trend analysis for continual improvement.

4.3.8 If the complaint is found valid based on the investigation, recommendations for improvement are made to the operator. A follow-up visit is conducted to verify if the operator has implemented the recommendations. If recommendations are not found implemented, a warning letter is issued for implementation of recommendation within the estimated time frame (based on the risk) and this is verified in the further follow-up activity after the completion of time-frame, in case recommendations are not found implemented even then a suspension of the operator take place which is subjected to time-frame based on risk. In case the operator is not able to implement recommendations within the suspension time frame, their license is revoked/canceled, and it is intimated to them in writing.

4.3.9 Based on the criticality of the issue BFDA's representative can take immediate action as well as per the Food Rules and Regulations of Bhutan 2017.

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5. REVIEW AND AMENDMENT

- 5.1 Periodically review the effectiveness of the committee's procedures and make recommendations for improvements.
5.2 Any changes or amendments to these Terms of Reference require the approval of the Director, BFDA.

6. DURATION

- 6.1 The Complaint Committee will remain in operation indefinitely, subject to periodic reviews and assessments.

7. REFERENCES

Chapter VII Penalties of Food Rules and Regulations of Bhutan 2017

8. RECORDS

BFDA-IS-FM-16 Letter acknowledging complaint
BFDA-IS-FM-17 Complaint register
BFDA-IS-FM-37 Complaint processing form
BFDA-IS-FM-38 Letter informing closure of complaint
BFDA-IS-FM-39 Closure of complaint

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