



དཔལ་ལྷན་འབྲུག་གཞུང་། གསོ་བ་ལྷན་ཁག་ འབྲུག་བཟའ་ཆས་དང་སློན་རིགས་དབང་འཛིན།
ROYAL GOVERNMENT OF BHUTAN
MINISTRY OF HEALTH
BHUTAN FOOD AND DRUG AUTHORITY
INSPECTION SERVICES



INSPECTION PROCEDURE– Licensing Process for Feed Mill Operator (FMO)

1. Objective

The Objective of this document is to regulate the operation of the Bhutan Food and Drug Authority (BFDA) Licensing Process and promote uniformity in its operation and the interaction between BFDA and the Feed Mills (FM) as required by the Livestock Act of Bhutan 2001 and Livestock Rules and Regulations of Bhutan 2017.

2. Scope

This document explains the process of Licensing of feed millers in Bhutan and lays down the requirements that shall be followed in order to obtain, operate and maintain the BFDA Feed Safety License for Feed millers. The requirement applies to Commercial purpose.

3. Scope of Licensing

The scope of the BFDA Licensing Process for Feed Mill covers processing of feeds in Bhutan as per the BFDA Licensing Criteria, which is the BFDA Criteria for Good Hygienic and Manufacturing Practices (GHP/GMP).

4. Licensing Process Requirements

4.1 In addition to the requirements specified in the applicable Licensing Criteria, the requirements specific to Licensing Process as described in this document shall also apply.

4.2 Licensing Terms & Conditions: The Licensing terms and conditions describe the requirements which the FM is required to abide by after the Feed Safety License is granted. The details of the requirements are also available on the BFDA website. These terms and conditions also cover requirements with respect to use of the Feed Safety License number by FM. BFDA shall exclusively conduct all Licensing activities with its own employees and shall not outsource any external personnel for licensing activities

5. Licensing process

5.1 Application

5.1.1 BFDA shall provide the Feed Mill applicant with an up-to-date and detailed description of the evaluation including inspection, Licensing process and the documents containing the requirements for Licensing, the applicants' rights and the duties. The above information along with the application format shall be made available on the BFDA website.

5.1.2 The application format for the Licensing of Feed Mill contains at least the following information:

- a. the general features of the Feed Mills including its name and the address of its physical location, contact details, legal entity status, its functions and relationship in a larger corporation, if any;
- b. the Licensing Criteria against which Feed Safety License is being sought;

Doc. No: BFDA-IS-PR -28	Prepared by: Technical Officer	Approved by: Division Head	Page 1 of 28
Issue No: 00	Issue Date: 9 July 2025	Revision No: 00	Revision Date: 00



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

ROYAL GOVERNMENT OF BHUTAN

MINISTRY OF HEALTH

BHUTAN FOOD AND DRUG AUTHORITY

INSPECTION SERVICES



- c. the product(s) that are to be/being processed by the FM's at the site mentioned above (a); information about judicial proceedings relating to its operations/product, any proceedings by any Regulatory body or suspension/cancellation/withdrawal of any relevant Licensing/approvals under any Regulations;
- d. in case of new establishments, copy of the Project Proposal providing general information about the applicant FM's activities, description of production processes, details of manufacturing facilities, technological context, facility layout, feed safety systems, its human and technical resources (Internal as well as external, contracted, etc.), number of shifts of operation, information on in-house laboratory, if any, accessibility to external testing facilities, expected date of commissioning etc.
- e. information concerning all processes outsourced by the applicant FM that have potential to affect the hygiene and safety of the feeds. If the FM is outsourcing or intends to outsource such processes then the information regarding what processes being outsourced / being planned to outsource, the name and address of the outsourced organization, the BFDA license it holds, the basis on which they are approved by the FM the controls FM exercises / plans to exercise for controlling the quality (including safety) of such materials, etc. , is required to be submitted at the application stage itself;
- f. the current status of functioning of the Feed Mill(project stage, already commissioned Feed Mill); and
- g. name of the trained Feed employees if any.
- h. Detailed identified water source of FM.

5. 1. 3 The prospective applicant organization shall declare whether it has previously applied for or been licensed by the BFDA. If so, it must submit its past inspection and product test reports to the BFDA. BFDA may verify the information provided in the application by reviewing their own records.

5. 1. 4 License is granted only against the current relevant BFDA Criteria for granting licenses. The FM shall submit the application either to the BFDA District Office or Head Office. The District Office shall receive the application for completeness and forward it to the Head Office.

5.2 Application Review

Technical Focal Officer (Animal Biosecurity Section) of BFDA Head Office shall review the application for ensuring the following:

- a. information about the FM and human resources, the type of Feed product being manufactured and other details are sufficient for the conduct of the application review and the subsequent Licensing Process
- b. Any known difference in understanding between BFDA and FM are resolved, including agreement regarding the Licensing Criteria.

Doc. No: BFDA-IS-PR -28	Prepared by: Technical Officer	Approved by: Division Head	Page 2 of 28
Issue No: 00	Issue Date: 9 July 2025	Revision No: 00	Revision Date: 00



དཔལ་ལྷན་འབྲུག་གཞུང་། གསོ་བ་ལྷན་ཁག་ འབྲུག་བཟའ་ཆས་དང་སླན་རིགས་དབང་འཛིན།
ROYAL GOVERNMENT OF BHUTAN
MINISTRY OF HEALTH
BHUTAN FOOD AND DRUG AUTHORITY
INSPECTION SERVICES



5. 2. 2 Application Review shall be done by the Technical Focal Officer (Animal Biosecurity Section) of BFDA Head Office. Based on the review of applications, and deficiencies observed, requirement of additional information if any, shall be informed to applicant FM within Five working days. Records of review shall be maintained.

5. 2. 3 Only applications filled and supported with all required documents shall be accepted and registered with a unique identification number, acknowledged and records are maintained. The applications shall be registered within five days of receipt of the application from the FM.

5. 2. 4 The application with complete supporting documents is forwarded to the concerned inspecting team for undertaking inspections. Copies of all the documents are also retained as records at the BFDA Head Office

5. 2. 5 Antecedents of the applicants shall be checked in relation to the BFDA Feed Licensing Process. If the BFDA Feed Safety License has been suspended and canceled the application from the same FM shall not be entertained till they provide evidence of having taken suitable corrective action

5. 2. 6 Applications from FM who have earlier been implicated due to feed safety related issues, or whose earlier Feed Safety License was canceled because of violation of terms & conditions of Licensing, shall not be re-registered for one year from the date of cancellation of the Feed Safety License by BFDA.

5. 2. 7 Applications from feed miller found to be violating/misusing the provisions of the Livestock Act of Bhutan 2001 and the Livestock Rules and Regulations of Bhutan 2017, while their application is being processed for grant of License shall not be processed any further, and rejected after a due notice of 10 days. Fresh applications from them shall be treated as per clause **5. 1** given above. Requests for grant of Feed Safety License from ex-applicants shall be processed like a fresh applicant and the entire procedure for grant of license be adhered to and/or subject to clauses 5. 2. 5 and 5. 2. 6.

5.3 Evaluation

5.3.1 BFDA undertakes evaluation of FM which includes carrying out inspections as per relevant Licensing Criteria and testing of product samples drawn from the Feed Mill as per applicable product standards in BFDA recognized laboratories or laboratories meeting the applicable requirements of ISO/IEC 17025.

5. 3. 2 BFDA requires the applicant FM to undergo a Feasibility Inspection prior to commissioning of the feed establishment and once the establishment is commissioned, an announced Preliminary Inspection to check the readiness of the establishment for licensing and Factory Inspection for obtaining the Feed Safety License are planned. Post Licensing, BFDA conducts announced

Doc. No: BFDA-IS-PR -28	Prepared by: Technical Officer	Approved by: Division Head	Page 3 of 28
Issue No: 00	Issue Date: 9 July 2025	Revision No: 00	Revision Date: 00



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

ROYAL GOVERNMENT OF BHUTAN

MINISTRY OF HEALTH

BHUTAN FOOD AND DRUG AUTHORITY

INSPECTION SERVICES



surveillance inspections once in 12 months. Follow-up inspections are announced inspections conducted as and when required for verification of actions taken by the FM for ensuring compliance to the Licensing Criteria.

