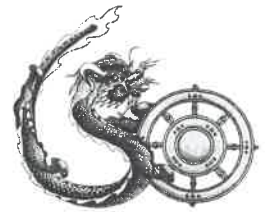




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ROYAL GOVERNMENT OF BHUTAN  
Ministry of Agriculture and Forests  
Thimphu : Bhutan



མོན་པོ།  
MINISTER

BAFRA/MoAF/5-25/1088

April 16 2018

**EXECUTIVE ORDER**

**Sub: Approval of Food Import Control Documents**

In exercising the power conferred under Chapter II of the Food Act of Bhutan 2005, the Ministry of Agriculture and Forests is pleased to formalize the following two Food Import Control documents with effect from 16 April 2018:

1. Good Importing Practices
2. Guideline for Import of Food into Bhutan

The above two guideline documents were endorsed during the 91<sup>st</sup> RNR-GNH Committee meeting held on 7<sup>th</sup> March 2018 and the National Food Quality and Safety Commission meeting held on 29<sup>th</sup> March 2018. These guideline documents were developed and adopted to ensure the quality and safety of imported food to protect consumers and facilitate fair practices in food while ensuring unjustified technical barriers to trade are not introduced.

  
Yeshey Dorji  
MINISTER

Cc:

1. The Secretary, Ministry of Agriculture and Forests, Thimphu
2. The Secretary, Ministry of Health, Thimphu
3. The Secretary, National Environment Commission, Thimphu
4. The Attorney General, Office of Attorney General, Thimphu



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**ROYAL GOVERNMENT OF BHUTAN**  
Ministry of Agriculture and Forests  
Thimphu : Bhutan



མོན་པོ།  
**MINISTER**

5. The Secretary General, Bhutan Chamber of Commerce and Industry, Thimphu
6. The Director General, Bhutan Agriculture and Food Regulatory Authority, MoAF, Thimphu
7. The Director General, Department of Livestock, MoAF, Thimphu
8. The Director, Department of Agriculture, MoAF, Thimphu
9. The Director, Department of Public Health, MoH, Thimphu
10. The Director, Department of Trade, MoEA, Thimphu
11. The Director, Department of Law and Order, MoHCA, Thimphu

# Guideline for Import of Food into Bhutan



**MINISTRY OF AGRICULTURE AND FORESTS  
ROYAL GOVERNMENT OF BHUTAN**

THIMPHU, 2018

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## Background

In accordance with sections 61-64 of Food Act of Bhutan 2005 and Sections 79-89 of Food Rules and Regulations of Bhutan 2017 importation of food into Bhutan requires food businesses to meet all regulatory requirements. This includes obtaining a trade licence (for organized importers) from the Ministry of Economic Affairs, and a food business licence/ clearance from the Bhutan Agriculture and Food Regulatory Authority (BAFRA).

On receiving appropriate licences, the food business shall submit a request to BAFRA for an import permit, which could be a food/livestock permit; a food/plant permit or simply a food permit. BAFRA will review the submission and if acceptable will issue the permit with the applicable conditions. All food imported by organized importers must be certified by the authority in the exporting country as per Annexure 3 of this guidelines.

Once the food business has the appropriate permits, they can arrange to import food as per the conditions of the permit. The food will arrive at a designated port of entry. At that time, the documentation accompanying the imported food will be reviewed by a BAFRA inspector, and as required, the imported food will be inspected. Based on the review and/or inspection, a decision on whether the food will be allowed into Bhutan will be made.

Food that meets the import requirements will be allowed into Bhutan for sale and distribution. Food that does not meet the import requirements will be rejected, (e.g., return to supplier) or destroyed if it presents imminent danger to public health.

Importers, as with other food businesses in Bhutan, are subject to inspection by BAFRA inspectors and are required to meet the Good Importing Practices.

The document has 3 parts:

- Chapter 1: Import Permit
- Chapter II: Border Controls and Admissibility Procedures
- Chapter III: Importer Inspection

## Objective

1. This guideline aims to:

- (1) Provide guidance on the importation of food into Bhutan
- (2) Outline processes and procedures for making decisions on issuing import permits and inspection processes ; and
- (3) Determine the admissibility of food into Bhutan.

**Scope**

2. This guideline shall:

- (1) Apply to all applications by Food Business Operators for food import ;
- (2) Govern the process for border controls and importer inspection;
- (3) Be read in conjunction with the Food Safety Licensing of Food Businesses – Licensing Process (BAFRA-LP-FSL 2017) and Good Importing Practices.
- (4) Extend to the whole of the kingdom of Bhutan.



## **CHAPTER I: IMPORT PERMIT**

### **Application**

3. Commercial importer intending to import food that is a plant product or livestock product shall submit an application to BAFRA seeking approval for an import permit and shall include all relevant information.
4. Import application for food of animal origin or plant origin or genetically modified foods shall include conditions applicable under relevant legislations.
5. Import of food for personal consumption do not require import permit however, such import shall comply with the requirements under the livestock regulations, plant quarantine and seed regulations and biosafety regulations.
6. A Food import permit shall be required for the import of any food and where appropriate, a livestock or plant quarantine import permit may be required; and
7. Registration for small scale importers shall be done at the respective BAFRA field offices for inspection and monitoring purposes.

### **Application Process**

8. A commercial importer shall apply to a nearest BAFRA field office for the import permit in a prescribed application form under Annexure 1 of this guideline prior to at least five working days from the date of import.

### **Organised Importers**

9. Any Organised Importers applying for import permit shall provide the following information in the prescribe format as specified in Annexure 1 of this guideline:
  - (1) The Food Safety Licence / Clearance and trade licence number and general information about the food business, including name, address, contact details;
  - (2) Operation model(e.g., import for sale only; import for domestic processing);
  - (3) Information on proposed food imports (e.g., product characteristics, supplier, processor);
  - (4) A copy of the label for both bulk and pre-packaged food;
  - (5) Address of responsible authority in exporting country having official control of the foreign supplier (e.g., competent authority, recognised certification body) and evidence that the foreign supplier is in good regulatory standing;
  - (6) A copy of the last inspection report issued by the responsible authority, if it is from new foreign supplier;



- (7) Transport details (e.g., plane; truck, designated port of entry; expected date of arrival, storage on import);
- (8) Permit duration (e.g., by lot; or by month); and
- (9) Evidence of appropriate corrective action, if the BAFRA Food Safety clearance has been suspended or cancelled during the last year.

### **Small Scale Importers**

10. Any Small-Scale Importers applying for import permit shall furnish the following information in the prescribed format as specified in Annexure 1 of this guideline. :
- (1) the Trade Licence number (where applicable), general information about the food business, including name, address, contact details;
  - (2) Information on food imports including:
    - (a) Name of person or person who will be importing the food;
    - (b) Country, region, town, and if known the local market(s) from which the food will be imported; and
    - (c) Categories of food to be imported and approximate quantities.
  - (3) Transport details (e.g., plane, truck, designated port of entry);
  - (4) Signed attestation that food products purchased will meet BAFRA's labelling requirements including language, list of ingredients and expiry dates;

### **Application Review**

11. An application for a food import permit shall be submitted to the field office and shall be reviewed by BAFRA Inspector in consultation with the head office, as and when required to ensure that all information related to BAFRA food safety clearance, eligibility, last BAFRA inspection results, information on foreign supplier are furnished.
12. The BAFRA field office shall review an application within five working days, and may process the application as follows:
- (1) For organized importers, forward the application to BAFRA head office with acknowledgement to the applicant, and for small scale importers receive the application with acknowledgement to the applicant, if the application is complete.
  - (2) Return to the applicant, If the application is incomplete; or
  - (3) Reject the application, if an applicant is ineligible.
13. The list of food to be imported by an Organised and Small-Scale Importers shall be reviewed as per the risk characterisation table provided under Annex 4 of this guideline.
14. In the event, the Organised Importer propose to import high risk product, both the





responsible authority in the exporting country and the importer shall adhere to Bhutan Food Certificate for all high-risk foods that require lot-by lot food safety certification as per Annexure 3 of this guideline.

15. In the event, an Organised Importer intends to import food from a new foreign supplier, BAFRA shall contact the exporting country to verify processor or an exporter's regulatory standing status.
16. On the import from the existing supplier, BAFRA shall confirm that the last consignment was free of complaint and the lot shall be inspected upon production of evidence of corrective action by the importer. In the event, the importer is not able to produce evidence of corrective action, the permit for import shall be refused.
17. A copy of the label submitted along with an application by an Organised Importer shall satisfy the following requirement:
  - (1) Language is in either English or Dzongkha;
  - (2) Meets the National labelling standards/Requirements;
  - (3) Ingredients are listed, if it is for bulk product; and
  - (4) Contains common name, list of ingredients, net content, name and address of manufacturer, country of origin, lot or batch identification number, manufacturing date, and best before expiry date.

