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MINISTER



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MINISTRY OF AGRICULTURE  
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“WALKING THE EXTRA MILE”

M(1)MOA/MISCE/2007/137

16<sup>th</sup> July 2007

**GOVERNMENT NOTIFICATION**

***Subject: Food Rules and Regulations of Bhutan 2007***

In exercise of power conferred under Chapter II and Chapter III of the Food Act of Bhutan 2005, the Ministry of Agriculture is pleased to issue the Food Rules and Regulations of Bhutan 2007. The Rules and Regulations will come into effect from 1<sup>st</sup> August 2007 and shall supersede all previous orders and any amendments issued till now.

The Bhutan Agriculture and Food Regulatory Authority (BAFRA) as empowered under Chapter IV of the Food Act of Bhutan 2005 shall be responsible for the implementation of the Food Rules and Regulations of Bhutan 2007.

  
Sangay Ngedup

Cc:

1. The Hon'ble Chairman, Council of Ministers, Thimphu
2. The Hon'ble Chief Justice, High Court, Royal Court of Justice, Thimphu
3. The Hon'ble Minister, Ministry of Home and Cultural Affairs, Thimphu
4. The Hon'ble Minister, Ministry of Finance, Thimphu
5. The Hon'ble Minister, Ministry of Health, Thimphu
6. The Hon'ble Minister, Ministry of Trade and Industry, Thimphu
7. The Hon'ble Minister, Ministry of Works and Human Settlement, Thimphu
8. The Hon'ble Minister, Ministry of Labour and Human Resources, Thimphu
9. The Hon'ble Minister, Ministry of Education, Thimphu
10. The Hon'ble Minister, Ministry of Information and Communications, Thimphu
11. The Hon'ble Minister, Ministry of Foreign Affairs, Thimphu
12. The Deputy Minister, National Environment Commission Secretariat, Thimphu
13. The Hon'ble Chairman, Royal Advisory Council, Thimphu

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14. The Hon'ble Cabinet Secretary, Cabinet Secretariat, Thimphu
15. The Hon'ble Secretary, Ministry of Agriculture/ Chairman of the National Codex Committee (NCC), Thimphu
16. The Commandant, Royal Body Guards, Dechenchholing
17. The Chief Operations Officer, Royal Bhutan Army, Lungtenphu
18. The Chief of Police, Royal Bhutan Police, Thimphu
19. The Hon'ble Secretary, Royal Civil Service Commission, Thimphu
20. The Auditor General, Royal Audit Authority, Thimphu
21. The Director General, Dept. of Local Governance, MoHCA/ Member, National Food Quality and Safety Commission (NFQSC), Thimphu
22. The Attorney General, Office of the Attorney General/ Member, NFQSC, Thimphu
23. The Director General, Dept. of Agriculture, MoA/ Member, NFQSC, Thimphu
24. The Director General, Dept. of Industry, MoTI/ Member, NFQSC, Thimphu
25. The Director, Dept. of Livestock, MoA/ Member, NFQSC, Thimphu
26. The Director, Dept. of Public Health, MoH/ Member, NFQSC, Thimphu
27. The Director, National Environment Commission Secretariat/ Member, NFQSC, Thimphu
28. The Secretary General, Bhutan Chamber of Commerce and Industry/ Member, NFQSC/, Thimphu
29. The Executive Director, Bhutan Agriculture and Food Regulatory Authority (BAFRA), MoA/ Member Secretary, NFQSC, Thimphu
30. All Dasho Dzongdags
31. The Resident Representative, UNDP, Bhutan Office, Thimphu
32. The Representative, World Health Organization, Bhutan Office, Thimphu
33. The Representative, World Food Programme, Bhutan Office, Thimphu
34. The Representative, UNICEF, Bhutan Office, Thimphu
35. The Assistant FAO Representative, FAO, Bhutan Office, Thimphu

  
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FOOD RULES AND REGULATIONS OF BHUTAN 2007

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Bhutan Agriculture and Food Regulatory Authority  
Ministry of Agriculture

  
MINISTER  
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## PREAMBLE

Whereas the Food Act of Bhutan 2005, under Section 88, gives the Ministry of Agriculture the general power to make the Rules and Regulations for the implementation of the Food Act of Bhutan 2005;