5.3.2 Tentative work plan

For managing all the inspections being conducted, the Technical Focal Officer (Animal Biosecurity Section) shall develop Tentative Work Plan for identified FM, along with details of the Inspection teams and the Inspection dates. The Work Plan shall include Feasibility Inspections, Preliminary Inspections, Factory Inspection, Follow-up Inspections and Surveillance Inspections. The Tentative Work Plan is developed on a risk-based approach. The tentative Work Plan shall cover the following Feed Mill:

- Applications received for Licensing need to be scheduled for a Feasibility Inspection, preferably within 5 working days of registration of application.
- For already commissioned FM, a preliminary Inspection to grant/not to grant Conditional Feed Safety Clearance may preferably be planned within 5 working days from date of receiving of application.
- Preliminary Inspection for fresh FM may preferably be planned within 6 months of grant of Conditional Feed Safety Clearance and
- FM whose last Inspections had identified non compliances need to be verified within the defined time frame agreed with the FM through Follow up Inspection.

5.3.3. The Tentative Work Plan is updated as and when any new applications, inspections report for inspections conducted in which noncompliance has been raised that requires a follow-up within a defined time frame and when complaints are received

5.3.4 Risk based inspection planning: For each Feed Mills, the Technical Focal (Animal Biosecurity Section) of BFDA HQ will assess the associated risk, which will serve as the foundation for prioritizing and planning inspections throughout the year.

5.3.4.1 Determination of risk associated with Feed Mill shall be done on following basis:

Risk Level	Non-Compliance Percentage	Description	Score
High Risk	Above 80%	When non-compliance exceeds 80%, it is categorized as high risk.	3

Doc. No: BFDA-IS-PR -28	Prepared by: Technical Officer	Approved by: Division Head	Page 4 of 28
Issue No: 00	Issue Date: 9 July 2025	Revision No: 00	Revision Date: 00



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

ROYAL GOVERNMENT OF BHUTAN

MINISTRY OF HEALTH

BHUTAN FOOD AND DRUG AUTHORITY

INSPECTION SERVICES



Medium Risk	50% to 80%	Non-compliance within the range of 50% to 80% is considered medium risk.	2
Low Risk	Below 50%	If non-compliance is less than 50%, it is classified as low risk.	1

Risk Level	Operational Scale	Indicative Criteria	Score
High Risk	Large-scale Feed Mill operations	- High production volume (>50, 000 MT/year) - Multiple product lines or sites	3
Medium Risk	Medium-sized Feed Mill operations	- Moderate production volume (e. g. 1, 000–50, 000 MT/year) - Limited product range	2
Low Risk	Small-scale or local Feed Mill operations	- Low production volume (e. g. <1, 000 MT/year) - Single product or niche market	1

Add all the scores for each of the Feed Mill to determine the Risk. The higher the total score, the higher is the risk as illustrated in Table below:

SN	Feed Mill Risk (Total score of Feed Mill based on the factor a and b	Risk categorization
	If Score is > 5	High
	If score is 3 – 4	Medium
	If Score is < 2	Low

This risk-based classification will serve as the foundation for preparing the Tentative Work Plan, ensuring appropriate oversight of all Feed Mills. For licensed Feed Mills, surveillance inspections will be scheduled based on their risk level: once every 6 months for high-risk, once every 12 months for medium-risk, and once every 18 months for low-risk categories.

5.44 The Inspection body must establish, implement, and maintain a comprehensive procedure for managing personnel competencies in the inspection process. This involves determining competence criteria for each function, identifying and addressing training needs, demonstrating personnel competency, formally authorizing personnel for specific roles, and monitoring

Doc. No: BFDA-IS-PR -28	Prepared by: Technical Officer	Approved by: Division Head	Page 5 of 28
Issue No: 00	Issue Date: 9 July 2025	Revision No: 00	Revision Date: 00



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

ROYAL GOVERNMENT OF BHUTAN

MINISTRY OF HEALTH

BHUTAN FOOD AND DRUG AUTHORITY

INSPECTION SERVICES



performance to ensure ongoing compliance. This structured approach ensures personnel are well equipped to maintain the integrity and effectiveness of the feed certification process. These inspectors possess the necessary qualifications, training, experience, and comprehensive knowledge required for conducting inspections. They are well versed in feed processing, including the technology used in product manufacturing, process operations, and service delivery. Additionally, they understand product usage, process operations, and service delivery, as well as potential defects, operational failures, and service deficiencies. They comprehend the implications of deviations from normal product use, process operations, and service delivery. Furthermore all livestock inspectors and Licensing committee members are required to sign a statement of confidentiality, non-disclosure and impartiality before conducting inspections. This ensures to avoid any conflict of interest, arising from their association with specific industry(ies) through employment, consultancy, relationships and commercial interests that could affect the impartiality of the licensing activities.

5. 5 Preparation and Planning for Inspection

5. 5. 1 Prior to undertaking the site inspection, the BFDA team of inspector

- study the application and the supporting documents received;
- prepare an Inspection Schedule in case of an announced inspection;
- inform the FM about the scheduled inspection along with a copy of the Inspection Schedule; and
- study the previous inspection report as applicable and non compliances, if any.

5. 5. 2 In case the FM responds indicating that the date of inspection is not suitable and requests and proposes a new date for inspection, the Technical Focal Officer (Animal Biosecurity Section) shall consider the suitability of proposed dates and reschedule the inspection. Necessary modification to the Inspection schedule shall be accordingly undertaken.

5. 6 Conducting Inspections

5. 6. 1 An opening meeting at the start of the inspection and a closing meeting at the conclusion of the inspection shall be carried out for each type of inspection conducted by BFDA.

5. 6. 2 Conducting the opening meeting

a) A formal opening meeting, where attendance shall be recorded, shall be held with the FM management and, where appropriate, those responsible for the functions or processes to be inspected. The opening meeting shall be conducted by the team leader. The purpose of the opening meeting is to provide a short explanation of how the inspection activities will be undertaken and shall include the following:

- introduction of the Inspection team, showing the official identification that provides legal authority for undertaking the inspection;
- introduction of the FM participants, including an outline of their roles;

Doc. No: BFDA-IS-PR -28	Prepared by: Technical Officer	Approved by: Division Head	Page 6 of 28
Issue No: 00	Issue Date: 9 July 2025	Revision No: 00	Revision Date: 00



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

ROYAL GOVERNMENT OF BHUTAN

MINISTRY OF HEALTH

BHUTAN FOOD AND DRUG AUTHORITY

INSPECTION SERVICES



- iii. confirming the purpose and type of the inspection, the Licensing Criteria against which the inspection shall be carried out;
- iv. confirming the product test parameters and the relating standard against which the product as and when drawn shall be tested;
- v. confirmation of the inspection plan and explaining the sequence of actions to inspect the processes;
- vi. confirming the time for the closing meeting;
- vii. confirmation of matters relating to confidentiality;
- viii. confirmation of relevant work safety, emergency, and security procedures for the inspection team;
- ix. confirmation of the availability, roles and identities of any guides and observers;
- x. the method of reporting, including any grading of inspection non compliance;
- xi. confirmation of the status of non compliances of the previous inspection, if applicable; confirmation that, during the inspection, the FM shall be kept informed of inspection progress, non compliances and concerns if any;
- xii. request for Guides to be present with the Inspection team to facilitate visits to specific areas within an FM; and
- xiii. opportunity for the FM to ask questions.

5. 7 Collecting and verifying information

5. 6. 1 During the inspection, the competent Livestock Inspectors shall collect and verify the information as is relevant to the Licensing Criteria for which license has been sought. The information shall be collected by a combination of techniques that includes:

- a) Observation of processes and activities which includes men, materials and products, machines and equipment, methods of work and the working environment;
- b) Interviews and questioning the personnel for their understanding of their roles and responsibilities (duties) and the procedures they are following; and
- c) Inspection team shall randomly collect and test sample of feed from the FM to ensure its conformity to the standards;
- d) The inspection team shall verify the FIFO system followed by the FM for both raw materials and final products. They shall also ensure that the rejected materials/products are handled and disposed in a proper manner; and
- e) Review of available documentation and records.

5. 7. 2 The Inspection team shall take notes of information collected through any of the means mentioned above, as they move through the facility during the inspection.

Doc. No: BFDA-IS-PR -28	Prepared by: Technical Officer	Approved by: Division Head	Page 7 of 28
Issue No: 00	Issue Date: 9 July 2025	Revision No: 00	Revision Date: 00



དཔལ་ལྷན་འབྲུག་གཞུང་། གསལ་བསྐྱོད་ལག་ འབྲུག་བཟའ་ཆས་དང་སློན་རིགས་དབང་འཛིན།
 ROYAL GOVERNMENT OF BHUTAN
 MINISTRY OF HEALTH
 BHUTAN FOOD AND DRUG AUTHORITY
 INSPECTION SERVICES



5. 8. Identifying Non-Compliances

5. 8. 1 From the information collected and notes taken, the Inspection team identifies and records the non compliances on the Inspection Checklist which is a part of the Inspection report. The Inspection team does a grading of the non compliance in terms of the risk they pose to Feed safety and animal health, as Critical, Major or Minor. Details of how the grading shall be done are detailed in Clause 5. 8. 3. and this is carried out only during Factory, Surveillance and Follow Up Inspections. Observations during the Preliminary inspection and Feasibility inspection that need to be improved upon by the FM are raised as Concerns.

