



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

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

INSPECTION SERVICES



SERVICE AGREEMENT FOR FOOD SAFETY LICENSING INSPECTION

This Service Agreement is entered into on...DD/MM/YYYY.... between

Bhutan Food and Drug Authority
Regional Office/Cluster Office.....
Name of Regional Chief/Officer In-charge.....

and

Name of the FB.....
Address of the FB.....
Representative from the FB.....
Designation.....

1. Purpose

The purpose of this Agreement is to establish the terms and conditions under which the Bhutan Food and Drug Authority (BFDA), as an ISO/IEC 17020 Type A Inspection Body, shall conduct inspection activities for the purpose of evaluating the applicant's compliance with the BFDA GHP GMP Criteria and other applicable requirements for Food Safety Licensing.

2. Scope

This Agreement applies to all inspection activities associated with the Food Safety Licensing of the Food Business including the following activities:

- Review of application and supporting documents;
- On-site inspection of the food business;
- Verification of compliance with applicable legal and technical requirements;
- Collection of samples where necessary;
- Review of corrective actions;
- Technical review and licensing recommendation.

3. Responsibility

3.1 Responsibilities of BFDA

BFDA shall:

- Assign competent inspection personnel;
- Conduct inspection activities impartially, independently and objectively in accordance

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with ISO/IEC 17020, BFDA-IS-PR-22 PROCEDURE FOR FOOD BUSINESS LICENSING and other applicable procedures under BFDA-IS;

- Maintain confidentiality of information obtained during inspection except where disclosure is required by law;
- Inform the applicants of inspection findings, non-conformities and specify the timeframe for implementing corrective actions;
- Make licensing recommendations solely on the basis of objective evidence;
- Handle complaints and appeals in accordance with established procedure.

3.2 Responsibilities of the FBO

The Food Business Operator shall:

- Provide complete and accurate information relating to the application;
- Grant inspectors unrestricted access to all relevant premises, facilities, equipment, records, personnel and products necessary for inspection;
- Cooperate fully with inspection personnel during inspection activities;
- Implement corrective actions for identified nonconformities within the specified timeframe;
- Notify BFDA of any significant changes affecting the licensed activities during the application process.

4. Impartiality

BFDA conducts all inspection activities independently and impartially. The applicant shall not attempt to influence the inspection outcome through gifts, inducements, pressure or by any other means. Any attempt to improperly influence inspection activities may result in suspension or termination of the inspection process and appropriate regulatory action.

5. Confidentiality

All information obtained during the inspection shall be treated as confidential and shall not be disclosed to third parties except:

- where required under applicable laws and regulations;
- with written consent of the applicant; or
- where disclosure is necessary for accreditation, legal proceedings or regulatory purposes.

6. Licensing Process

The applicant acknowledges that:

- Acceptance of the application by BFDA does not guarantee issuance of a Food Safety License.

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- Licensing decisions shall be based solely on demonstrated compliance with applicable requirements.
- Additional inspections may be conducted by BFDA where necessary.

7. Applicable Fees for Food Safety Licensing

While the inspection services provided by BFDA is free, the FBO shall pay Nu. 100/- as registration fee and Nu. 500/- for Food Safety License as per Section 53 of the Food Act of Bhutan, 2005 and Section 33 of the Food Rules and Regulations of Bhutan 2017.

8. Complaints and Appeals

The applicant may file a complaint regarding inspection activities or licensing decisions via email, phone (toll free number 1555) or text to BFDA officials. BFDA-IS will handle all complaints and appeals as per BFDA-IS-PR-08 PROCEDURE FOR HANDLING COMPLAINTS and BFDA-IS-PR-09 PROCEDURE FOR HANDLING APPEALS.

9. Suspension and Termination

BFDA may suspend or discontinue inspection activities where:

- False or misleading information is provided;
- Access required for inspection is denied;
- Inspection personnel are threatened, obstructed or unduly influenced; or
- Any other circumstances prevent the inspection from being conducted impartially and effectively.

10. Governing Law

This agreement shall be governed by the Food Act of Bhutan 2005 and its Rules and Regulations 2017 and other applicable regulatory requirements.

11. Validity of the agreement

This Agreement shall become effective on the date of signature and shall remain valid until the completion of Food Safety Licensing process or until otherwise terminated in accordance with this agreement.

12. Declaration

We hereby acknowledge that we have read, understood and agree to comply with the terms and conditions of this agreement.

Issued in duplicate and signed by an authorized representative of the Bhutan Food and Drug Authority (BFDA) and Food Business Operator (FBO).

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For Inspection Body (IB):

Name of Chief/OIC:

Name of BFDA Office:

Signature and seal:

Date:

For Food Business Operator (FBO):

Name of FBO representative:

Name of Food Business:

Signature and Seal:

Date:

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