Whereas the Food Act of Bhutan 2005, under several Sections, specifically recognizes the power of the Ministry of Agriculture to adopt Rules and Regulations in particular cases and establishes the framework within which such Rules and Regulations shall apply;

Where it seems appropriate to draft the Rules and Regulations following, as close as possible, the order of Chapters of the Food Act of Bhutan 2005 so as to facilitate its comprehension and implementation;

Where it seems also appropriate to regulate, at this stage, the Food Act of Bhutan 2005 only through those Rules and Regulations that are necessary or most convenient for its implementation;

Whereas the National Codex Committee in accordance with Section 31 (d) of the Food Act, BAFRA in accordance with Section 21 (g) of the Food Act, and the National Food Quality and Safety Commission in accordance with Section 18 (g) (ii) of the Food Act, have either proposed, considered, reviewed or approved this Rules and Regulations;

The Ministry of Agriculture hereby adopts the following Food Rules and Regulations.

## CHAPTER I: PRELIMINARY

### TITLE, EXTENT, AND COMMENCEMENT

1. This Rules and Regulations shall be called the *Food Rules and Regulations of Bhutan 2007*.
2. It shall extend to the whole of the Kingdom of Bhutan.
3. It shall come into force from the date specified in the notification of enforcement issued by the Minister for Agriculture.

### PURPOSE

4. The general purpose of this Rules and Regulations is to implement the Food Act of Bhutan 2005. Where appropriate, the specific purpose of a particular set of provisions of this Rules and Regulations is indicated in order to facilitate the application of such provisions.

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## **SCOPE**

5. In accordance with the Food Act of Bhutan 2005, this Rules and Regulations applies to:
  - a. All stages of production, processing, transport, storage, distribution and preparation, trade, import and export of food, as well as of feed as far as it is necessary to prevent the introduction of feed-borne hazards into the human food chain. They do not apply to primary production for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption and not for sale.
  - b. All persons within the jurisdiction of the Kingdom.

## **CHAPTER II: GENERAL POWERS OF THE MINISTER**

6. **Payment of fees and fines.** Pursuant to Sections 8, 18 (h), and 21 (e) of the Food Act.
  - 6.1. The fees due for specific services shall be collected by BAFRA. The amount of fees will be established by the Minister from time to time.
  - 6.2. The fines imposed in accordance with Sections 73-76 of this Rules and Regulations shall be collected also by BAFRA, which will keep detailed records regarding all warnings and penalties imposed, including whether the level of penalties is linked to the seriousness of the offence.
  - 6.3. Fines shall be paid subject to official receipts issued by BAFRA for the amount payable.

## **CHAPTER III: NATIONAL FOOD QUALITY AND SAFETY COMMISSION**

7. **Functions.** The National Food Quality and Safety Commission shall function in accordance with Sections 15-17 of the Food Act.

  
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**CHAPTER IV: THE “BHUTAN AGRICULTURE AND FOOD  
REGULATORY AUTHORITY” (BAFRA)**

8. **Mandate.** The Bhutan Agriculture and Food Regulatory Authority (BAFRA) shall carry out its mandate in accordance with Sections 20-21 of the Food Act.

**LABELLING PRE-PACKAGED FOOD AND FOOD ADVERTISING**

9. **Specific Purpose.** Food labelling and food advertising are the primary means of communication between the producer and seller of food on one hand and the purchaser and consumer on the other. The following provisions aim, within the purview of the mandate of BAFRA in accordance with Sections 20 and 21 of the Food Act, at the best possible information of purchasers and consumers regarding important characteristics of food to prevent misleading consumers and to facilitate informed choices while purchasing food.

10. **Food labelling**

10.1 Any pre-packaged food shall be labeled.

10.2 Food shall be deemed to be correctly labeled if the relevant standards, guidelines and recommendations related to labelling of the *Codex Alimentarius Commission* and/or appropriate national requirements have been followed, and if the information on the label does not mislead the purchaser and/or consumer.

11. **Labelling of genetically modified foods and ingredients**

11.1 Food, food ingredients and food additives obtained through certain techniques of genetic modification (i.e. a modification that does not occur naturally by multiplication and/or by natural recombination) shall be clearly identified on the label as being a ‘*product of gene technology*’ or as ‘*genetically modified*’ or as ‘*containing a genetically modified food or ingredient*’.