5. 8. 2 The Concerns and non compliances with their grading shall be informed in writing to the FM discussed with them for ensuring that the findings are accurate and that they have understood the non-compliance(s).

5. 8. 3 Non Compliance Grading system - The primary objective of the inspection (Preliminary/ Factory/Surveillance/Follow-Up) is to assess the possibility if any condition or combination of conditions could render the feed unsafe or unsanitary, and assess if the feed mills is complying with the Licensing Criteria.

a) Minor non-conformities:

These are less severe deviations from GHP and GMP criteria that do not immediately impact feed safety or quality.

b) Major non-conformities:

These are significant deviations that could potentially impact feed safety or quality.

c) Critical non-conformities:

These are severe violations that pose an immediate threat to feed safety or quality. Deficiency when a direct feed safety impact without appropriate action by the FM is observed during the audit or when legality and/or certification integrity are at stake.

5. 8. 4 Handling of Non compliances

The FM is advised to take necessary corrections and corrective action on the non-compliances within the time frame below;

NC	Application process	Licensed client
Critical Non-conformity	Cease all relevant feed-related operations immediately to prevent further non-compliance or potential risks to safety and	The Feed Mill shall immediately halt feed processing and remain closed until all corrective actions are fully

Doc. No: BFDA-IS-PR -28	Prepared by: Technical Officer	Approved by: Division Head	Page 8 of 28
Issue No: 00	Issue Date: 9 July 2025	Revision No: 00	Revision Date: 00



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

ROYAL GOVERNMENT OF BHUTAN

MINISTRY OF HEALTH

BHUTAN FOOD AND DRUG AUTHORITY

INSPECTION SERVICES



	<p>quality.</p> <p>The proposed corrective action plan must be submitted to BFDA within 14 days following the audit. A follow-up audit will be conducted within six months to confirm the resolution of the critical non-conformity, or sooner if the corrective actions are completed earlier. Failure to implement the corrective actions within the six-month timeframe will result in the closure of application. In case the corrective action is not implemented within 6 months, audit shall be repeated.</p>	<p>implemented.</p> <p>The License shall be immediately suspended for a maximum period of six (6) months</p> <p>The proposed corrective action plan must be submitted to BFDA within 14 days following the audit. A follow-up audit will be conducted within six months to confirm the resolution of the critical non-conformity, or sooner if the corrective actions are completed earlier. Failure to implement the corrective actions within the six-month timeframe will result in the withdrawal of the license.</p>
Major Non-conformity	<p>License is not granted unless the FM provides objective evidence of planned corrective action within 14 days and all major nonconformities are resolved within 1 month. If resolving the major non-conformities requires additional time due to their severity or the effort needed to address the root causes, the client must implement temporary measures or controls to mitigate the associated risks until permanent corrective actions are fully implemented.</p> <p>When a major nonconformity is issued during an audit, the client must provide the IB with objective evidence planned corrective action. This shall be provided to the IB within 14 days after the audit. Corrective action shall be implemented by the organization within 14 days after the audit. The major nonconformity shall be closed by the CB within a further 14 days after implementation of the corrective action by the organization. The organization shall submit objective evidence of</p>	<p>A license is not suspended for a major non-conformity unless the proposed corrective action plan is not submitted within 14 days, and all major non-conformities are resolved within one month. If resolving the major non-conformities requires additional time due to their severity or the effort needed to address the root causes, the client must implement temporary measures or controls to mitigate the associated risks until permanent corrective actions are fully implemented.</p> <p>When a major nonconformity is issued during an audit, the client must provide the IB with objective evidence planned corrective action. This shall be provided to the IB within 14 days after the audit. Corrective action shall be implemented by the organization within 14 days after the audit. The major nonconformity shall be closed by the CB within a further 14</p>

Doc. No: BFDA-IS-PR -28	Prepared by: Technical Officer	Approved by: Division Head	Page 9 of 28
Issue No: 00	Issue Date: 9 July 2025	Revision No: 00	Revision Date: 00



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

ROYAL GOVERNMENT OF BHUTAN

MINISTRY OF HEALTH

BHUTAN FOOD AND DRUG AUTHORITY

INSPECTION SERVICES



	<p>implementation to the IB. The IB shall review the corrective action and related objective evidence of implementation, challenge it if necessary and determine its effectiveness and approve the CA. The IB shall conduct a follow-up audit to verify the implementation of the CA to close the major nonconformity. In cases where documentary evidence is sufficient to close out the major nonconformity, the IB may decide to perform a desk review. The completion of corrective actions might take more time depending on the potential severity of the major nonconformity and the amount of work necessary to eliminate the causative factors. In such cases the Client shall include any temporary measures or controls necessary to mitigate the risk until the permanent corrective action is implemented. A follow-up audit shall be conducted to verify the permanent corrective action and to close the major nonconformity.</p> <p>A critical nonconformity is raised in the event of non-completion of the approved corrective action within the agreed dates.</p>	<p>days after implementation of the corrective action by the organization. The organization shall submit objective evidence of implementation to the IB. The IB shall review the corrective action and related objective evidence of implementation, challenge it if necessary and determine its effectiveness and approve the CA. The IB shall conduct a follow-up audit to verify the implementation of the CA to close the major nonconformity. In cases where documentary evidence is sufficient to close out the major nonconformity, the IB may decide to perform a desk review. The completion of corrective actions might take more time depending on the potential severity of the major nonconformity and the amount of work necessary to eliminate the causative factors. In such cases the Client shall include any temporary measures or controls necessary to mitigate the risk until the permanent corrective action is implemented. A follow-up audit shall be conducted to verify the permanent corrective action and to close the major nonconformity.</p> <p>A critical nonconformity is raised in the event of non-completion of the approved corrective action within the agreed dates.</p>
Minor Non-conformity	<p>When a minor nonconformity is issued during an audit, the organization shall provide the IB with objective evidence the proposed corrective action This shall be provided to the auditor within three (3) months after the audit. License may be granted with unresolved</p>	<p>When a minor nonconformity is issued during an audit, the organization shall provide the IB with objective evidence the proposed corrective action This shall be provided to the auditor within three (3) months after the audit.</p>

Doc. No: BFDA-IS-PR -28	Prepared by: Technical Officer	Approved by: Division Head	Page 10 of 28
Issue No: 00	Issue Date: 9 July 2025	Revision No: 00	Revision Date: 00



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

ROYAL GOVERNMENT OF BHUTAN

MINISTRY OF HEALTH

BHUTAN FOOD AND DRUG AUTHORITY

INSPECTION SERVICES



	<p>minor conformities if the FM provides objective evidence of planned corrective action within 3 months of the audit. Corrective action (CA) shall be implemented by the organization within 12 months after the audit. The IB shall review the design of the corrective action, challenge it and approve it when acceptable. Implementation of the corrective action shall be reviewed, at the latest, at the next scheduled on-site audit. The IB shall review the corrective action and determine its effectiveness of implementation through recording auditor name and date of review on the CA.</p> <p>A major nonconformity is raised in the event of non-completion of the approved action plan at the next scheduled on-site audit.</p>	<p>A license will not be suspended or revoked due to minor non-conformities. Corrective action (CA) shall be implemented by the organization within 12 months after the audit. The IB shall review the design of the corrective action, challenge it and approve it when acceptable. Implementation of the corrective action shall be reviewed, at the latest, at the next scheduled on-site audit. The IB shall review the corrective action and determine its effectiveness of implementation through recording auditor name and date of review on the CA.</p> <p>A major nonconformity is raised in the event of non-completion of the approved action plan at the next scheduled on-site audit.</p>
--	---	---

Note: While the general descriptions of non-conformities for each category are provided above, the final determination depends on the inspector's judgment, taking into account the specific circumstances and context of the Feed Mill.

5.9 Conducting a closing meeting

5.9.1 A formal closing meeting shall be held with the FM management and, where appropriate, with those responsible for the functions or processes inspected. The closing meeting shall be conducted by the Inspection Team Leader, with the purpose of presenting the Inspection's conclusions, including the recommendation regarding Licensing. If required the non-compliances shall be read and discussed and the time frame for taking action and subsequent verification agreed upon. Attendance of all participating in the Closing meeting shall be recorded.