If the results of the review are unacceptable, the permit application shall be refused. If the results of the review are acceptable, the permit shall be issued.

### **General Conditions for Import Permit**

#### ***Duration***

18. The duration of permit for foods regulated under Livestock or Plant Quarantine regulations shall correspond to livestock or plant quarantine permits.
19. The initial duration of permit for import by an organised importer from the new suppliers shall not exceed 3 months, and for established suppliers the duration shall not exceed 6 months for high risk foods and 12 months for low risk foods. In the event, there is a combination of low and high-risk foods, a separate permit shall be issues for low and high-risk food.

#### ***Certificate from foreign competent authority***

20. Import of high risk food by an Organised Importer shall be accompanied by a certificate issued by the competent authority in the exporting country as per prescribed form and content in Annexure 3 of this guideline.
21. The importer shall communicate with BAFRA about any changes to the consignee, point of entry, or transport details due to unforeseen circumstances.



### ***Inspection***

22. The Importer shall co-operate with BAFRA for inspection if required.

### ***Information***

23. The importer shall inform BAFRA of any change in the status of the foreign supplier, or any issues arising from transport conditions, or any other circumstance that may affect the safety and suitability of the food.

### ***Revocation***

24. BAFRA reserve the right to revoke the issued import permits on the following grounds:

- (1) There is a zoonotic disease outbreak in the exporting country/country of origin;
- (2) There is a plant quarantine or phytosanitary issue in the exporting country/country of origin;
- (3) There is a food safety issue in the exporting country, or the processor is no longer in good regulatory standing;
- (4) If the importers has not complied to the conditions prescribed in the permit;



## **CHAPTER II: BORDER CONTROL AND ADMISSIBILITY PROCEDURES**

### **Notification**

25. The Importer or their representatives, prior to importation of food shall notify on the import of food to BAFRA office at the designated point of entry (refer Annexure 6 : flow chart)
26. The notification shall include following information on each lot of food to be imported into Bhutan as prescribed in the Annexure 5 of this guideline.

### **Validation of documentation**

27. Import document shall be reviewed by a BAFRA inspector in consultation with the BAFRA head office as and when required to assess the admissibility of the lots into the country and shall inspect all import documents submitted on notification of import.
28. Only the required documentation will be inspected and validated.

### **Admissibility**

29. The following documents shall be reviewed by BAFRA inspector to ensure that the food product is eligible for import:
  - (1) valid licence;
  - (2) valid import permit,
  - (3) certificate for foods, originating from an approved country; and
  - (4) Any other documents required under the Livestock, Plant Quarantine and Seed regulations.
30. BAFRA shall also ensure that the documents submitted are complete, legible and the information provided either in English or Dzongkha.
31. In the event, there are some problems with the documentation such as major and minor(editorial / does not affect food safety), then the following steps are to be taken
  - (1) If minor, particularly for perishable products, proceed to next step
  - (2) If major, request the importer to provide the correct documents, or required information, within (72 hours).
32. Failure to provide the correct information/documents within the stipulated time, the entry of product shall be denied.



### **Documentation**

33. Any evidence of documents being tempered or altered or any discrepancies in the information provided (e.g. documents are not originals, significant changes in writing style, strikeouts, overwriting of information) the lot shall be held pending for investigation and the importer shall be responsible to explain such tempering, alteration or discrepancies. In the event, the discrepancies in the document is an administrative or inadvertent error, lot shall be subject to inspection at the point of entry into the country.
34. Import of high risk product shall require an original certificate/certified copy issued by the competent authority in the exporting country complying to the requirement of the importing country which shall be validated by the BAFRA field office, failure to meet this requirement shall be denied entry into the country.

### **Inspection decision**

35. Product shall be subject to mandatory inspection where the product is being imported for the first time or the importers have record of non-compliance to the import conditions or regulatory requirement.
36. If inspection and /or sampling is required then the inspectors shall be guided by the pre-established sampling plan. If it is not required then the consignment shall be released to the importer.

### **Inspection requirements**

37. The BAFRA Inspector shall have access to the entire lot for the mandatory sampling and analysis.
38. Imported products either in the containers or trucks shall be directed to the port of entry.

### **Inspection of imported food**

39. The imported food which warrants inspection shall be unloaded (destuffed), and made available to the BAFRA inspector for inspection and /or sampling.
40. Inspection or sampling shall be carried out in presence of importer or their representatives.
41. There should be no interference or pressure on the inspector to expedite the procedures. The inspector shall note and report any interference, particularly if it compromises the inspection and/or sampling.
42. Inspection should proceed in systematic manner with decisions made at each step of the process.



43. The inspector shall not be prevented or denied access to the entire lot except when there is imminent threat or danger to the health of the inspector.
44. The inspector shall verify the import document with the lot presented for inspection and any incidences of fraudulent import shall be reported to the relevant authority for action.

#### **Visual inspection**

45. Inspection shall be carried out to check any leakages in the containers or presence of water stains, off odours or insects in the product, and appropriate remedial measures shall be taken, if any.
46. In the event, there are physical damages to few containers, such containers shall be segregated or culled and where the physical damage is significant and segregation and culling cannot solve the problem, such containers shall be detained and the product may be returned back or destroyed without any compensation.
47. The inspector shall report such incidence to the BAFRA Head office, which shall assess if same product is being imported by other importers and determine if further inspections are required. BAFRA shall also inform the responsible authority in the exporting country accordingly.

#### **Label inspection**

48. The inspector shall also determine whether the labelling of the product is in compliance with the requirement under Food Rules and Regulations of Bhutan, 2017.
49. Any product which is not in compliance with the labelling requirement shall be detained and the importer or their representatives may re-label or return to the supplier or the product may be destroyed.

#### **Sampling**

50. The Inspector may collect the samples of the product, if necessary and send the samples to the laboratory for analysis.
51. The sampling shall be done based on the principle of integrity and continuity of sample associated with the lot.
52. The importer or their representatives shall assist the inspector in moving the carton or container to the desired location for conducting sampling, if the imported food is packed in large carton or container.

#### **Decision on Imported Food**

53. The inspector shall make final decision on the imported food based on the information provided in the document and where necessary, visual inspection or sampling and analysis. The BAFRA inspector shall document the decision and provide the information to the importer.
54. The imported foods which are in compliance with the requirement shall be released for sale. In the event, the imported food is not in compliance with the requirement,



such food shall be detained until final decision is made on segregation, culling, re-labelling, and returning to the supplier or the food may be destroyed.

55. Importers or clearing agents are responsible for ensuring that all requirements of the “re-importing” country are met for any “return to supplier” decision.

### **Appeal**

56. In accordance with Sections 69 to 70 of the Food Act of Bhutan, 2005, the importer has the right to appeal against the decision of the Inspector as per the procedures prescribed in section 5.26 of the Food Safety Licensing of Food Businesses: Licensing Process (BAFRA –LP –FSL Version 2 - 2017).



## CHAPTER III: IMPORTER INSPECTION

### Licensing

57. Food safety clearance or licence from BAFRA and valid trade licence are pre-requisite documents for the organised importers to apply for the import permit.
58. Small scale importers will not be required to have BAFRA Food safety clearance /license.
59. An Organised Importer shall apply for the food safety licence from BAFRA in accordance with the procedure prescribed under Section 5 of the Food Safety Licensing of Food Businesses: Licensing Process (BAFRA –LP –FSL Version 2 – 2017) with the modification noted on the risk-based inspection planning below.