11.2 In all matters relating to genetically modified food, pursuant to Sections 59 and 60 of the Food Act, the provisions of the *Biosafety Rules and Regulations of Bhutan*, as amended, shall apply.

12. **Food advertising.** Food shall not be advertised, described or presented in a manner that is false, misleading or deceptive, or is likely to create an erroneous impression regarding its character in any respect.

## CHAPTER V: NATIONAL CODEX COMMITTEE

13. **Functions.** The National Codex Committee shall function in accordance with Sections 27-30 of the Food Act.

## CHAPTER VI: FOOD INSPECTORS AND ANALYSTS

### MINIMUM QUALIFICATIONS OF FOOD INSPECTORS

14. **Specific Purpose.** The following provisions aim, pursuant to Section 34 of the Food Act, at the enhancement of food safety and the orderly development of the food industry by defining minimum qualifications enabling people to be eligible for appointment as Food Inspectors.
15. **Minimum qualifications**
  - 15.1 A person wishing to be considered for appointment as a Food Inspector shall provide proof that he/she has successfully obtained a degree or diploma in food safety from an appropriate institute.
  - 15.2 Beside this academic qualification, he/she shall also to provide proof of a good, incorruptible character and, in the opinion of the Minister in accordance with Section 34 of the Food Act, has to be free from any adverse administrative record.
16. **Curriculum of the diploma course of food safety.** The curriculum of the degree or diploma course on food safety as mentioned in Section 15 of this Rules and Regulations shall be approved by the Minister to allow for the optimal training of Food Inspectors.
17. **Appointment as Food Inspector.**
  - 17.1. The Minister may consider, for appointment to Food Inspectors, only persons who comply with the minimum qualifications outlined in Section 15 of this Rules and Regulations.
  - 17.2. Food Inspectors shall be provided with an identification card in accordance with Section 36 of the Food Act.
18. **General requirement.** Only Food Inspectors appointed by the Minister shall be authorized to inspect food and food businesses, as outlined in Sections 45-51 of this Rules and Regulations.

## ANALYSTS AND APPROVED LABORATORIES

19. **Procedures.** The Food Analyst and the approved laboratories pursuant to Section 35 and 36 of the Food Act shall carry out their functions in accordance with the *Manual of Food Analysis for Food Analysts* issued by BAFRA.

## PROCEDURE IN CASES OF UNSAFE FOOD AND IN CASES OF URGENT DESTRUCTION

20. **Collection of samples.** Pursuant to Sections 42-44 of the Food Act, in cases of unsafe food, and to Sections 46-47 of the Food Act, in cases where food is destroyed or ordered to be destroyed, the Food Inspector shall collect a sample of the food and divide it in three parts. The Food Inspector shall submit one part to the National Quality Control Laboratory, Yusipang, send the second part to BAFRA for retention, and hand the third part over to the person responsible for the place where the sample was collected.
21. **Package and seal.** The three parts of the sample must be properly packed and sealed to ensure its integrity and thereby to avoid tampering while on handling and transportation.
22. **Testing.** The samples submitted to the National Quality Control Laboratory, Yusipang, will be analysed in accordance with the provisions of Section 19 of these Rules and Regulations, and tested for its required parameters based on history of problem identified and documented.
23. **Confirmatory samples.** The samples retained at the concerned BAFRA field offices and clients will be used as confirmatory samples in case of any disputes relating to testing reports.

## CHAPTER VII: FOOD AND FOOD BUSINESS

### LICENSING FOOD BUSINESSES AND FOOD BUSINESS OPERATORS

24. **Specific Purpose.** The following provisions aim, pursuant to Sections 53, 54 and 55 of the Food Act, at the enhancement of food safety and the orderly development of the food industry by defining hygienic minimum requirements for food businesses and requirements and procedures for licensing of food businesses and their operators.
- I. Licensing of food businesses**
25. **Need for a license.** Any business wishing to operate as food business requires a license.

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**26. Requirement for licensing.** A food business that complies with section IV of the latest revision of the *Recommended International Code of Practice – General Principles of Food Hygiene* [at present CAC/RCP 1-1969] of the *Codex Alimentarius* and, where applicable, with the requirements of a commodity specific *Codex Recommended Code of Technological and/or Hygienic Practice* shall be eligible for a food business license.