5.9.2 The Closing meeting shall also include the following:

- the method and time frame of reporting, including any grading of Inspection non compliances and concerns
- BFDA's process for handling Concerns and non compliances and including any consequences relating to the status of the FM License;

Doc. No: BFDA-IS-PR -28	Prepared by: Technical Officer	Approved by: Division Head	Page 11 of 28
Issue No: 00	Issue Date: 9 July 2025	Revision No: 00	Revision Date: 00



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

ROYAL GOVERNMENT OF BHUTAN

MINISTRY OF HEALTH

BHUTAN FOOD AND DRUG AUTHORITY

INSPECTION SERVICES



- c) the time-frame for the FM to take correction and corrective action for the non compliances and concerns raised during the Inspection;
- d) BFDA's post inspection activities; and
- e) information about BFDA's complaint handling and appeal processes.
- f) Signing of non-compliances summary report by FM and inspection team.

5.10 The Inspection report

The Inspection team shall write an Inspection report for each Inspection conducted. The Inspection Report shall be written in prescribed formats and shall provide complete and accurate information, adequate details including evidence and conclusions for ensuring appropriate evaluation, review and decision in respect of grant of License or continuation of the same. The inspection reports shall preferably be submitted to the Technical Focal Officer (Animal Bio-security Section), BFDA HQ within 10 working days of conduct of inspection.

5. 11 The Feasibility Inspection

5. 11. 1 The Feasibility inspection is the first of the inspections carried out before the Feed establishment has been set up and commissioned. The objective of the Feasibility Inspection is to determine:

- a) if the location and the surroundings of the Feed establishment would fulfill the requirements of the Licensing Criteria;
- b) if the planned structures, layout, facilities and equipment, water supply, adequacy of air and light at the proposed feed establishment as evidenced on site, or on drawings would fulfill the requirements of the Licensing Criteria;
- c) conformity of the quality of water at the feed establishment with those mentioned in the Licensing Criteria;

5. 11. 2 The Inspection team undertakes a site tour, examines the planned structures, layout, facilities and equipment, water supply, adequacy of air and light at the proposed Feed establishment as evidenced on site, or on drawings for their compliance to the Licensing Criteria, and also draws samples of water for testing at BFDA Recognized Laboratory or laboratory meeting the applicable requirements of ISO/IEC 17025. The sample of water shall be drawn from the actual site of the FM but in case the water supply has not been commissioned then, the sample of water shall be drawn from the source from where the water would subsequently be sourced. The water samples shall be drawn in triplicate, labeled with name of product, date of sampling, name of FM source from where sampled and sealed with a tape and signed by the Livestock Inspector. While one sample shall be sent to NFTL along with Feed Sample Submission Form, the second sample

Doc. No: BFDA-IS-PR -28	Prepared by: Technical Officer	Approved by: Division Head	Page 12 of 28
Issue No: 00	Issue Date: 9 July 2025	Revision No: 00	Revision Date: 00



དཔལ་ལྷན་འབྲུག་གཞུང་། གསེ་བ་ལྷན་ཁག་ འབྲུག་བཟའ་ཆས་དང་སླན་རིགས་དབང་འཛིན།

ROYAL GOVERNMENT OF BHUTAN

MINISTRY OF HEALTH

BHUTAN FOOD AND DRUG AUTHORITY

INSPECTION SERVICES



is kept with the FM as a confirmatory sample and the third sample is retain at the respective BFDA Office under prescribed conditions of storage in terms of temperature and humidity, if any.

5. 11. 3 Deficiencies observed with respect to the Licensing Criteria during the Feasibility Inspection shall be discussed on site with the applicant and also informed in writing as Concerns to the applicant FM for their proposed action plan.

5. 11. 4 The Inspection team shall take notes during the Feasibility Inspection and that shall form the basis for preparing the Feasibility Inspection Report and making recommendations, at the end of the Inspection. The Feasibility Inspection report is prepared and submitted to the Technical Focal Officer (Animal Bio-security Section) for their comments if any. On receipt of the test report for water from BFDA Recognized Laboratory or laboratory meeting the applicable requirements of ISO/IEC 17025. , and the response on the Concerns received from the FM, Technical Focal Officer (Animal Bio-security Section) will issue conditional feed safety clearance based on the Feasibility Report, test report for water along with the response received from the FM.

5. 11. 5 The Conditional Feed Safety Clearance is issued by the Technical Focal Officer (Animal Bio-security Section) to the FM, with a copy to the Director, BFDA and Department of Livestock, MoAL.

5.12 The Preliminary Inspection

5. 12. 1 The Preliminary Inspection of FM is carried out once the establishment has been set up. . The Objectives of the Preliminary Inspection is to check the establishment's preparedness of licensing and to validate the information provided during the application process.

5.13. The Factory Inspection

5. 13. 1 The factory inspection is carried out;

- a) to verify compliance with the applicable Licensing Criteria and assess their appropriateness and adequacy on a continuous basis vis-à-vis the products, processes and risk category. This would involve a detailed inspection of the facility, verification of compliance to relevant GHP/GMP and conformance to other Licensing requirements including trained feed employee(s).
- b) The sample of the product(s) shall be 10% of the representative of normal production capability and is typical of production, for independent testing at BFDA recognized lab and laboratory meeting the applicable requirements of ISO/IEC 17025. The samples shall be drawn in triplicate, labeled with details of name of product, date of sampling, name of FM, source from where sampled and sealed with a tape and signed by the Livestock Inspector. The Inspection team sends one sample to a BFDA recognized lab and laboratory meeting the applicable requirements of ISO/IEC 17025. along with Sample Submission Form, the second sample is kept with the FM as a Confirmatory sample and the third sample is retained at BFDA

Doc. No: BFDA-IS-PR -28	Prepared by: Technical Officer	Approved by: Division Head	Page 13 of 28
Issue No: 00	Issue Date: 9 July 2025	Revision No: 00	Revision Date: 00



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

ROYAL GOVERNMENT OF BHUTAN

MINISTRY OF HEALTH

BHUTAN FOOD AND DRUG AUTHORITY

INSPECTION SERVICES



Office under prescribed conditions of storage in terms of temperature and humidity, if any; and

- c) to draw a sample of water from the actual manufacturing site, in triplicate, labelled with details of name of product, date of sampling, name of FM, source from where sampled and sealed with a tape and signed by the livestock Inspector. The Inspection team sends one sample to BFDA recognized lab or laboratory meeting the applicable requirements of ISO/IEC 17025. along with Sample Submission Form, the second sample is kept with the FM as a confirmatory sample and the third sample is retained at BFDA office under prescribed conditions of storage in terms of temperature and humidity, if any.

5. 13. 2 The Inspection team shall take notes during the Inspection and later fill out the Inspection Checklist and grade the non compliances as per methodology defined at Clause 5. 8. 3 above. The non compliances observed during the Factory Inspection with respect to the Licensing Criteria shall be informed in writing to the applicant for taking necessary action. An acknowledgement of the Non compliances observed shall be obtained from the FM.

5. 13. 3 All non-compliances are required to be acted upon and closed through follow-up inspections for verification of adequacy of the actions taken by the FM before the grant of License.

5.14 Independent testing of samples

The Inspection team shall draw Feed samples from the FM site taking care of the following:

- a) care shall be taken to ensure that sample is drawn in such a manner so as not to contaminate the Feed while sampling and packing;
- b) packing and sealing of the samples shall be such that the product integrity is maintained for its intended shelf life;
- c) the samples shall be clearly identified with their name and type, batch identification and suitable identification to enable traceability to the applicant and the date and names of Livestock inspector conducting the inspection;
- d) draw samples in quantities adequate to facilitate their testing for all requirements specified in the product standards;
- e) if the product is affected by the conditions of temperature, handling and storage, then care shall be taken to ensure that the sample is drawn and maintained under those conditions for testing its conformity to specified product standards; and
- f) samples of feed products drawn for independent testing shall be forwarded to the BFDA Recognized lab or laboratory meeting the applicable requirements of ISO/IEC 17025 for ascertaining conformance to specified product standard for each test parameter. The specified standard for each test parameter, product details and quantity of samples shall be clearly mentioned and communicated to the testing laboratory through the Feed Sample Submission Form. The sample(s) shall be dispatched so that they do not get damaged and or contaminated, undergo deterioration, and the product integrity is maintained.