### Risk based Inspection Planning

60. BAFRA Inspector shall determine the risk associated with the business and plan risk-based inspection to be carried out.
61. The BAFRA Inspector shall determine risks associated with each food business based on the following parameters:
  - (1) The risks associated with the food being imported:
    - (a) Physical risks (risk score 1);
    - (b) Chemical risks (risk score 2); and
    - (c) Microbiological risks (risk score 3).
  - (2) The intended use of the food:
    - (a) Not Ready to eat food (risk score 1);
    - (b) Processed Ready to eat food (risk score 2); and
    - (c) Raw Ready to eat food (risk score 3).
  - (3) The risks associated with food processing (as determined by compliance history of food from that supplier and/or country):
    - (a) Low – good compliance (no problems in the last year) (risk score 1);
    - (b) Medium (minimal (less than 5% of lots rejected in the last year) (risk score 2); and
    - (c) High –poor compliance; more than 5 % of lots rejected in the last year (risk score 3).
  - (4) The volume of imported food, and product category:
    - (a) Low volumes and low risk product category (risk score 1);
    - (b) Large volumes and low risk product category (risk score 1);





- (c) Large volumes and high-risk product category (risk score 2); and
  - (d) Low volumes and high-risk product category (risk score 2).
- (5) Food safety:
- (a) No cold chain required and adequate packaging (risk score 1);
  - (b) Presence of adequate cold chain and packaging (risk score 2); and
  - (c) Absence of adequate cold chain and packaging (risk score 3).
- (6) Importer compliance record (Previous Inspection):
- (a) Satisfactory Compliance with requirements of BAFRA Good Importing Practices (risk score 1);
  - (b) Minor non-compliance(s) with requirements of Criteria for Good Importing Practices (risk score 2);
  - (c) Major non-compliance(s) with requirements of Criteria for Good Importing Practices (risk score 3); and
  - (d) Critical non-compliance(s) with requirements of Criteria for Good Importing Practices (risk score 4).
- (7) Importer compliance record (Imported Food Inspection or Analysis):
- (a) Imported food was accepted for document, visual inspection or analytical results that demonstrate compliance with National requirements(risk score 1); and
  - (b) Imported food was not accepted for document, visual inspection or analytical results that were not in compliance with National requirements (risk score 2).
- (8) Importer complaints received since the last inspection:
- (a) No complaints or illnesses reported (risk score 1);
  - (b) Complaints reported (risk score 2); and
  - (c) Illnesses reported (risk score 3).
62. Upon completion of the risk assessment, BAFRA Inspector shall add all the scores for each of the food business and determine the Food Business Risk. The risk being higher for the higher total score, the risk-based categorization shall be the basis for the BAFRA Inspector to plan for risk-based inspection.
63. The inspector shall collect and verify the information in consonance to the criteria for Good Importing Practices.
64. The Inspectors shall refer to the Food Safety Licensing of Food Businesses: Licensing Process (BAFRA –LP –FSL Version 2 –2017) for further information on inspection approach.





## CHAPTER IV: MISCELLANEOUS

### Amendment

65. This guideline shall be amended by the Ministry or National Food Quality and Safety Commission (NFQSC) as and when deemed necessary.

### Rules of construction

66. In this guideline, the singular shall include the plural and the masculine shall include the feminine and vice versa.

### Definition

67. The terms used in this guideline shall have the meanings as given below:

**Certification:** is a procedure by which a third party, generally a competent authority in the exporting country provides assurance that a product, process or food business is in conformity with the Bhutan, Codex or where specified, the exporting country's standards.

- Certification: with respect to application for an import permit, as per section 62 of the Food Act of Bhutan, 2005 and section 80 of the Food Rules and Regulations of Bhutan, 2017 means the importer provides assurance that there is an appropriate regulatory control of the foreign supplier, thus providing assurance the food will meet Bhutan, Codex or other specified standards.
- Certification with respect to the importation of food means that each lot of high risk food presented for import into Bhutan is accompanied by a certificate signed by the competent authority or other recognised third party in the exporting country as specified in the import permit (See Annex 1 for template)

**Clearing agent** is a person or other business entity that assists an importer with the procedures for importation (i.e., revenue and customs paper work).

**Conditions of entry:** Specific requirements established by BAFRA and included on import permit.

**Lot:** a definite quantity of some commodity manufactured or produced under conditions, which are presumed uniform. A continuous series of lots is a series of lots produced or manufactured in a continuous manner, under conditions presumed uniform.

**Consignment:** is a defined quantity of food products delivered at one time. It may consist of one lot, a portion of a lot or several lots, and is normally covered by a single certificate.

**Importer:** is a person or food business that brings food products from a foreign country into Bhutan either for themselves or under contract for another food business. If the food is processed in Bhutan prior to sale (e.g., repacking, processing), the food business shall be considered a domestic food business.

- Commercial importers:
  - Organised importers are characterised by distribution chains and sale of imported food to other food businesses.
  - Small Scale importers are characterised by the specified individual purchasing food sourced from local markets of neighbouring countries that are only sold in their food business to consumers (exclusively).
- Non-commercial importers are individuals who import food for personal consumption only. Non-commercial importers do not need a food import permit, however, they shall comply with the requirements of the livestock regulations, biosafety regulations, plant quarantine and seed regulations.

***Ineligible food imports:*** Is food, food ingredients or foreign suppliers that are inadmissible in Bhutan, as published by BAFRA (e.g., livestock/plant products from regions affected by an animal/plant disease).

***Recognised authority:*** a food safety authority in the exporting country recognised by BAFRA as having oversight of food safety.

- Reference BAFRA list of recognised authorities

***Designated country:*** is a country with which the BAFRA has established an arrangement or MOU with the competent authority in the exporting country with respect to food safety and trade.

- Reference BAFRA list of recognised authorities



## **Annexure 1: Import Permit Application Form**

**Royal Government of Bhutan**

**Ministry of Agriculture and Forests**

**Bhutan Agriculture and Food Regulatory Authority**

### **Application for Issuance of import permits for food and food ingredients (Organised Importers/Small Scale Importers)**

The Director General

Bhutan Agriculture and Food Regulatory Authority

Ministry of Agriculture, Thimphu

The undersigned hereby applies for a permit authorizing the import of food as per the details given below:

1. Name and Address of Applicant
2. Contact information (e.g, email, phone, SMS)
3. Operations: Import only \_\_\_\_\_ Import for further processing \_\_\_\_\_
4. Requested duration of permit \_\_\_\_\_

5. Food Business clearance	
6. Valid Trade Licence number	

#### 7. Details of consignment(s)

Food Product Description	Packaging (e.g., size, weight)	Producer and/or exporter (if different)

8. Label: Please attach a copy for packaged goods

9. Country of origin of food \_\_\_\_\_



10. Where applicable, country of transit: \_\_\_\_\_

11. Means of conveyance \_\_\_\_\_

12. Place of entry \_\_\_\_\_

13. Final destination \_\_\_\_\_

**Place** \_\_\_\_\_ **Date** \_\_\_\_\_ **Signature of applicant:**  
**Seal**



## Annexure 2: Food Import Permit

**Royal Government of Bhutan**  
**Ministry of Agriculture and Forests**  
**Bhutan Agriculture and Food Regulatory Authority**

**Application for Issuance of import permits for food and food ingredient  
(Organised Importers/small scale importers)**

IMPORT PERMIT FOR FOOD (Food not covered under Livestock, Plant and Biosafety Regulations)

This import permit is granted in accordance with the Food Act of Bhutan, 2005.	
Name and Address of Importer	Name and Address of Exporter First time supplier Yes No
Entry Point	Country of Origin
Description of Product	Common Name Quantity
Final Destination	Expected Date of arrival
<b>General Entry Conditions :</b>	
<p>The consignment of food should –</p> <ol style="list-style-type: none"><li>1. Be accompanied by Bhutan Food Safety Certificate (Annexure 1) only for high risk products.</li><li>2. Meet National Food labelling Requirements</li><li>3. Have atleast 50% of its shelf during the time of import</li><li>4. The consignment of Food Lot must be unloaded from transport for inspection and or sampling (if required)</li></ol>	



<p>5. Evidence they are in good regulatory standing from responsible authority in exporting country</p> <p>6. For first time imports from new suppliers, please attach a copy of the last inspection report</p> <p>7. Transported in appropriate transport condition</p> <p>The importer must:</p> <ul style="list-style-type: none"> <li>advise BAFRA of any circumstance that may affect the safety and suitability of the food.</li> </ul> <p>The import permit may be revoked where BAFRA determines that :</p> <ul style="list-style-type: none"> <li>the zoonotic disease outbreak has occurred in the exporting country ,</li> <li>there is a food safety problem in the exporting country or the processor is no longer in good regulatory standing,</li> <li>Importer is determined to be non compliant following an inspection</li> </ul>		
Special Entry requirements		
Permit duration		
Date of Issue		Name and signature of Authorised Officer
Valid until:		



### Annexure 3: Royal Government of Bhutan Food Safety Certificate

**Name of Country and Competent Authority Issuing the Certificate (High risk products only)**

Country

Type of Certificate

(Official, Copy, Replacement)

1. Consignor/Exporter		2. Certificate number			
		3. Competent authority			
		4 BAFRA Import Permit No.			
5. Consignee/Importer					
6. Place and Country of origin					
7. Country of destination					
8. Place of loading					
9. Means of transport			10. Declared point of entry		
11. Conditions for transport			12. Total quantity		
13. Identification of container(s)/seal number(s)			14. Total number of packages		
15. Identification of food products as described below: Multiple lines may be needed					
No.	Nature of the food and/or commodity code (HS Code)		Species*		Intended used
No	Producer/manufacturer		Approval No. (Establishment)		Region
No	Name of the product	Lot identifier*	Type of packaging	Number of packages	Net weight



16. Attestations					
17. Certifying officer					
Name:			Official position:		
Date:					
Official stamp			Signature		

\*if required.