**27. Application of license**

27.1. A person who intends to operate a food business may, in the prescribed form and accompanied by the prescribed fee, apply for a business license to both the Minister responsible for trade and the Minister, to operate that food business.

27.2. The Minister responsible for trade shall grant a business license only after the Minister has informed him in writing that he/she is satisfied that the food business complies with the requirements defined in Section 26 of this Rules and Regulations.

27.3. The time between the arrival of the application in the office of the Minister responsible for trade and in the office of the Minister and the decision to grant or to refuse the license shall not exceed three weeks.

27.4. In case a license is not granted, the applicant shall be informed in writing of the reasons for refusal.

27.5. Failure by the Minister responsible for trade and/or by the Minister to decide on the granting or refusal of the license does not constitute granting of the license.

27.6. The Minister hereby delegates on BAFRA the authority to act in all issues referred to in Sections 27-31 of this Rules and Regulations.

**28. Suspension or revocation of license**

28.1. The Minister responsible for trade shall suspend or revoke, as the case may be, the license upon request of the Minister, if the Minister is not satisfied that the conditions that led to the granting of the license, as outlined in Section 26 of this Rules and Regulations, are any longer applicable.

28.2. The non-compliance with requirements of the Food Act or any of its Rules and Regulations may also lead to either suspension or revocation of the license.

28.3. In case of suspension or revocation of the license, the license holder shall be informed in writing of the reasons that lead to the suspension or revocation.

28.4. A license shall be suspended if the Minister considers the non-compliance of such a nature that it can be corrected within a reasonable time and public health is not at stake.

28.5. A license shall be revoked if the Minister considers the non-compliance of such a nature that it cannot be corrected within a reasonable time and/or public health is at stake.

## II. Licensing of food business operators

29. **Need for a license.** Any person wishing to assume the responsibility as operator of a food business requires a license that is issued by BAFRA.

### 30. Prerequisite for a license

30.1. A person is eligible for a license as food business operator if he/she is in possession of minimum qualifications in food safety and has a satisfactory knowledge of the Food Act and its Rules and Regulations.

30.2. A person shall be deemed to possess the minimum qualifications in food safety if he/she is in possession of a license as food handler and has successfully passed a course of the Food Act, approved by BAFRA.

31. **Exception.** The Minister may exempt certain categories of food businesses from the requirement of Sections 25 and 29 of this Rules and Regulations, if such businesses do not handle high-risk foods and their sales volume is very small.

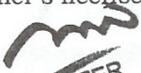
## KNOWLEDGE AND LICENSING OF FOOD HANDLERS

32. **Specific Purpose.** The following provisions aim, pursuant to Sections 53, 54, 55 and 56 of the Food Act, at the enhancement of food safety and the orderly development of the food industry by defining minimum requirements enabling people to be eligible to receive a license as food handlers.

33. **Appointment as licensed food handler.** A person who complies with the requirements outlined in the following three Sections of this Rules and Regulations is eligible for receiving from BAFRA a license as food handler.

### 34. Need for license

34.1. A food handler who has responsibility for the operation of a food business and/or supervises non-licensed food handlers requires a food handler's license.

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- 34.2. To acquire this license, food handlers have to undergo successfully a health interview, provide proof of their knowledge of food safety, and sign an agreement that they themselves and all those under their supervision oblige themselves to restrain from handling food under certain conditions of illness as detailed in the document Health status and proof of knowledge of food safety of food handlers, attached to this Rules and Regulations as Appendix 1.
- 35. Food handler's knowledge of food safety.** A food handler must be knowledgeable of how food can become contaminated and how such contamination can be avoided. He/she must also be knowledgeable under which conditions bacterial contaminants can grow and survive and how important personal hygiene is for the prevention of food borne diseases.
- 36. Proof of knowledge.** A food handler shall be deemed to possess the minimum knowledge of food safety, as required in Section 34 of this Rules and Regulations, if he/she has successfully attended a training course conducted or approved by BAFRA.
- 37. Obligation of licensee**
- 37.1. The licensee has the obligation to ensure that food is handled, processed and stored in a way that the relevant food safety requirements as detailed in the *Codex Recommended International Practice – General Principles of Food Hygiene* and, where appropriate, the requirements of commodity-specific *Codex Recommended Codes of Practice* are complied with so that contamination, growth and survival of pathogens and/or product deterioration is prevented.
- 37.2. The licensee has also the obligation to assure that no staff under his/her supervision suffers from any illness as listed in the document Health status and proof of knowledge of food safety of food handlers, attached to this Rules and Regulations as Appendix 1.
- 38. Control of license.** While working in the food business, the licensee has the obligation to carry the license with him/her and to present it, upon request, to the Food Inspector.
- 39. Renewal of license.** Food handlers holding a license have to renew their license every 3 years by **successfully attending refresher courses in food safety** that are conducted or approved by BAFRA.