Doc. No: BFDA-IS-PR -28	Prepared by: Technical Officer	Approved by: Division Head	Page 14 of 28
Issue No: 00	Issue Date: 9 July 2025	Revision No: 00	Revision Date: 00



དཔལ་ལྷན་འབྲུག་གཞུང་། གསོ་བ་ལྷན་ཁག་འབྲུག་བཟའ་ཆས་དང་སྐྱོན་རིགས་དབང་འཛིན།
ROYAL GOVERNMENT OF BHUTAN
MINISTRY OF HEALTH
BHUTAN FOOD AND DRUG AUTHORITY
INSPECTION SERVICES



5. 15 Follow Up Inspections

5. 15. 1 Follow Up Inspections are conducted as and when required for verification of actions taken by FM on the Concerns or Non compliances observed during the previous Inspection. Follow Up Inspections are thus carried out both before and after Licensing, that is after Feasibility Inspection, Preliminary Inspection, Factory Inspection or a Surveillance Inspection, as required. The livestock Inspector verifies the actions taken on the Concerns or Non compliances as the case be, and reports their findings. If the action taken by the FM is observed to be incomplete, inadequate and compliance to Licensing Criteria has not been fulfilled, the Inspection team shall handle the non-compliances as per the clause 5. 8. 4.

5. 16 Final Evaluation

5. 16. 1 The purpose of this process step is to conduct an evaluation of all the information gathered through the process steps of Feasibility Inspection, Preliminary Inspection, Factory Inspection and Follow Up Inspections, if any, and the results of independent testing of samples of water and product(s), to ascertain if all the process steps as described in the Licensing Process leading to grant of license have been fulfilled and if the evaluation confirms that the FM has the capability and has maintained good hygienic and manufacturing practices in the establishment as per relevant Licensing Criteria and produce the relevant feeds that comply with the requirements of the specific product standard.

5. 16. 2 The final evaluation shall be carried out by the Technical Focal Officer (Animal Bio-security Section) to ensure the following:

- compliance to the BFDA Licensing Criteria; ,
- compliance to requirements of the BFDA Licensing Process.
- Evaluation regarding conformity of the Feed(s) with parameters/ requirements of the feed standard and Licensing Criteria;
- evaluation regarding the conformity of the sample of water as per Bhutan Drinking Water 2016.
- necessary documentation for proof of legal entity and authentication of premises of manufacture where Licensing is being sought;
- verification of implementation of corrective actions and closure of all non compliances and concerns raised; and
- any other requirements prescribed by BFDA.

5. 16. 3 Based on the evaluation as above, recommendations for proceeding to next step (independent review and decision making) shall be made. In case the evaluation indicates that

Doc. No: BFDA-IS-PR -28	Prepared by: Technical Officer	Approved by: Division Head	Page 15 of 28
Issue No: 00	Issue Date: 9 July 2025	Revision No: 00	Revision Date: 00



དཔལ་ལྷན་འབྲུག་གཞུང་། གསལ་བ་ལྷན་ཁག་ འབྲུག་བཟའ་ཆས་དང་སློན་རིགས་དབང་འཛིན།
ROYAL GOVERNMENT OF BHUTAN
MINISTRY OF HEALTH
BHUTAN FOOD AND DRUG AUTHORITY
INSPECTION SERVICES



some requirements of the Licensing Criteria or the Licensing Process have not been met, then these need to be completed and evaluated before proceeding to the next step.

5. 16. 4 Records of final evaluation along with all supporting documents and reports shall be maintained with Technical Focal Officer (Animal Bio-security Section).

17. Review

5. 17. 1 An independent review is carried out by a Technical Reviewer for Review and put up to committee for decision making at BFDA Head Office. The Technical Reviewer should have the relevant competence. The review is carried out within 10 working days of receipt of final evaluation report from the Inspection Team.

5. 17. 2 The review is based on the requirements specified in Licensing Criteria and the Licensing Process as stated in this document.

5. 17. 3 Any information on which a review and decision is based which comes from any source other than the evaluation process, for example complaints, information received from other Departments (like the Department of Livestock, etc) is made known to the applicant along with information on the evaluation process. The applicant is given the opportunity to comment on it.

5. 17. 4 Concerns and non-compliances raised during any of the Inspections like Feasibility Inspection/Preliminary/Factory Inspection/Follow-Up Inspection relating to the Licensing Criteria shall be corrected and the correction verified by the Inspection team before the license is granted. The concerns and non-compliances and their resolution as indicated in subsequent inspection reports shall be documented and made available for the purpose of review.

5. 17. 5 The records of review are retained and provide adequate confidence that all relevant aspects were examined prior to making recommendations.

5. 17. 6 The recommendation for licensing decisions, whether positive or negative, shall be justified and the basis for the same document.

5. 18 Licensing Decision

5. 18. 1 Licensing decisions are the sole responsibility of BFDA and the Committee takes the decisions for Review and Licensing based on the review report and inspection report submitted by the Technical Review Officer. The Review and Licensing Committee member shall not be involved in the earlier process of Feed safety licensing.

Doc. No: BFDA-IS-PR -28	Prepared by: Technical Officer	Approved by: Division Head	Page 16 of 28
Issue No: 00	Issue Date: 9 July 2025	Revision No: 00	Revision Date: 00



དཔལ་ལྷན་འབྲུག་གཞུང་། གསལ་ལྷན་ཁག་ འབྲུག་བཟའ་ཆས་དང་སླན་རིགས་དབང་འཛིན།
ROYAL GOVERNMENT OF BHUTAN
MINISTRY OF HEALTH
BHUTAN FOOD AND DRUG AUTHORITY
INSPECTION SERVICES



5. 18. 2 The Technical Focal Officer (Animal Bio-security Section) appoints the Technical Reviewing Officer to review the report submitted for the grant of Feed Safety License. The Technical Reviewing Officer shall not be part of the FSL process of that particular Feed Mill and shall have sufficient knowledge and experience to evaluate the report and to provide the review recommendation. The review and licensing decision is completed by the Review and Licensing Committee.

5. 18. 3 The roles of the Review and Licensing Committee are:

a) Review of Feed Mill's documents and reports

The Technical Reviewing Officer reviews and evaluates all the necessary documents and reports submitted by the Technical Focal Officer (Animal Bio-security Section) . The Reviewing Officer ensures that application and records are completed and in compliance with GHP/GMP criteria. Finally, prepares and submits the review report of the Feed Mill for the Committee. The Committee reviews the review report submitted by the Technical Reviewing Officer.

b) Recommendations for Approval

Provided recommendations for the approval or rejection of applications based on the review report by the Technical Reviewing Officer. They provide the rationale for approval or denial of FSL and ensure transparency in the licensing process in accordance with BFDA-IS-PR- 28.

c) Approval for FdSL

The final approval for the grant of FdSL is done by the Director, BFDA.

5. 18. The final evaluation is carried out by a Committee for Review and Decision Making for Licensing, comprising of competent personnel, duly authorized for this function. The 5 member Committee comprises of the Heads of Agency, Chief of Regulatory & Quarantine Officer of Plant and Animal Biosecurity Division, Specialist (PABD/FQSD), Technical Focal Officer (Animal Bio-security Section) and Chief of Regulatory & Quarantine Officer of Food Quality and Safety Division, co-opt member as relevant to the Application. A quorum of three is necessary for decision making.

5. 18. 5 BFDA grants Feed Safety License after ensuring complete compliance to the requirements of the Licensing Criteria, Licensing Process and after all non-compliances and concerns have been closed.

5. 18. 6 On grant of Feed Safety License, the Conditional Feed Safety Clearance ceases to be valid if provided.

5. 18. 7 In case, based on the evaluation, BFDA decides not to grant Feed Safety License to the FM, then it shall notify the FM of the decision of not granting the Feed Safety License along with reasons for the decision. If the FM expresses interest in continuing the Licensing Process,

Doc. No: BFDA-IS-PR -28	Prepared by: Technical Officer	Approved by: Division Head	Page 17 of 28
Issue No: 00	Issue Date: 9 July 2025	Revision No: 00	Revision Date: 00



དཔལ་ལྷན་འབྲུག་གཞུང་། གསལ་བ་ལྷན་ཁག་ འབྲུག་བཟའ་ཆས་དང་སློན་རིགས་དབང་འཛིན།
ROYAL GOVERNMENT OF BHUTAN
MINISTRY OF HEALTH
BHUTAN FOOD AND DRUG AUTHORITY
INSPECTION SERVICES



BFDA can resume the process for evaluation from the process as described from clause 5. 3 onwards-

5. 18. 8 Impartiality and absence of conflict of interest shall be ensured before entrusting the task of Licensing Decision Making to the Committee for Review and Decision Making.

5.19 Licensing Documentation

5. 19. 1 On grant of Feed Safety License, Technical Focal Officer (Animal Bio-security Section) informs the FM and issues a Feed Safety License, within 5 working days of decision making by the Committee for Review and Decision Making. The Feed Safety License shall include the following information:

- the name and address of the Licensing body (BFDA);
- the name and address of the FM and the address of the site licensed.
- the effective date (the date on which license is granted, which shall not precede the date on which the Licensing decision was completed);
- the Licensing Criteria against which the license has been awarded. Reference to the Licensing Criteria document shall include issue number and/or revision, used for evaluation of the licensed FM.
- unique identification code for the Feed Safety License.
- any other information required by the Licensing Criteria used for Licensing.
- in the event of issuing any revised Licensing document, a means to distinguish the revised documents from any prior obsolete documents; and the formal Licensing documentation shall include the signature of the authorized signatory of BFDA.