***Explanatory notes:***

**General**

- The certificate should be completed in a legible manner. If the consignee, point of entry, or transport details change after the certificate has been issued, it is the responsibility of the importer to advise the competent authority of the importing country. Such a change should not result in a request for a replacement certificate to be issued. The model certificate includes numbers designed to facilitate establishing a link between a particular section and the corresponding explanatory note. It is not intended that these numbers appear in the actual certificates issued by the certifying body.

***Specific:***

***Certificate type:*** the certificate should be marked with “ORIGINAL”, “COPY” or “REPLACEMENT” as appropriate.

1. **Consignor/Exporter:** name and address (street, town and region/province/state, as applicable) of the natural or legal person or entity who sends the consignment.
2. **Certificate number:** this identification number should be unique for each certificate and authorized by the competent authority of the exporting country. For multiple page certificates, see paragraph 38 of document CAC/GL 38-2001.
3. **Competent Authority:** name of the Competent Authority of the country responsible for certification.
4. **Certifying Body:** name of the Certifying Body when it is different from the



Competent Authority.

5. **Consignee/Importer:** name and address of the natural or legal person or entity to whom the consignment is shipped in the country of destination, at the time the certificate is issued
6. **Country of origin:** name of the country in which the products were produced, manufactured or packaged.
7. **Country of destination:** name of the country of destination of the products.
8. **Place of loading:** name of a seaport, airport, freight terminal, rail station or other place at which goods are loaded onto the means of transport being used for their carriage.
9. **Means of transport:** air/ship/rail/road/other, as appropriate and the identification (name or number) of these if available, or relevant documentary references.
10. **Declared point of entry:** if required and available the name of the point of entry authorised by the competent authority of the importing country and, its UN/LOCODE (refer to the United Nations Code for Trade and Transport Locations).
11. **Conditions for transport/storage:** appropriate temperature category (ambient, chilled, frozen) or other requirements (e.g. humidity) for transport/storage of the product.
12. **Total quantity:** in appropriate units of weight or volume for the whole consignment.
13. **Identification of container(s)/Seal number(s):** identify the containers and seal numbers where applicable or if known.
14. **Total number of packages:** total number of packages for all products in the consignment.
15. **Identification of food product(s):** give the descriptive information specific to the product or products to be certified.
  - Where appropriate: nature of the food (or description of the commodity), commodity code (HS code), species, intended purpose, producer/manufacturer, approval number of establishments (slaughterhouse, production plant, store (cold store or not)), region or compartment of origin, name of the product, lot identifier, type of packaging, number of packages, net weight per type of product.
  - **Nature of the food (or description of product):** description of the product(s) precise enough to allow the product(s) to be classified in the World Customs Organisation's Harmonised System, including the commodity code (HS code) where appropriate
  - **Intended purpose (or Food products certified for):** the end use of the product should be specified in the certificate (e.g. direct human



consumption, further processing, and trade samples).

- Trade samples: the certificate should clearly indicate they are trade samples, not intended for retail sale and has no commercial value.
- **Region or compartment of origin:** if applicable: This is only for products affected by regionalisation measures or by the setting up of approved zones or compartments.
- **Type of packaging:** identify the type of packaging of products as defined in Recommendation No. 21 of UN/CEFACT (United Nation Centre for Trade Facilitation and Electronic Business).

**16. Attestations:**

1. All food products must meet National or Codex standards.
2. All foods must be labelled in English or Dzongkha
3. All food products that are, or contain GMOs must be clearly identified on the label as “genetically modified” or ‘containing a genetically modified food or food ingredient” or “product of gene technology”.

**17. Certifying officer:** name, official position, official stamp (optional), date of signature and signature.



## Annexure 4: Risk Categorisation and Requirements for Certificates

### Characterisation of risk (foods)

BAFRA has developed a risk characterisation system that is used to establish priority for inspection of importers (See page 16).

BAFRA uses two key risk factors from the risk characterisation system to identify high risk foods, i.e., the risk associated with the food and the intended use of the food.

	Physical risks (risk score 1)	Chemical risks (risk score 2)	Microbiological Risks (risk score 3)
Not Ready to eat (risk score 1)	Risk score 2	Risk score 3	Risk score 4
Processed Ready to eat (risk score 2)	Risk score 3	Risk score 4	Risk score 5
Raw ready to eat (risk score 3)	Risk score 4	Risk score 5	Risk score 6

Food Products (risk score 5 or 6) are deemed high risk

BAFRA provides the food safety risk score, the animal health and plant quarantine risk scores as follows:

Note: this list should be published and updated as needed

Category	Food	Animal Health	Food Safety Risk score	Plant Quarantine
Livestock products	Fresh, Frozen meat	High	4	N/A
	Dried meat	High	2/3	N/A
	Salted meat	High	2/3	N/A

Category	Food	Animal Health	Food Safety Risk score	Plant Quarantine
	Fresh dairy products	High	6	N/A
	Fresh, frozen fish	High	4	N/A
	Canned meat, dairy, fish	Low	5	N/A
	Dried fish	Low	4	N/A
	Shelf stable dairy products	Low	2/3	N/A
Plant products	Fresh, frozen vegetables	N/A	3/4	Fresh Medium Frozen Low
	Seaweed	N/A	3	N/A
	Fresh, Frozen fruits	N/A	4	Fresh Medium Frozen Low
	Canned vegetables and fruits	N/A	4	N/A
	Vegetable and fruit juices.	N/A	Shelf stable or pasteurised 4 Un pasteurised 6	N/A  N/A
	spices	N/A	Dried 3, 4  Fresh 4,	Ground spices Medium Whole spices/grains Medium Bark, leaves, seed grains High



Category	Food	Animal Health	Food Safety Risk score	Plant Quarantine
	Dried pulses, grains, rice	N/A	3/4	If post harvest treated: medium Un treated -high
	Dried pasta	N/A	3	N/A
Pre packaged foods	Breads, cookies, biscuits	N/A	3/4	N/A
	Soft drinks	N/A	2/3	N/A
	Chips, snacks,	N/A	2/3	N/A
	Crackers,	N/A	2/3	N/A
	Sauces, dressings	N/A	3/4	N/A
	Sweets, candies, chocolate,	N/A	2/3	N/A
	Beverages (e.g., tea, coffee)	N/A	3	N/A
	Sugar, sweeteners	N/A	3	N/A
Specialty foods	Infant foods	N/A	5	N/A
	Meal replacements (e.g., boost, horlicks)	N/A	4	N/A
	Geriatric foods.	N/A	5	N/A



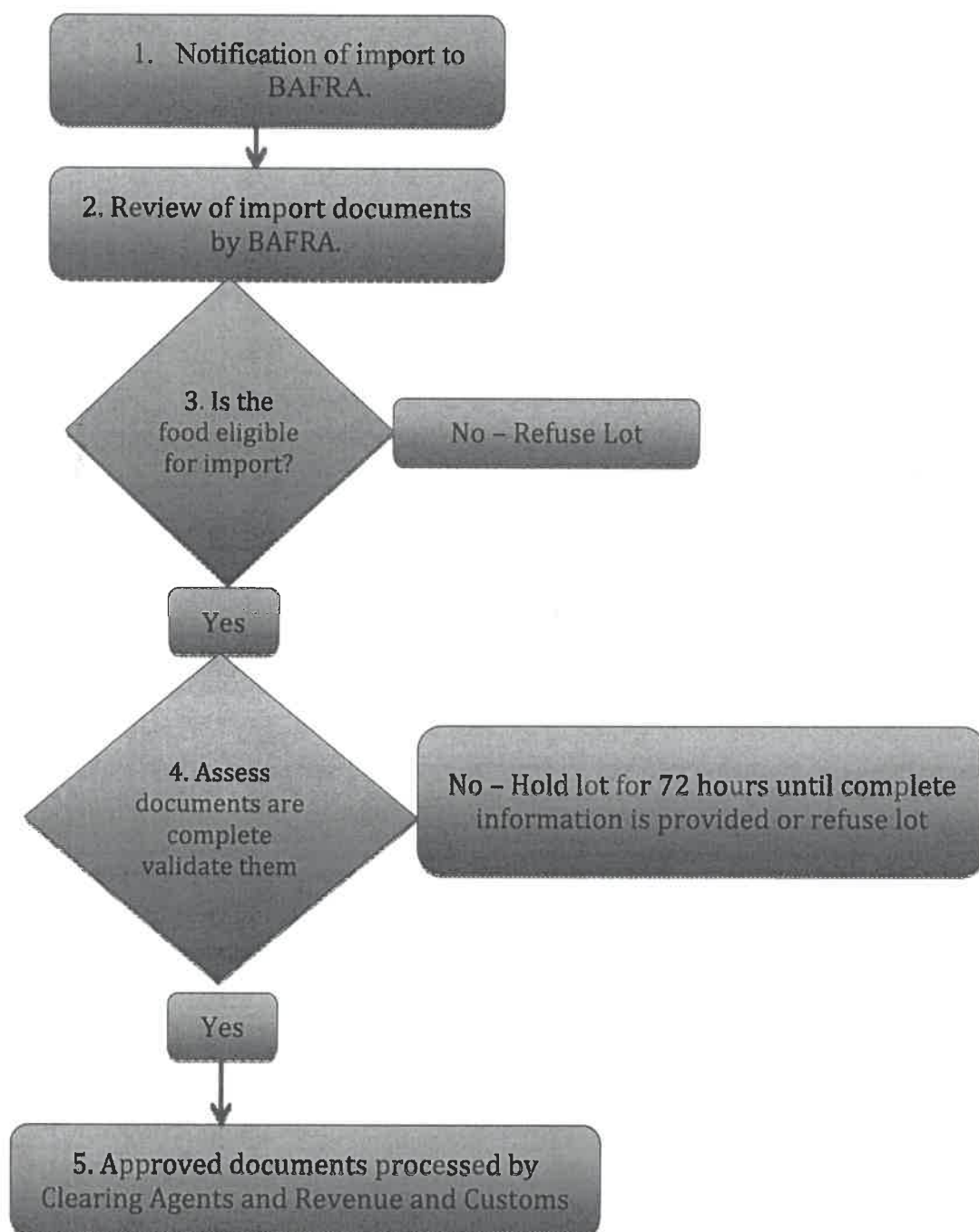
### Annexure 5: Consignment Arrival Notification