- 40. Revocation of license.** The license may be revoked by BAFRA if:
- a. the licensee handles or allows food to be handled, processed or stored in a manner that jeopardizes food safety and poses a risk for public health;
  - b. the licensee and/or food handlers under his/her supervision suffer knowingly from any condition or illness, as detailed in the attached document *Health status and proof of knowledge of food safety of food handlers*, and continue to handle food.
- 41. Training of non-licensed food handlers.** The food business operator is encouraged to train all non-licensed food handlers working in his/her food business by letting them from time to time attending a training course conducted or recommended by BAFRA.

**GENERAL REQUIREMENTS FOR FOOD REGULATED UNDER THE FOOD ACT**

- 42. Specific Purpose.** The following provisions aim, pursuant to Section 57 of the Food Act, at the enhancement of food safety and the orderly development of the food industry by defining the scope of the Food Act and several general requirements.
- 43. General food safety requirements**
- 43.1. Food shall not be placed on the market, to be sold or given away, if it is unsafe, adulterated and/or contaminated.
  - 43.2. Food should be deemed safe, unadulterated and uncontaminated if it has been produced, processed, transported, stored, distributed and prepared according to relevant codes of hygienic and/or technological practice and if it complies with the safety requirements of relevant standards, both established by the *Codex Alimentarius Commission* and/or with relevant national requirements. National requirements take precedence if there is a difference between the two.
- 44. General requirements for food business operators**
- 44.1. Food business operators have the primary legal responsibility for ensuring food safety and for not misleading the consumer.

- 44.2. Operators shall assure that, at all times the food business is operating, at least one licensed food handler is present.
- 44.3. Operators also have the obligation to co-operate with and facilitate the work of Food Inspectors.

#### **INSPECTION OF FOOD BUSINESSES AND FOOD**

**45. Specific Purpose.** The following provisions aim, pursuant to Sections 57 and 68 of the Food Act, at the enhancement of food safety and the orderly development of the food industry by inspection of food as well as all activities and businesses related to the production, processing, transportation, distribution, exportation, importation and handling of food to ensure that all relevant standards and codes of practice are complied with, consumers are not deceived and foods and food businesses comply with the requirements of the Food Act.

**46. Inspection of food and food businesses.**

- 46.1. All food and food businesses shall be subject to inspection by Food Inspectors appointed by the Minister.
- 46.2. In conducting the inspection, the Food Inspector shall act in accordance with Chapter VI of the Food Act and particularly its Section 50, with Sections 48 - 52 of this Rules and Regulations, and with the *Manual of Food Inspection for Food Inspectors* issued by BAFRA.

**47. Duties, powers and rights of Food Inspectors.** Without prejudice to the general powers of Inspectors as set out in Section 39 - 51 of the Food Act, a Food Inspector shall have the following duties and rights.

47.1. A Food Inspector shall have the duty to:

- a. Inspect food businesses to verify that they comply with the relevant codes of practice and all other requirements contained in the Food Act and its Rules and Regulations;
- b. Inspect the production, processing, storage, importation, exportation, handling and distribution of food along the entire food chain;
- c. Sample, examine or have examined food to verify compliance with relevant standards and guidelines;

- d. Advise the food business operator in the application of state-of-the-art food safety assurance systems, e.g. Hazard Analysis Critical Control Point System (HACCP);
- e. Audit the food safety assurance system employed by the food business operator;
- f. Provide advice, recommendations and guidance related to food safety issues, when needed or requested;
- g. Coordinate with other law enforcement personnel, if and when required.