5. 19. 2 The Brand names of the feed processed by the FM shall not be mentioned on the license document or any other document intimating grant of License.

5.20 Directory of Feed Safety Licenses

5. 20. 1 BFDA shall maintain and make publicly available on its website, directory of valid Feed Safety Licenses that as a minimum shall show the name, relevant Licensing Criteria (normative document), scope and geographical location (e. g. District and country) for each licensed FM. BFDA shall also display suitably on its website the names of FM under suspension and those whose Feed Safety Licenses have been cancelled.

5. 20. 2 Apart from the information made available on its website, BFDA shall also have a provision and system for confirming validity of a Feed Safety License on request.

5. 20. 3 BFDA shall have a mechanism for frequent updating of the information on its website.

5. 21 Surveillance Inspection

Doc. No: BFDA-IS-PR -28	Prepared by: Technical Officer	Approved by: Division Head	Page 18 of 28
Issue No: 00	Issue Date: 9 July 2025	Revision No: 00	Revision Date: 00



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

ROYAL GOVERNMENT OF BHUTAN

MINISTRY OF HEALTH

BHUTAN FOOD AND DRUG AUTHORITY

INSPECTION SERVICES



5. 21. 1 BFDA shall conduct Surveillance Inspections of licensed FM on a risk-based approach. For Licensed Feed Mill with high-risk scoring, surveillance inspection should be conducted once in 6 months, for high risk, once every 12 months for medium-risk, and once every 18 months for low-risk categories.

5. 21. 2 Surveillance inspections shall be planned as per risk-based approach described in the Tentative Work Plan described in Clause 5. 3. 3 above.

5. 21. 3 Surveillance Inspections shall be carried out for verifying on-going compliance to the Licensing Criteria and shall be carried out very much like the Factory Inspection as described in Clause 5. 13 above. The Surveillance Inspection Report shall be prepared using the Inspection Report Format.

5. 21. 4 Surveillance inspections shall be announced depending on the risk assessment. . The inspection schedule shall be prepared in advance and sent to the FM, along with the names of the inspection team members.

5. 21. 5 During the Surveillance Inspection, the Inspection team shall as a minimum check and report on the following:

- a) compliance to the requirements of the Licensing Criteria and other requirements of Licensing Process;
- b) actions taken on non compliances observed during the previous inspection, failure of samples if any reported shall be informed to the FM; and
- c) draw samples for testing in a BFDA Recognized laboratory or laboratory meeting the applicable requirements of ISO/IEC 17025.

5. 21. 6 If any non-compliance is observed, the same shall be graded as Critical, Major or Minor as per the description given in clause 5. 8. 3. The non compliance report shall be provided to the FM in writing for correction and corrective action. Details of the same shall be reported in the Inspection Report for the Surveillance Inspection.

5. 21. 7 Non compliances observed during Surveillance Inspections shall be handled as per Clause 5. 8. 4.

5. 22. Dealing with failure of samples reported in independent laboratory reports

5. 22. 1 Failure of samples of feed product, drawn from the factory or the market, to comply with the requirements of the relevant product standards, shall be communicated to the licensed FM. FM is advised to undertake a root cause analysis and propose correction and corrective actions within 5 working days of intimation. BFDA shall respond to the proposed corrective actions within 5 working days and the FM shall implement the corrective actions within agreed time frame from acceptance of the corrective actions by BFDA.

Doc. No: BFDA-IS-PR -28	Prepared by: Technical Officer	Approved by: Division Head	Page 19 of 28
Issue No: 00	Issue Date: 9 July 2025	Revision No: 00	Revision Date: 00



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

ROYAL GOVERNMENT OF BHUTAN

MINISTRY OF HEALTH

BHUTAN FOOD AND DRUG AUTHORITY

INSPECTION SERVICES



5. 22. 2 BFDA shall inform the FM and organize a Follow-Up Inspection for verification of corrective action and after the corrective action has been taken. If the failure was observed in a sample drawn from the market, then the sample should be drawn from the market itself.

5. 22. 3 When the failure of the sample is in requirements relating to, contaminants, toxins and residues BFDA shall:

- a) suspend the BFDA Feed Safety License till adequate and effective corrective actions are taken;
- b) advise the licensed FM to;
 - i. stop dispatches of the failing Batch if stocks are available either at the site or in their warehouses;
 - ii. recall the failing Batch from the market;
 - iii. identify all feeds products manufactured with same raw material, or those manufactured during the same time under similar controls, and examine their production and quality records of the failing Batch and retest the Confirmatory samples of these Batches in the custody of the FM

5. 22. 4 Based on the satisfactory demonstration of root cause analysis and corrective actions to prevent such re-occurrences in future, the decision to revert back to the normal operation of Licensing shall be taken by BFDA. Testing of fresh samples of the specific product manufactured after implementation of corrective actions may be one of the mechanisms of satisfactory demonstration. Based on the specific situations BFDA shall decide the appropriate actions and record the justification for the same.

23. Suspension

5. 23. 1 BFDA shall issue instructions to the licensed FM for suspension of License when:

- a) the corrective actions taken by the FM on critical, major and minor non compliances within stipulated time period as defined in clause 5. 8. 4 above are observed to be incomplete and inadequate and do not ensure compliance to the Licensing Criteria;
- b) 2 consecutive samples, from the factory or market, as determined by date of manufacture, fail to conform to the specified product requirements;
- c) the FM has been non-operational for a year as reported in the surveillance inspection report; and

5. 23. 2 On receipt of instructions for suspension of License, the FM shall suspend production. The FM shall be advised to undertake a root cause analysis and identify the necessary corrective actions for resolving the same.

5. 23. 3 When license is suspended, BFDA requires that, during the period of suspension, the FM makes no misleading claims and should advise relevant existing and potential purchasers and

Doc. No: BFDA-IS-PR -28	Prepared by: Technical Officer	Approved by: Division Head	Page 20 of 28
Issue No: 00	Issue Date: 9 July 2025	Revision No: 00	Revision Date: 00



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

ROYAL GOVERNMENT OF BHUTAN

MINISTRY OF HEALTH

BHUTAN FOOD AND DRUG AUTHORITY

INSPECTION SERVICES



consumers regarding the status of Feed Safety License. BFDA shall ensure that the FMhas procedures in place to ensure that feeds that gave rise to suspension of Feed Safety License are recalled.

5. 23. 4 While under suspension, BFDA advises for withholding of dispatches of feed.

5. 23. 5 The information about the suspension and withdrawal of Feed Safety License shall be made publicly available by the BFDA on its website and any other mass media.

5. 23. 6 BFDA shall revoke suspension only when:

a) corrective actions have been taken and verified by the BFDA inspection team; reports of samples of feeds manufactured after corrective actions, confirm compliance to the specific product test parameters on independent testing as given in 5. 21 above.

b) reports of samples of feeds manufactured after corrective actions, confirm compliance to the specific product test parameters on independent testing as given in 5. 21 above.

5. 23. 7 Suspension shall not exceed a period of six months. The FM's inability to resolve issues relating to suspension within this period shall lead to cancellation of Feed Safety License.

5. 23. 8 The Technical Focal Officer (Animal Bio-security Section) of the BFDA head Office reviews the status of the licensed FM once every year to assess:

a) if the inspection reports are complete and provide adequate details on compliances and non-compliances reported;

b) if the grading of the non-compliances has been done appropriately.

c) if the licensed FM has undertaken action to address the non-compliances reported within the defined time frames.

d) Complaints if any received have been investigated.

5. 23. 9 Based on this review, the Technical Focal Officer (Animal Bio-security Section), Head office may decide upon organizing a surveillance inspection within a month having at least one common member from the previous inspection. The results of the review shall be shared with the livestock Inspectors and the need for training if any shall be identified and shared with the BFDA Head Office for organizing the necessary training.

5. 24 Cancellation

5. 24. 1 BFDA shall cancel the license when:

a) The FM contravenes the terms and conditions of Feed Safety License and provisions of Licensing Process like suspension of license beyond the stipulated period, inadequate corrective actions, etc;

Doc. No: BFDA-IS-PR -28	Prepared by: Technical Officer	Approved by: Division Head	Page 21 of 28
Issue No: 00	Issue Date: 9 July 2025	Revision No: 00	Revision Date: 00



དཔལ་ལྷན་འབྲུག་གཞུང་། གསལ་བསྐྱོད་ལྷན་འབྲུག་བཟའ་ཆས་དང་སློན་རིགས་དབང་འཛིན།
ROYAL GOVERNMENT OF BHUTAN
MINISTRY OF HEALTH
BHUTAN FOOD AND DRUG AUTHORITY
INSPECTION SERVICES



- b) Repeated failures of feeds to the specified standard and criteria and the inability of the corrective actions taken to ensure compliance, or if the proposed plan for corrective actions is likely to take considerable time, beyond 6 months for implementation.