Name and Address of Importer	License No
Product Name;	Brand Name:
Quantity of Product:	Batch/Lot No:
Expiry date:	Intended Use: consumer package/bulk import/further processing
Name and Address of Producer:	Country of Origin and transit country
Location where food will be stored in Bhutan:	Date of arrival
Enclosed:– 1. Copy of Import Permit	



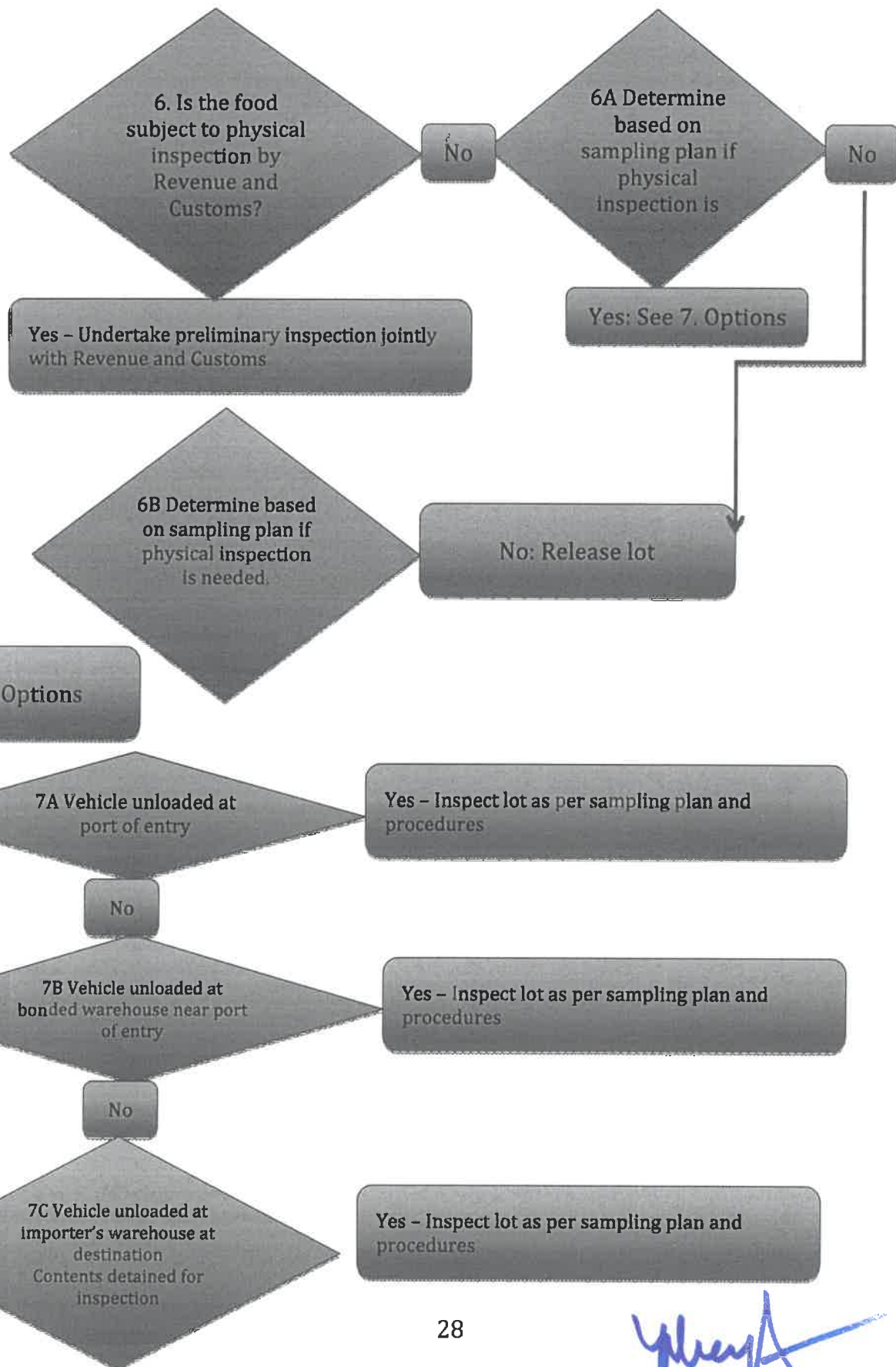
## Annexure 6: Food Products Clearance Process Flow Charts

### 1. Notification and Document Review





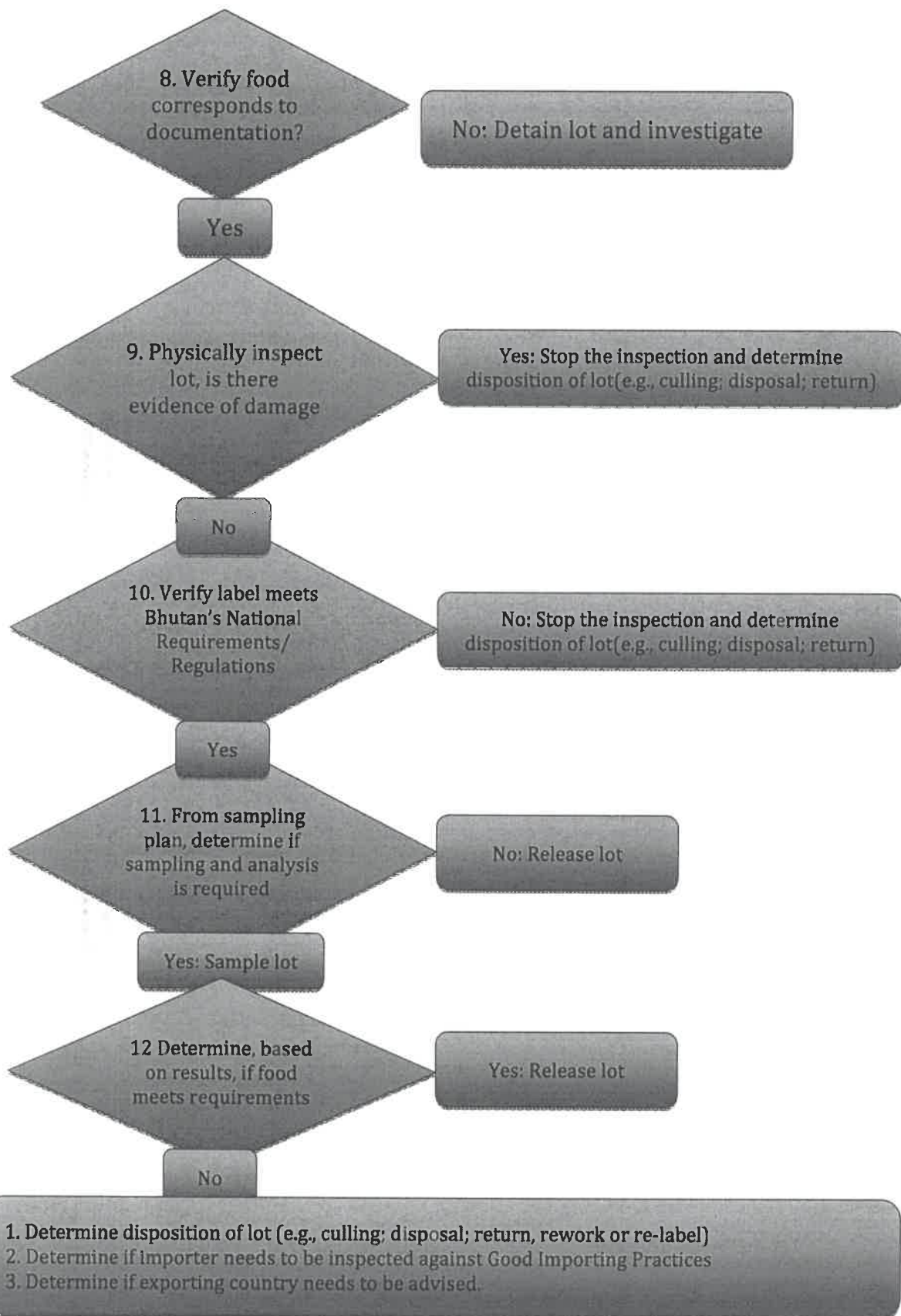
## 2. Food Products Inspection and Sampling Process