47.2.A Food Inspector shall have the right to:

- a. Enter any place related to the food business;
- b. Examine the records related to the food business;
- c. Issue an improvement notice, if deemed necessary, to the food business operator;
- d. Confiscate or, if deemed necessary, destroy food that is found to be in violation of standards or guidelines;
- e. Warn, or fine in accordance with Sections 72-76 of this Rules and Regulations, the food business operator, depending on the seriousness of the violation.

**48. Frequency of inspection of food businesses.** Food businesses shall be inspected by a Food Inspector at least once every three months. More frequent inspections will be necessary if:

- a. the food business has a reputation of not complying with the Food Act; and
- b. the food being produced, stored, handled, distributed and/or served is considered to be a high risk food.

**49. Report of inspection.** After inspection of a food business, the Food Inspector shall submit a report of the inspection to the food business operator within 10 working days of completion of the inspection, unless otherwise specified in accordance with Section 51 of this Rules and Regulations.

  
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**50. Content of report.** The report must, in respect of the food business, specify:

- a. whether the food business has a valid license and if it complies with the conditions of the license;
- b. whether the food business has been expanded or altered in a way without approval by BAFRA;
- c. whether the food business operator or the operator's representative has a valid license;
- d. if the food handler with overall responsibility over the operation of the food business has a valid license;
- e. whether the recommendations contained in the *Codex Recommended International Code of Practice – General Principles of Food Hygiene* and those contained in any other applicable *Codex Recommended Code of Practice* are consistently complied with;
- f. whether the food business has a *Hazard Analysis Critical Control Point System* (HACCP) plan and with what result the inspector has conducted an audit of that plan;
- g. whether, in case the food business has no *Hazard Analysis Critical Control Point System* (HACCP) plan, the Food Inspector was successful in convincing the food business operator of the need to have a *Hazard Analysis Critical Control Point System* (HACCP) plan and if the Food Inspector was able to encourage the operator in designing a plan;
- h. whether non-licensed food handlers receive training in food safety according to Section 39 of this Rules and Regulations;
- i. whether the requirements of the Food Act related to labelling pre-packaged food as well as any other relevant requirements are complied with;
- j. any other relevant information and recommendation.

**51. Notification of food business operator in case of non-compliance**

- 51.1. If there is a non-compliance with the Food Act and/or its Rules and Regulations, the Food Inspector shall verbally, at the time of the inspection, notify the food business operator or the operator's representative of the correction required.

- 51.2. A written report detailing the non-compliance and the required correction and the time in which the corrections have to be completed has to be given to the operator within 5 working days of the inspection.
- 51.3. In case the non-compliance is of such a serious degree that, without immediate correction, a risk to public health may be expected, the Food Inspector shall submit the written report on the day of inspection. The report shall clearly describe that aspect of the business that is in non-compliance, refer to the appropriate Section(s) of the Food Act and/or its Rules and Regulations that are violated, and provide information on what must be done to correct said violation. If the correction does not take place in the time period set forth in the notice, the license to operate shall be suspended.
- 51.4. In case the operator is unable or unwilling to initiate immediate correction in order to prevent a risk to public health, the Food Inspector shall revoke the license to operate the food business or parts of it, as the case might be.
52. **Re-inspection in case of non-compliance.** In case of non-compliance, a Food Inspector shall re-inspect the food business within a time that is appropriate to the degree of non-compliance.

#### **GENERAL REQUIREMENTS FOR FEED**

53. **Specific Purpose.** The following provisions aim, pursuant to Section 88 of the Food Act, at the enhancement of food safety by preventing the introduction of feed-borne hazards into the human food chain.
54. **General feed safety requirements**
- 54.1. Feeds shall be considered safe if it has been produced, processed, stored, transported and distributed according to the recommendations contained in the *Codex Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004). Other relevant recommendations, such as those referring to labelling, traceability, inspection and control procedures contained in that code, shall apply as well.
- 54.2. Feed shall not be placed on the market or fed to any food-producing animal if it is unsafe.
- 54.3. Feed shall be deemed to be unsafe for its intended use if it is considered to:

- a. have an adverse effect on animal or human health;
- b. make the food derived from food producing animals unsafe for human consumption.