5. 24. 2 BFDA shall cancel the license at the request of the licensed FM, if the operation(s) in the licensed FM's 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.

5. 25 Changes affecting Licensing

5. 25. 1 When the requirements of the Licensing Criteria and Licensing Process undergo changes that affect the FM, BFDA shall ensure these changes are communicated to all FM. BFDA shall verify the implementation of the changes by its FM and shall take actions required under Feed Safety Licensing of Feed Mill.

5. 25. 2 The terms and conditions of Feed Safety License shall have a clearly defined clause which makes it mandatory for the licensed FM to implement the changes in their processes and product, necessitated by the changes in above requirements.

5. 25. 3 Upon the decision to revise and publish the updated Licensing Criteria and/or Licensing Process requirements, BFDA will ensure that each licensed FM makes the necessary adjustments within a timeframe deemed reasonable by BFDA, unless BFDA specifies the timelines. This verification process includes steps such as inspections, retesting samples in an BFDA recognized laboratory or laboratory meeting the applicable requirements of ISO/IEC 17025. , evaluation, review, decision-making, and the issuance of revised formal Licensing documentation.

5. 25. 4 The licensed FM shall also be bound by the Licensing terms and conditions to inform BFDA about changes initiated by the FM; including changes in process and product design, changes in technology of manufacturing, etc, which have the potential to affect compliance to the Licensing Criteria. Based on the nature of changes informed, BFDA shall undertake an Inspection for verification of compliance to Licensing Criteria including testing of a sample of the product.

5. 25. 5 Change of location/Ownership/Name

5. 25. 5. 1 The licensed FM shall inform BFDA of any change in its location.

5. 25. 5. 2 On receipt of such information, BFDA shall issue instructions to the licensed FM for cancellation of Feed Safety License with immediate effect and advised to seek a new Feed Safety License for the new premises following the process steps listed above.

5. 25. 3 In the event of change of Ownership, the Feed Mill shall provide necessary documentary evidence. The new management of the organization shall submit its acceptance to the Terms and Conditions for Licensing. The same process shall be followed as and when an existing applicant undergoes a change in management. Such changes shall not call for a visit to the production site.

Doc. No: BFDA-IS-PR -28	Prepared by: Technical Officer	Approved by: Division Head	Page 22 of 28
Issue No: 00	Issue Date: 9 July 2025	Revision No: 00	Revision Date: 00



དཔལ་ལྷན་འབྲུག་གཞུང་། གསོ་བ་ལྷན་ཁག་འབྲུག་བཟའ་ཆས་དང་སློན་རིགས་དབང་འཛིན།
ROYAL GOVERNMENT OF BHUTAN
MINISTRY OF HEALTH
BHUTAN FOOD AND DRUG AUTHORITY
INSPECTION SERVICES



5. 25. 4 In case of change of Name, the manufacturer shall inform the change in the name to BFDA along with documentary evidence, and if satisfied BFDA shall endorse the License Document in the new name.

5. 26 Records

5. 26. 1 BFDA shall have documented procedures in respect of the retention of records to demonstrate that all Licensing Process requirements have been effectively fulfilled.

5. 26. 2 The Licensing related records shall be retained for a period of 5 years whereas the license document itself shall be retained as long as it is valid and beyond that, for a period of 5 years. BFDA shall keep records confidential. Records shall be transported, transmitted and transferred in a way that ensures confidentiality.

5. 26. 3 The Licensing records shall include records for all FM, that submitted the application, were evaluated, licensed or with licenses suspended or withdrawn/cancelled. The records of Licensing of FM shall include the following:

- a) Application information and results of application review;
- b) Inspection planning and preparation records, Inspection Schedules and other related records;
- c) Records of Feasibility Inspection, Preliminary Inspection, Follow-Up Inspection and Surveillance Inspections reports and related records, Test reports from BFDA recognized Laboratory or laboratory meeting the applicable requirements of ISO/IEC 17025.
- d) Initial and final evaluation records, Records of verification of correction and corrective actions.
- e) Records of review and Licensing decisions, committee deliberations and decisions, if applicable.
- f) Licensing Documentation (Feed Safety License);
- g) Records of complaints and appeals, and any subsequent correction or corrective actions.
- h) Related records necessary to establish the credibility of the Licensing Process, such as evidence of the competence of livestock Inspectors, review and review and licensing committee members, etc. as relevant; and
- i) In order to provide confidence that the Licensing process requirements were complied with

5. 27 Complaints and Appeal

5. 27. 1 BFDA shall have a documented procedure for handling complaints and appeals.

5. 27. 2 The procedure for complaint handling shall include complaints from all stake holders, especially its FM as well as customers of its FM.

Doc. No: BFDA-IS-PR -28	Prepared by: Technical Officer	Approved by: Division Head	Page 23 of 28
Issue No: 00	Issue Date: 9 July 2025	Revision No: 00	Revision Date: 00



དཔལ་ལྷན་འབྲུག་གཞུང་། གསོ་བ་ལྷན་ཁག་འབྲུག་བཟའ་ཆས་དང་སློན་རིགས་དབང་འཛིན།
ROYAL GOVERNMENT OF BHUTAN
MINISTRY OF HEALTH
BHUTAN FOOD AND DRUG AUTHORITY
INSPECTION SERVICES



5. 27. 3 The procedure for receipt and handling of complaints shall be made available to the public on the BFDA website and shall also be easily accessible on the website.

5. 27. 4 Upon receipt of a complaint or appeal, BFDA shall confirm whether the complaint or appeal relates to Licensing activities for which it is responsible and, if so, shall address it. BFDA shall acknowledge receipt of a formal complaint or appeal.

5. 27. 5 BFDA shall be responsible for gathering and verifying all necessary information (as far as possible) to progress the complaint or appeal to a decision.

5. 27. 6 The procedure shall include the process steps for receiving and recording, evaluating and establishing validity of the same, investigating and making decisions on complaints and appeals. The process step shall also include the activities of root cause analysis, correction and corrective actions.

5. 27. 7 If the complaint relates to a licensed FM and the product supplied by it, then the examination and evaluation of the complaints shall take into consideration the effectiveness and implementation of the FM's system. This would involve an inspection of the FM's premises. The decisions on complaint shall then be based on the result of this additional inspection.

5. 27. 8 BFDA shall record and track complaints and appeals, as well as actions undertaken to resolve them.

5. 27. 9 The decision resolving the complaint or appeal shall be made by, or reviewed and approved by, person(s) not involved in the Licensing activities related to the complaint or appeal. To ensure that there is no conflict of interest, personnel (including those acting in a managerial capacity) who have provided consultancy for a FM, or been employed by a FM, shall not be used by BFDA to review or approve the resolution of a complaint or appeal for that FM within two years following the end of the consultancy or employment.

5. 27. 10 Whenever possible, BFDA shall give formal notice of the outcome and the end of the complaint process to the complainant.

5. 27. 11 In respect of appeals, BFDA shall ensure that the individual(s)/committee entrusted with handling of appeal and its resolution decision shall be independent of the persons involved in Licensing related recommendations and decision and their position in the BFDA shall be such that it shall not be possible to influence their decisions with respect to the subject of the appeal.

Doc. No: BFDA-IS-PR -28	Prepared by: Technical Officer	Approved by: Division Head	Page 24 of 28
Issue No: 00	Issue Date: 9 July 2025	Revision No: 00	Revision Date: 00



དཔལ་ལྷན་འབྲུག་གཞུང་། གསལ་བ་ལྷན་ཁག་ འབྲུག་བཟའ་ཆས་དང་སྨན་རིགས་དབང་འཛིན།
ROYAL GOVERNMENT OF BHUTAN
MINISTRY OF HEALTH
BHUTAN FOOD AND DRUG AUTHORITY
INSPECTION SERVICES



5. 27. 12 The procedure shall also have provision for giving a written statement to the appellant, of the appeal findings including the reasons for the decisions reached and also communicating to the appellant about the provision for giving an opportunity to formally present their case.

5. 27. 13 Based on the presentation made, the individual or a committee appointed for hearing the case shall take a final decision on the appeal and a formal notice of the outcome and the end of the appeal process shall be given to the appellant.

5. 27. 14 BFDA shall take any subsequent action needed to resolve the complaint or appeal.