*Y. Khan*



### 3. Inspection Process and Decision Flow Chart



*Y. Khan*

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# Good Importing Practices



**MINISTRY OF AGRICULTURE AND FORESTS  
ROYAL GOVERNMENT OF BHUTAN**

THIMPHU, 2018

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## **Background**

Bhutan is a food import dependent economy, as a result of which the country is potentially at greater risk of facing issues of contaminated/adulterated food and food borne disease outbreaks. High percentage of imports places additional demands on the food safety system because of the lack of direct control over production and processing practices. This as a result leads to a lack of predictability as to potential contaminants that may be in any particular shipment of goods. Therefore, implementation of risk based food import control system at the entry points of the country is a way forward for ensuring the safety of imported food.

A strengthened food safety system will not only positively impact the food safety within the country but will also contribute towards a safer cross border food trade. Food Import control system is a risk based preventive approach which focuses on allowing products which are safe and suitable for consumption in the country.

Importers are a sub-set of food businesses in Bhutan and are responsible to ensure that the products they import are safe, suitable and meet regulatory requirements. To meet their responsibilities, importers will have to understand and be aware of the hazards associated with the imported food and of the controls needed to demonstrate compliance. This would mean buying food products from sources that meet BAFRA's established requirements.

Where an imported food is packaged or processed in any manner after importing, the importer shall be considered as a food processor and, in addition to meeting the GIPs, shall meet the Criteria for Good Hygienic and Manufacturing Practices for Licensing of Food Business.

## **Objective**

1. This document aims to:
  - (1) Establish Good Importing Practices (GIP) requirements for organized and small scale importers to ensure the importation of safe and suitable food;
  - (2) Outline the responsibility of the commercial importer to ensure compliance with the requirements Good Importing Practices; and
  - (3) Enable the Bhutan Agriculture and Food Regulatory Authority (BAFRA) to use the GIPs to verify that the importers meet food regulation and clearance requirements.

## **Scope**

2. This document specifies good importing practices and shall apply to:
  - (1) Import of safe and suitable food for all commercial food importers in Bhutan.



- (2) Import by individual for personal consumption is not included under the scope of this document. However, livestock and plant quarantine import permits are required for importation of products for personal consumption.
- (3) Whole of the kingdom of Bhutan.

## **Import Permit**

### **Categories of importer**

3. For the purpose of this document, BAFRA establishes two categories of commercial food importers as follows:
  1. Organised importers:
    - (a) Characterised by existing distribution chains and sale of imported food to other food businesses, but may sell to consumers as well.
    - (b) Shall have a valid trade licence with BAFRA food safety clearance and food import permit, and where appropriate, a food or livestock; food or plant quarantine import permit.
  2. Small Scale importers:
    - (a) Characterised by the specified individual purchasing food sourced from neighbouring country markets that are only sold in their food business to consumers (exclusively).
    - (b) Food import permit is required and where appropriate, a livestock or plant quarantine import permit may be required.

## **Organised Importers**

### **Specifications**

4. To understand the hazard(s) associated with the product and to source product from producers capable of meeting requirements. The importer shall have following written specifications that identify the minimal requirements for the type of food to be imported and these specifications shall be part of the contract with the foreign supplier:
  1. Description of the food (e.g., meat, fish, vegetables, dairy, sweets)
  2. Processing requirements, if appropriate (e.g., produced under GMP, HACCP)
  3. Content of ingredients,
  4. Storage and transport requirements
  5. Label requirements for pre-packaged foods, including appropriate expiry date (e.g., the expiry date is sufficient for distribution, sale and consumption), language requirements (English or Dzongkha)
5. The Importer shall maintain specifications of the imported foods provided to suppliers during the course of food business and shall be made available for inspection.

6. The importer shall also ensure that the supplier provides evidence (e.g., written documentation) on the scientific establishment of the best before or expiry dates wherever necessary.

#### **Supplier verification**

7. Importers shall complete supplier verification process as part of their quality control process to assure that the imported food is safe and meets Bhutan's regulatory requirements and commercial importers shall verify that their foreign supplier is:
  1. Regulated by a recognised foreign country competent authority and is eligible to export food to Bhutan; or
  2. Subject to third party audits by internationally recognized and accredited inspection or certification body;
8. The importer shall obtain and maintain a report of the inspection carried out by either the competent authority or the 3<sup>rd</sup> party audit for each supplier from the supplier.

#### **Food shipment information requirements**

9. Upon providing specifications to the supplier, the importer shall retain information on each imported food at their food business and shall be made available to a BAFRA inspector on request, recall and for inspection.
10. The following information may be maintained in a format determined by the importer including detailed information to identify the product, information on origin, transport, distribution, storage, handling and use:
  1. Common name of the product;
  2. Brand name;
  3. Net quantity declaration;
  4. Grade;
  5. Product specifications and characteristics;
  6. Container size;
  7. List of ingredients;
  8. Packaging material;
  9. Final use of the product;
  10. Origin of the product, including shipment details (e.g., date shipped, transport method, date and port of arrival);
  11. Labelling instructions when further handling is required; and
  12. Handling and storage instructions when special requirements exist. (Examples include the following: do not store with non-food items; keep refrigerated; keep frozen; store at room temperature; etc.).





### **Quality Assurance (Importer)**

11. All incoming lots shall be visually inspected on the following parameters by qualified personnel:

1. Confirmation and cross reference of the information on the physical lot with the import documentation and specifications (e.g., food product, size of lot, brand, identification marks, producer);
2. Confirmation that the label meets Bhutan regulations (e.g., language, codes);
3. Confirmation that there are no physical signs of defects that might affect food safety (e.g., no water damage, physical damage, leaking containers, off odours);
4. If damage or defects, are detected, the lot should be detained until remedial action, is determined; and
5. Records of the inspections should be maintained, including distribution of compliant product, any required remedial action, and disposal of all defective products.

### **Laboratory sampling and analysis**

12. The Importer shall conduct regular sampling and analysis of the lots to be imported on regular basis to validate information and develop compliance history. The importer should sample the first lot from every new supplier for analysis. Importer should also ensure regular product sampling to verify compliance with regulatory requirements.
13. Alternatively, the importer may also request a certificate of analysis be provided by the competent authority of the exporting country or an accredited 3<sup>rd</sup> party for specified lots.
14. The Importer shall document following information during sampling:
  1. Information about the lot (e.g., Customs entry number; Location sampled, size of lot, and amount available when sampled; Lot size and identification number, Production code);
  2. Name and affiliation of the person collecting the sample; and
  3. All required information about the sample (e.g., Sample collection date, Sample collection method; Sample preparation techniques; Sample size;) and should include any observations that could affect the sample's integrity.
  4. Indicate the analysis or the multiple analysis, being requested such as:
    - (a) Microbiological (e.g., bacteriological, commercial sterility, viral);
    - (b) Chemical (e.g., additives, composition, drug residues, contaminants, toxins);
    - (c) Container or package integrity;
    - (d) Sensory, Net content and package integrity





5. Clearly note the sample storage and transport information including temperature (e.g., refrigeration, freezing) transport time (e.g., maximum time), the designated laboratory.
6. The importer shall bear the testing charges, if applicable.