## **CHAPTER VIII: IMPORT AND EXPORT**

### **IMPORTATION OF FOOD**

- 55. Specific Purpose.** The following provisions aim, pursuant to Section 61 of the Food Act, at the enhancement of food safety and the orderly development of the food industry by defining requirements for the commercial importation of food.
- 56. National requirements**
- 56.1. All food to be imported into Bhutan shall meet the national requirements of the Food Act and its Rules and Regulations as well as all the other applicable legislation.
  - 56.2. In those cases where there are no national requirements, the food shall be in compliance with the official requirements of the exporting country.
- 57. Inspection.** All food to be imported into Bhutan shall be subject to inspection by a Food Inspector to verify its compliance with the Food Act and its Rules and Regulations or the official requirements of the exporting country, as the case might be. It shall also be subject to inspection by Inspectors appointed under other applicable legislation.
- 58. Import Permit.** A person who wishes to import food commercially into Bhutan has to obtain an import permit prior to presenting the food for import inspection.
- 59. Issuance of Import Permits by BAFRA.** The Minister hereby delegates on BAFRA the authority to issue import permits.
- 60. Official Certificate.** The application for an import permit has to be accompanied by an official certificate, issued by a recognized authority of the exporting country. This certificate has to state that the food to be imported complies with the requirements of all applicable legislation of Bhutan or the official requirements of the exporting country, as the case might be.
- 61. Points of entry.** Food may only be imported into Bhutan at an officially designated border point.

  
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## EXPORTATION OF FOOD

62. **Specific Purpose.** The following provisions aim, pursuant to Section 65 - 67 of the Food Act, at the enhancement of food safety and the orderly development of the food industry by defining requirements for the commercial exportation of food.
63. **Export Permit.** A person who wishes to export food commercially from Bhutan has to obtain an export permit prior to presenting the food for export inspection.
64. **Issuance of Export Permits by BAFRA.** The Minister hereby delegates on BAFRA the authority to issue export permits.
65. **Inspection.** The containers, packaging material, labelling and ingredients of food exported from Bhutan are subject to inspection by a food inspector, and fees for such inspection may be levied as established by the Minister after consultation with the Commission.
66. **Official Certificate.** Exporters wishing to export food from Bhutan shall inform the BAFRA of any inspection, analysis or documentation required by the relevant importing country or countries, and any such inspection, analysis or documentation may be subject to such fees as the Minister may establish after consultation with the Commission.
67. **Points of exit.** Food may only be exported from Bhutan at an officially designated border point.

## CHAPTER IX: ENFORCEMENT

68. **Inspection of a food business.** In addition to the provisions of Section 68 of the Food Act regarding the serving of an improvement notice to a food business, the Food Inspector shall carry out the inspection of a food business and food in accordance with Sections 45-52 of this Rules and Regulations.

## APPEAL

69. **Appeal to BAFRA.** In accordance with Section 69 of the Food Act, any person aggrieved by a decision or action of a Food Inspector under the Food Act or under this Rules and Regulations may appeal to BAFRA in writing within thirty (30) working days from the moment of the grievance.

70. **Further Appeal.** In accordance with Section 70 of the Food Act, any person not satisfied with a decision of the BAFRA under the previous Section may lodge a complaint with the Royal Court of Justice in accordance with the relevant provisions of the Civil and Criminal Procedure code.

#### CHAPTER X: OFFENCES AND PENALTIES

71. **Bhutan Penal Code.** In accordance with Section 85 of the Food Act, offences which are not covered under the Food Act or under this Rules and Regulations shall be imposed as per the Bhutan Penal Code.
72. **Offences and penalties under the Food Act.** Offences and Penalties under this Rules and Regulations shall be established and imposed in accordance with the provisions of Chapter X (Sections 72-87) of the Food Act.
73. **Fine in lieu of appearance.** For the purposes of Section 79 (b) read together with Section 80 (b) of the Food Act, the fixed fine to be imposed on the person or food establishment and to be paid to BAFRA shall be 10 (ten) times the market value of the incriminating commodity. An official receipt for the fine collected shall be issued by the Food Inspector. In any case, the Food Inspector shall seize any incriminating food.
74. **Daily fines in cases of non-compliance.** In the case of any person failing to comply with the provisions of the Rules and Regulations regarding the licensing of food business and food business operators, and knowledge and licensing of food handlers, or with the order served to the person to discontinue, close down, vacate or stop management of a food establishment, the Food Inspector may impose on the person a fine of Nu. 500.00 (Five hundred Ngultrum) per day from the date of serving the order till the time of complying with the order. An official receipt for the fine collected shall be issued by the Food Inspector.
75. **Fine upon a first conviction through a court process.** For the purposes of Section 79 (c) read together with Section 82 (a) of the Food Act, the fixed fine to be imposed on the person or food establishment and to be paid to BAFRA shall be 50 (fifty) times the market value of the incriminating commodity. An official receipt for the fine collected shall be issued by the Food Inspector.