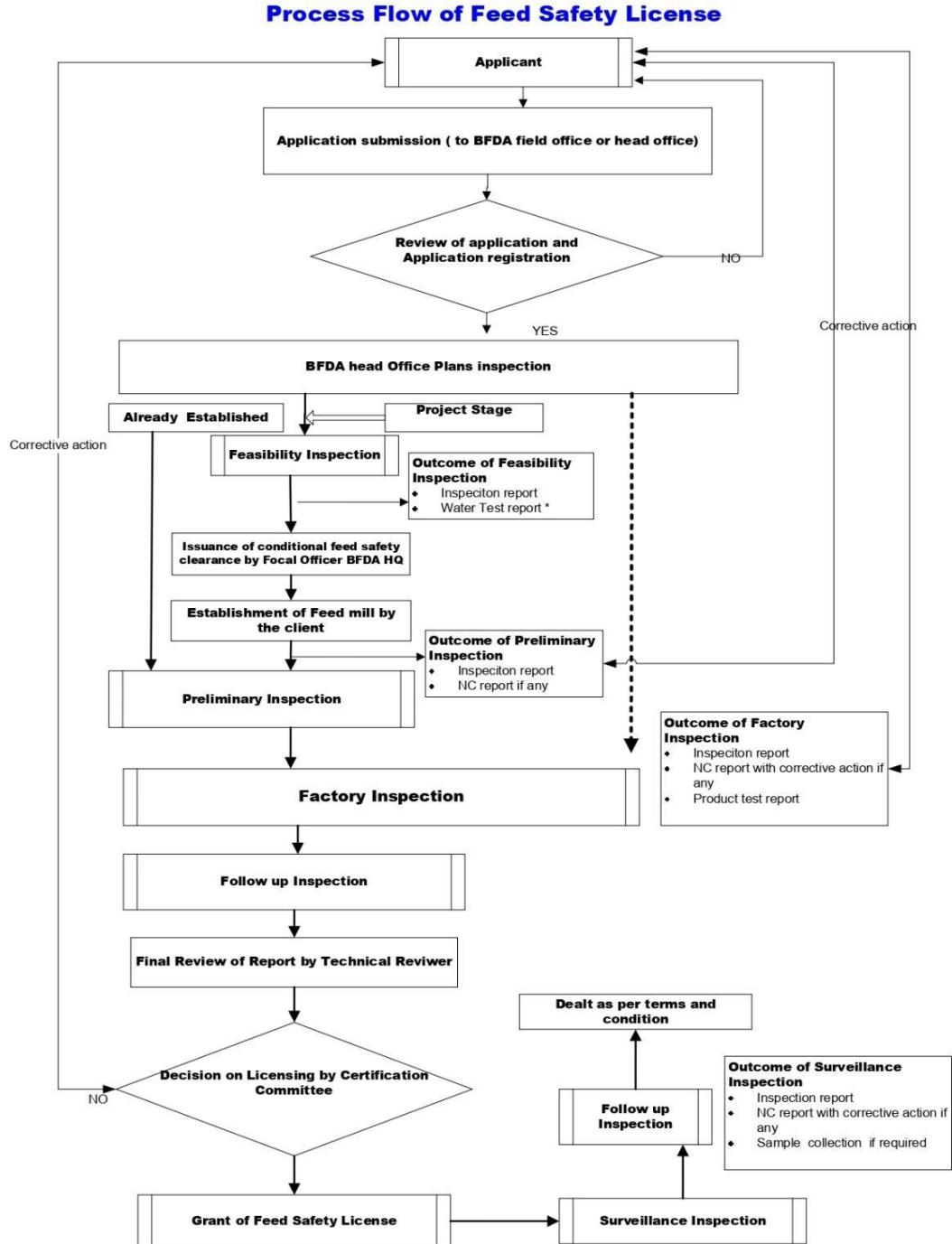
Doc. No: BFDA-IS-PR -28	Prepared by: Technical Officer	Approved by: Division Head	Page 25 of 28
Issue No: 00	Issue Date: 9 July 2025	Revision No: 00	Revision Date: 00



དཔལ་ལྷན་འབྲུག་གཞུང་། གསེ་བ་ལྷན་ཁག འབྲུག་བཟའ་ཆས་དང་སློན་རིགས་དབང་འཛིན།
ROYAL GOVERNMENT OF BHUTAN
MINISTRY OF HEALTH
BHUTAN FOOD AND DRUG AUTHORITY
INSPECTION SERVICES



Annexure I: Process Flow of Feed Safety License



Doc. No: BFDA-IS-PR -28	Prepared by: Technical Officer	Approved by: Division Head	Page 26 of 28
Issue No: 00	Issue Date: 9 July 2025	Revision No: 00	Revision Date: 00



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

ROYAL GOVERNMENT OF BHUTAN

MINISTRY OF HEALTH

BHUTAN FOOD AND DRUG AUTHORITY

INSPECTION SERVICES



Annexure II: Forms and Format

Document Name	Name of Format
Doc. No: BFDA-IS-FM-155	Application Form- Feed Safety Licensing
Doc. No: BAFRA-IS-FM-157	Inspection Schedule- Feed Safety Licensing
Doc. No: BFDA-IS-FM-158	Feasibility Report-Feed Safety Licensing
Doc. No: BFDA-IS-FM-160	Conditional Feed Safety Clearance
Doc. No: BFDA-IS-FM-161	Inspection Report for Feed Safety Licensing (Factory/ Surveillance)
Doc. No: BFDA-IS-FM-162	Follow Up Inspection Report
Doc. No: BAFRA-IS-CL-29	Basic Compliance Checklist GHP/GMP Criteria For Licensing Of Feed Business
Doc. BFDA-IS-FM-216	Application Review: Feed Safety Licensing
Doc. BFDA-IS-FM-217	Man-hour calculation: Feed Safety Licensing
Doc. BFDA-IS-FM-218	Confidentiality of the Inspector/Application Reviewer: Feed Safety Licensing
Doc. BFDA-IS-FM-219	Confidentiality of the Technical Reviewer: Feed Safety Licensing
Doc. BFDA-IS-FM-220	Confidentiality of the licensing committee: Feed safety Licensing
Doc. BFDA-IS-FM-221	Application Acknowledgement: Feed Safety Licensing
Doc. BFDA-IS-FM-222	Tentative workplan : Feeds Safety Licensing
Doc. BFDA-IS-FM-223	Nomination of Team: Feed Safety Licensing
Doc. BFDA-IS-FM-224	Registration of Opening Meeting and Closing Meeting: Feed Safety Licensing
Doc. BFDA-IS-FM-225	Sample submission form: Feed Safety Licensing
Doc. BFDA-IS-FM-226	Preliminary report: Feed Safety Licensing
Doc. BFDA-IS-FM-227	Final Evaluation Report: Feed Safety Licensing
Doc. BFDA-IS-FM-228	Risk Based Inspection: Feed Safety Licensing
Doc. BFDA-IS-FM-229	Legally Enforceable Agreement: Feed Safety Licensing
Doc. BFDA-IS-FM-230	Technical Review Report: Feed Safety Licensing
Doc. BFDA-IS-FM-213	Complaint Handling Report

Doc. No: BFDA-IS-PR -28	Prepared by: Technical Officer	Approved by: Division Head	Page 27 of 28
Issue No: 00	Issue Date: 9 July 2025	Revision No: 00	Revision Date: 00



དཔལ་ལྷན་འབྲུག་གཞུང་། གསེ་བ་ལྷན་ཁག་འབྲུག་བཟའ་ཆས་དང་སྨན་རིགས་དབང་འཛིན།
ROYAL GOVERNMENT OF BHUTAN
MINISTRY OF HEALTH
BHUTAN FOOD AND DRUG AUTHORITY
INSPECTION SERVICES



Annexure III: Abbreviations:

Abbreviation	Full Form
BFDA	Bhutan Food and Drug Authority
CA	Corrective Action
CB	Certification Body
DoL	Department of Livestock
FM	Feed Mill
FMO	Feed Mill Operator
FQSD	Food Quality and Safety Division
FdSL	Feed Safety License
GHP	Good Hygienic Practices
GMP	Good Manufacturing Practices
IB	Inspection Body
ISO	International Organization for Standardization
MT	Metric Tonnes
MoAL	Ministry of Agriculture and Livestock
MoH	Ministry of Health
NC	Non-Conformity
NFTL	National Food Testing Laboratory
PABD	Plant and Animal Biosecurity Division
RCSC	Royal Civil Service Commission

Doc. No: BFDA-IS-PR -28	Prepared by: Technical Officer	Approved by: Division Head	Page 28 of 28
Issue No: 00	Issue Date: 9 July 2025	Revision No: 00	Revision Date: 00