### **Product control**

15. The importer shall have a documented process to manage stock, under the first in or first out (FIFO) /first expiry or first out (FEFO) principle to ensure that food and food ingredient imported and sold are within their established and labelled best before or expiry dates.

### **Tracking and traceability**

16. The importer shall have documented procedures to maintain the identity of all lots of imported food, and where they are located, from reception to distribution.
17. The importer shall maintain documents on product reception including description of product, quantities, date received and storage location.
18. The importer shall maintain documents on product distribution:
  1. Description of the product, including quantities;
  2. The name and address of the person to whom the food was shipped/ distributed; and
  3. The date on which it was shipped or distributed.

### **Corrective Action**

19. Where an imported food is determined to be non-compliant to the specifications, or fails the inspection or an analytical test, the importer must advise BAFRA, and their supplier.
20. The importer must segregate, inspect and assess all further imports from that supplier until they have evidence that the issue(s) causing the problem has been identified and corrected.
21. Evidence can include:
  1. Information from the supplier, confirmed by the competent authority or 3<sup>rd</sup> party certification body of the corrective action; and
  2. Two consecutive lots from that supplier that are demonstrated to meet Bhutan's regulatory requirements (i.e., sampled, analysed and determined to be compliant).
  3. Laboratory Report (from accredited laboratory) from that supplier



### **Record keeping**

22. The importer shall maintain an appropriate record keeping system and any deviations from the documented procedures and corrective action taken, if any.

## **Small Scale Importers**

### **Specifications**

23. To understand the hazard(s) associated with the purchased food products, this means buying food products that meet BAFRA's established requirements. In sourcing at markets in neighbouring countries, small scale importers shall ensure that the food products:
1. Are properly labelled in English or Dzongkha;
  2. Meet the National Labelling requirements or standards;
  3. Ensure that the product will not expire during distribution and sale (i.e., there is sufficient time between purchase, distribution and sale);
  4. Product shall have at least 50% of its shelf life during the time of import; and
  5. Ingredients are listed for bulk products.

### **Quality control**

24. All foods shall be visually inspected by the importer prior to purchase to verify that there are no physical signs of defects such as water damage, physical damage, leaking containers and off odours.

### **Product control**

25. The importer shall have a documented process to manage stock, under the first in or first out or first expiry or first out principle to ensure that food and food ingredients imported and sold are within their established and labelled best before or expiry dates.

### **Tracking and traceability**

26. The importer shall document information including description of the product, quantities (e.g. copy of the label), date purchased, and name of supplier to maintain the identity of all lots of imported food until the sale to the consumer.



## **Annexure - Criteria for Good Hygienic Practices for Licensing of Food Business for the Organized Importer**

In addition to the specific requirement associated with importing food, the food business (organised importers) shall meet Good Hygienic Practices as set out below.

### **Design and Facilities**

#### ***Location***

- Establishment shall have clearly defined boundaries, be located away from toxic chemical or odour producing industries, approach road to the site shall be concreted or cemented, surrounding areas shall be clean with no garbage accumulation and stagnant water, and not prone to pest infestation and flooding. There shall be no uncontrolled vegetation at least 6 feet from building walls.
- Open drains, garbage dumps, water logging; open spaces, such as yards, streets, side or rear lanes and roof tops, shall not be used for preparation or storage of food, cleansing or storage of equipment or utensils.

### **Premises and rooms**

#### ***Design and layout***

3. Basic infrastructure appropriate to the import operations shall be in place. The buildings shall provide sufficient space to allow a logical flow of materials, products and personnel.
4. Adequate space shall be provided for various activities such as receipt and storage of imported food or food ingredients, change facilities for personnel, separate eating area, toilets, and do not open directly into the storage areas.
5. There shall be adequate separation between food storage areas and all other areas.
6. There shall be a provision of appropriate loading and unloading points to facilitate movement of material and such points shall be suitably covered to provide adequate protection from pests, rain, etc.
7. Openings intended for transfer of materials and products (e.g. transport hoses, conveyors) shall be designed to prevent entry of foreign matter and pests.

#### ***Internal Structures and Fittings***

8. Flooring shall be smooth, impervious, with no crevices or damage. Floors shall be constructed to allow adequate drainage. The junctions with walls shall be such that they are cleanable e.g. coved (without sharp angles).



9. Roof shall be constructed so as to be gap free, water resistant, and finished so as to minimize build up of dirt and shedding of particles. Overhead fixtures, if any, shall be constructed and finished to minimize the build up of dirt and condensation and the shedding of particles.
10. Walls and partitions shall have a smooth surface. Wall paint shall not be flaking off. There shall be no crevices to harbour pests. If applicable and as appropriate to the operations, the walls up to a desired height shall be impervious and easy to clean.
11. Windows and ventilators shall be easy to clean, and where necessary fitted with cleanable insect-proof screens. Windows shall be protected to ensure that food is not contaminated in the event the glass breaks. Mesh on windows and ventilator shall prevent entry of pests.
12. Doors shall have smooth non-absorbent surfaces and be easy to clean and disinfect as appropriate. Entry and exit points shall be suitably fitted with measures such as strip PVC or air curtains or wire mesh doors or doors with self-closing devices, etc. to ensure dust, insects, birds and animals are kept out.

### *Equipment*

13. Equipment shall be located so that it permits adequate maintenance and cleaning, functions in accordance with its intended use and facilitates good hygienic practices, including monitoring, if required.
14. Where necessary, equipment shall be movable or capable of being disassembled to allow for maintenance, cleaning, disinfection, etc.
15. Non-food contact surfaces of equipment shall be free from unnecessary projections and crevices and designed and constructed to allow easy cleaning and maintenance.
16. Equipment used to cool, store or freeze food shall be designed to achieve and maintain the required food temperatures as rapidly as necessary for food safety and suitability and to be effectively maintained and allow parameters to be monitored and controlled. The monitoring and measuring devices shall be periodically calibrated and records maintained. The frequency of calibration shall be based on the type of equipment, criticality of the measurement, location and extent of usage.

### *Containers for waste and inedible substances*

- Containers for waste, by-products and inedible or dangerous substances shall be identifiable, suitably constructed and where appropriate made of impervious



material. Those used to hold dangerous substances shall also be lockable and access restricted to authorized personnel.

## **Facilities**

### ***Water supply***

17. An adequate supply of potable water with appropriate facilities for its storage, distribution and temperature or any other controls, shall be available as necessary. Potable water shall comply with WHO Guidelines for Drinking Water Quality. In case water is stored in tanks, the tanks shall be such that they prevent contamination of water. They shall be suitably covered to prevent access by animals, birds, pests and other extraneous matters.
18. The water pipes shall be made of material that is non-toxic, corrosion resistant, free from cracks, impervious and shall be sealed.
19. Separate non-potable water systems (e.g. fire control, steam production, refrigeration, sanitary conveniences) shall be identified and shall not connect with or allow reflux into, potable water systems.

### ***Drainage and waste disposal***

20. Drainage and waste disposal systems relevant to importation and storage of food shall be appropriately designed and constructed.
21. The water effluent discharged shall comply with the requirements of the National Environment Commission. No manhole shall be situated inside a food storage area. Drains shall allow for effective cleaning as relevant such as fat trap, pressure cleaning, etc. They shall not allow any stagnation or backflow of water.
22. Food waste and other waste shall be periodically cleared avoiding a build up. Waste bins of adequate size that can be operated without hand contact shall be provided.

### ***Cleaning***

- Adequate facilities, suitably designated, where necessary, shall be provided for cleaning raw materials and ingredients, food, utensils and equipment, etc. These facilities shall have an adequate supply of hot and cold potable water where appropriate.

### ***Personal hygiene facilities and toilets***

23. Adequate means of hygienically washing, drying and sanitizing hands as relevant, including wash basins and supply of adequate water of potable quality shall be provided.



24. Hand wash basins or sanitizers shall be situated where they are required.
25. Toilets of appropriate hygienic design at suitable locations with adequate natural or mechanical ventilation, natural or artificial lighting and hand washing and drying facilities shall be provided. These shall not open directly into the food or other storage areas.
26. Adequate changing facilities for personnel shall be provided, as appropriate to the operations.

#### *Temperature control*

27. Adequate facilities for storage of imported food such as refrigeration and freezers shall be available.
28. Where necessary, ambient temperatures shall be controlled to ensure the safety and suitability of imported food.

#### *Air quality and ventilation*

29. Adequate ventilation as appropriate to the food and the operations shall be provided for minimizing air borne contamination, controlling ambient temperatures and humidity where necessary which might affect the safety and suitability of food. These shall be achieved through either natural or mechanical ventilation.
30. Ventilation systems shall ensure that air does not flow from unclean to clean areas and, where necessary, they can be adequately maintained and cleaned.