  
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76. **Fine upon a second conviction through a court process.** For the purposes of Section 79 (c) read together with Section 82 (b) of the Food Act, the fixed fine to be imposed on the person or food establishment and to be paid to BAFRA shall be 100 (hundred) times the market value of the incriminating commodity. An official receipt for the fine collected shall be issued by the Food Inspector.

## CHAPTER XI: MISCELLANEOUS

### DEFINITION OF TERMS

77. In addition to the definitions set out in Section 91 of the Food Act of Bhutan 2005, for the purpose of this Rules and Regulations the following terms shall have the meaning ascribed to them in this Section, unless the context clearly indicates otherwise:

77.1. **“Feed”** means any single or multiple materials, whether processed, semi-processed or raw, which is intended to be fed directly to food producing animals.

77.2. **“Food Act”** means the Food Act of Bhutan 2005.

77.3. **“Food business operator”** means the natural or legal person responsible for ensuring that the requirements of the Food Act of Bhutan 2005 are met within the food business under their control.

77.4. **“Food handler”** means any person who directly handles packed and unpackaged food, food equipment and utensils, or food contact surfaces and is therefore expected to comply with food safety requirements.

77.5. **“Health interview”** means a dialogue between a qualified health worker (e.g. physician, nurse) and a food handler or food handler to be, to determine whether the person interviewed suffers from certain conditions of illness, and whether he/she is aware of what diseases may be spread from person to person via food.

77.6. **“High risk food”** means a food that either easily supports growth of bacterial pathogens or has been shown by epidemiological evidence to be frequently implicated in the causation of food borne illness.



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**77.7. "Licensed food handler"** means a food handler who has obtained a license as stipulated in the Rules and Regulations on knowledge and licensing of food handlers.

**77.8. "Primary production"** means the production, rearing or growing of primary products including harvesting, milking, and farmed animal production prior to slaughter. It also includes hunting and fishing and the harvesting of wild products for domestic consumption and not for sale.

**REPEAL**

**78.** This Rules and Regulations repeals the BAFRA Food Safety Regulations October 2005, as well as, in accordance with the definition given in Section 91 (xxxv) of the Food Act, any other rule, notification or order which is inconsistent with this Rules and Regulations.

  
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**APPENDIX 1:**

**HEALTH STATUS AND PROOF OF KNOWLEDGE OF FOOD SAFETY  
OF FOOD HANDLERS**

(Pursuant Sections 34.2 and 37.2 of this Rules and Regulations)

**Name of food handler** .....

**Address** .....

**Date of birth** .....

**1. Health interview**

Date.....

Place .....

Name and title of authorized person who conducted the interview  
.....  
.....

Time and title of food safety training course attended  
.....  
.....

Comments  
.....  
.....  
.....  
.....

Signature of interviewer.....

  
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**2. Agreement of food handler**

I have read (or had explained to me) and understood the rules of personal hygiene and of hygienic food-handling practices.

I accept that I will report to my supervisor and restrain from handling food if I suffer from an illness involving any of the following:

- a. Hepatitis A (jaundice),
- b. Diarrhoea,
- c. Vomiting,
- d. Fever,
- e. Sore throat with fever,
- f. Visibly infected skin lesions (boils, cuts, etc.),
- g. Other skin lesions (boils, cuts, etc., however small),
- h. Discharge from ear, eye, and nose.

**I understand that failure to comply with this agreement could lead to the revocation of my license and/or to my dismissal.**

**Signature of food handler .....** **Date .....**

  
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