#### *Lighting*

31. Natural or artificial lighting shall be provided in food premises throughout the facility. The intensity of lighting shall be adequate for the nature of operations, where inspection and testing require greater intensity of light. Where necessary, lighting shall be such that the resulting colour is not misleading.
32. Lighting fixtures shall, especially where food or food contact surface is exposed to open, be shatter proof or protected with shatterproof covers to ensure that food is not contaminated in the event of breakage. The fixtures shall be designed to avoid accumulation of dirt and be easy to clean.

#### *Power Back up*

- Suitable power back up facilities such as generators or invertors shall be provided to ensure uninterrupted power supply as necessary for storage and maintenance of safe food.





## **Control of operations for storage of imported food**

### ***Control of storage***

33. Food storage facilities shall be designed and constructed to enable maintenance of cleanliness, ventilation, avoid pest access and harbourage; prevent contamination and where necessary, provide suitable conditions of temperature and humidity to minimize the deterioration of food.
34. Food products shall be stored under conditions that prevent spoilage, protect against contamination and minimize damage. Food shall be stored away from the wall and not directly on the floor. It shall be stored preferably either on pallets or racks or any other manner to facilitate cleanliness, avoid ingress of moisture, etc. Food shall be stored in clean areas and stacked in a manner that facilitates ease of movement. Food that requires specific storage conditions e.g. temperature and humidity, air circulation etc. shall be maintained under the specific conditions.
35. All products in storage shall be clearly identified.
36. When storing imported food, adequate steps shall be taken to prevent microbiological cross contamination. Imported foods shall also be adequately protected from contaminated by harmful fumes and hazardous chemicals, or in the case of bulk foods, by foreign bodies such as glass, metal particles from machinery, plastic, dust etc.
  1. Raw, unprocessed food shall be effectively separated physically from ready-to-eat foods, with effective cleaning and where appropriate disinfection.
  2. Vegetarian food shall be effectively separated physically from non-vegetarian products.
37. Storage of cleaning materials and hazardous chemical substances shall have restricted access and be available only to authorized personnel.

### ***Specifications***

38. Specifications for all imported foods are required to ensure food safety and compliance to regulatory and statutory requirements.
39. Water
40. Water, ice and steam in contact with food
41. Where used for making ice, or washing hands, only potable water shall be used. Water, ice and steam shall be produced, handled and stored to protect them from contamination.
42. Water that is re-circulated shall be treated and maintained so that it is safe for use, and the treatment process shall be effectively monitored. Re-circulated water, which has received no further treatment and water recovered from



processing of food by evaporation or drying may be used, provided its use does not constitute a risk to the safety and suitability of food.

***Water, ice and steam not in contact with food***

43. For steam production, fire control and other similar purposes not connected with food may not require the use of potable water.

***Water pipes and storage tanks***

44. Water pipes, either hot or cold, shall be maintained in good condition and order at all times to prevent leakage or defects that would result in contamination of food. Water storage tanks for potable water shall be regularly cleaned and disinfected at least once in 3 months to prevent contamination.

**Management and supervision**

45. All operations shall be monitored and supervised appropriately. The control and extent of supervision will depend on the size of the business, the nature of its activities and the types of food involved.

**Documentation and records**

46. Appropriate records shall be kept and retained for a period of at least one year beyond the shelf life of the product.
47. At a minimum, the following records shall be maintained:
1. Incoming material checks
  2. Inspection and tests
  3. Temperature and time
  4. Product recall and traceability
  5. Storage
  6. Cleaning and sanitation, as appropriate
  7. Pest control
  8. Medical and health
  9. Training
  10. Complaint and customer feedback
  11. Corrective and preventive action

**Product recall and traceability**

48. Effective procedures shall be in place to enable a complete and rapid recall of any implicated lot or batch of imported food. Where a product has been recalled, other imported products from the same producer shall be evaluated for safety to determine if they need to be recalled.
49. Recalled products shall be held under supervision until they are destroyed, or determined to be safe for human consumption. Records of recalled products shall be maintained.





50. In case of a food recall, records shall be maintained that demonstrate effective identification, recall, subsequent handling and disposal of recalled food.
51. Mock recall shall be conducted at least once annually, and records of the same maintained.

#### **Maintenance, cleaning and sanitation**

52. Establishment and equipment shall be maintained under an appropriate state of repair and condition to
- a. Facilitate all sanitation procedures
  - b. Function as intended
  - c. Prevent contamination of food
53. Maintenance programs shall be in place which shall cover maintenance schedule, responsibilities, methods, tools and gadgets, etc. and appropriate records maintained.
54. Cleaning and sanitation programs as appropriate shall be in place which shall cover cleaning and sanitation schedule, responsibilities, methods, equipment and cleaning and sanitizing aids etc. to effectively control contamination of food. These shall be continuously monitored for their effectiveness. It shall be ensured that cleaning and sanitizing chemicals do not contaminate food.

#### **Pest Control**

55. Suitable pest control program shall be in place and effective to ensure there are no signs of pest infestation including flies, cockroaches, lizards, rats, etc. The pest control program shall identify the pests to be controlled, the area / locations where control is to be applied, the method of control e.g. physical, chemical etc., the dosage in case of usage of chemical, schedule, responsibilities, etc. These shall include use of insectocutors, traps and baits as appropriate; maintaining cleanliness, covering exposed foods and wastes, blocking drainpipes, etc.
56. Pest control activities shall be performed by trained personnel. These shall be continuously monitored for their effectiveness. It shall be ensured that pest control chemicals do not contaminate food.
57. The measures shall be documented and records maintained.

#### **Waste management**

58. Suitable waste management and waste disposal system shall be in place. Waste shall not accumulate in food processing and storage areas. Food waste and other waste shall be periodically cleared avoiding a build up in the premises. Waste bins and areas shall be identified, covered and kept appropriately clean.



### Personal hygiene

59. Personnel working with high risk imported food shall be checked for communicable and infectious diseases once a year by a Government medical doctor. Records of the medical fitness certificate shall be maintained.
60. Personnel working with imported food shall maintain a high degree of personal cleanliness and shall wear appropriate clean clothing.
61. Personnel shall always wash hands with soap/disinfectant after use of toilets and after touching any contaminated material (including raw material, money, files, etc.) or unclean product, food contact surface, body parts and waste.
62. No spitting, smoking, eating food and chewing gum, *doma* and tobacco shall be permitted in the processing areas.
63. Visitors shall follow the same norms for protective clothing and personal hygiene as those working in the unit.
64. Personal hygiene practices in simple local language, understood by the personnel or pictorial displays shall be made at appropriate places.

### Quality Control

65. The quality control program shall include inspection and testing imported product.
66. Infrastructure shall be available for carrying out testing. In case the same is not available, a proper system for testing in NFTL or accredited external laboratories shall be in place.
67. The laboratory shall have
  - a. Competent manpower,
  - b. Appropriate equipment,
  - c. Suitable environmental conditions,
  - d. Methods of sampling and testing,
  - e. Standard reference materials,
  - f. Documented processes including calibration processes,
  - g. Process for waste disposal,
  - h. Quality assurance through in-house or external program,
  - i. Records of testing, calibration, manpower competence, quality assurance program.



## **Transportation**

68. Food shall be adequately protected during transport to assure food safety.

69. The transportation or transport containers shall be designed and constructed so that they do not contaminate food. These shall be kept clean and disinfected. Food and non-food shall be suitably segregated during transportation. Where the same conveyance or container is used for transporting different foods or non-foods, effective cleaning and where necessary, disinfection shall take place between loads.

**The temperature, humidity, atmosphere and other necessary conditions, as appropriate to the product shall be maintained. Product information, consumer awareness and complaints**

70. All imported products shall be suitably identified for product identification, inspection and test status, etc. so as to avoid inadvertent use. All legal or statutory requirements shall be clearly given on the label of the final product as per the Food Rules and Regulations of Bhutan (2017). Any special requirements of handling, storage, processing, by customer etc. shall be clearly indicated on the labels.

71. All complaints shall be analysed for any improvements with regard to food suitability and food safety.

## **Competence and Training**

72. All food businesses shall have food handlers with a valid Food Handlers License issued by BAFRA.

73. Managers and supervisors shall have appropriate knowledge of food hygiene principles and practices. Suitable training shall be given to all persons to enable them to have the required knowledge and skills in GHP and GIP for the tasks to be performed by them effectively to enable safe food. Trainings shall be held at required frequencies and records of the same shall be maintained. Training can be provided on the job and/or through classroom sessions.

## **Self-Evaluation**

74. Food establishments shall evaluate themselves periodically and at least once in a year for all the requirements of the document. Records of the same shall be maintained.



