

Criteria for Good Hygienic and Manufacturing Practices for Licensing of Food Business



Bhutan Agriculture and Food Regulatory
Authority (BAFRA)
Ministry of Agriculture and Forests

Criteria for Good Hygienic and Manufacturing Practices for Licensing of Food Business

1. Objective

The objective of this document is to define a set of basic Good Hygienic and Manufacturing Practice (GHP/GMP) requirements that Food Business (FB) need to implement for production of suitable and safe food. This document shall be used for food regulations and Licensing requirements by Bhutan Agriculture and Food Regulatory Authority (BAFRA). It shall be the responsibility of the FBs to ensure compliance to this BAFRA Criteria for Good Hygienic and Manufacturing Practices for Licensing of FB. This document can also be used for the purpose of internal and/or external evaluation of compliance to these requirements.

2. Scope

This document specifies the basic Good Hygienic and Manufacturing Practices for production of safe and suitable food. The requirements as given in this document apply to all FBs except street food¹, temporary food stalls² and primary producers. The document has specified requirements described as 'shall' where compliance to the Criteria is essential.

3. Design and Facilities

3.1. Location

- a) Establishment shall have clearly defined boundaries, be away from toxic chemical/odour producing industries, approach road to the site shall be concreted/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.
- b) 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.

3.2 Premises and rooms

¹ BAFRA Criteria for Good Hygienic and Manufacturing Practices for Street Food Vendors

² BAFRA Minimum Standard for the Operation of Temporary Food Stalls

3.2.1 Design and layout

- a) Basic infrastructure appropriate to the operations shall be in place. The buildings shall provide sufficient space to allow a logical flow of materials, products and personnel through the production process. The movement patterns of materials, products and personnel and the layout of equipment shall be so designed that there is no criss-cross movement. Entry and exit points for materials and personnel shall be separate as far as possible. Food flow shall be in one direction, as far as possible.
- b) Adequate space shall be provided for various activities such as raw material receipt and storage, processing, final product storage, change facilities for personnel, foot dip facilities as appropriate to the industry, separate eating area which is located away from process area, toilets, and do not open directly into the processing, packing and storage areas.
- c) There shall be adequate separation between storage areas (raw material, packaging material and finished goods), processing area, packing area, utility area, etc.
- d) There shall be a provision of appropriate loading and unloading points which facilitate movement of material and such points shall be suitably covered to provide adequate protection from pests, rain, etc.
- e) Openings intended for transfer of materials and products (e.g. transport hoses, conveyors) shall be designed to prevent entry of foreign matter and pests.

3.2.2 Internal Structures and Fittings

- a) Flooring shall be smooth, impervious, with no crevices or damages. 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).
- b) Roof shall be constructed so as to be gap free, water resistant, and finished so as to minimize buildup of dirt and shedding of particles. Overhead fixtures, if any, shall be constructed and finished to minimize the buildup of dirt and condensation and the shedding of particles.
- c) Walls and partitions shall have a smooth surface. Wall paint shall not be flaking off. There shall be no crevices to harbor pests. If applicable and as appropriate to the operations, the walls up to a desired height shall be impervious and easy to clean.
- d) Windows and ventilators shall be easy to clean, and where necessary fitted with cleanable insect-proof screens. Window glasses shall be protected to ensure that food is not contaminated in the event of glass breakages. Mesh on windows and ventilator shall not have cuts or damages to avoid entry of pest.

- e) 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/air curtains/wire mesh doors/doors with self-closing devices, etc. to ensure dust, insects, birds and animals are kept out.
- f) Working surfaces that come into direct contact with food shall be in sound condition (free from cracks, crevices, open seams, etc.), durable and easy to clean, maintain and disinfect. They shall be made of smooth (such as free from sharp internal angles or corners; protruding rivets, nuts and bolts, etc.), non-absorbent materials and inert to food, detergents and disinfectants under normal operating conditions.

3.3 Equipment

- a) 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.
- b) Equipment and re-usable containers coming into contact with food shall be durable, designed and constructed to ensure that they can be adequately cleaned, disinfected where necessary, and maintained to avoid the contamination of food. Where necessary, equipment shall be movable or capable of being disassembled to allow for maintenance, cleaning, disinfection, monitoring, etc.
- c) Equipment shall be made of materials that are impervious, non-reactive, with no toxic effect in intended use and do not pass colors, odors or taste to food.
- d) Non-food contact surfaces of equipment shall be free from unnecessary projections and crevices; and designed and constructed to allow easy cleaning and maintenance.
- e) Equipment used to cook, heat treat, cool, store or freeze food shall be designed to achieve the required food temperatures (and other parameters as relevant) 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.

3.4 Containers for waste and inedible substances

- a) 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.

3.5 Facilities

3.5.1 Water supply

- a) 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.
- b) The water pipes shall be made of material that is non-toxic, corrosion resistant, free from cracks, impervious and shall be sealed.
- c) 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.

3.5.2 Drainage and waste disposal

- a) Drainage and waste disposal systems as relevant to the operations shall be appropriately designed and constructed.
- b) Drainage shall flow from clean to contaminated areas. Drains shall not pass over process lines. The water effluent discharged shall comply with the requirements of the National Environment Commission. No manhole shall be situated inside any food processing area.
- c) Drains, if any, in the processing area shall be made of impervious rust proof material and shall be covered. These shall have adequate trapping devices to avoid entry of pests. 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.
- d) Food waste and other waste shall be periodically cleared avoiding a build up in the process area. Waste bins of adequate size that can be operated without hand contact shall be provided.

3.5.3 Cleaning

- a) 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.

3.5.4 Personal hygiene facilities and toilets

- a) 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. Where food is being handled with bare hands, taps used for washing hands shall be non-hand operated.
- b) Hand wash basins/ sanitizers shall be situated at the entrance to process areas and/or where they are required.
- c) Toilets of appropriate hygienic design at suitable location 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 process area.
- d) Adequate changing facilities for personnel shall be provided, as appropriate to the operations.

3.5.5 Temperature control

- a) If operations require heating, cooling, cooking, refrigerating and freezing food, storing refrigerated or frozen foods, monitoring food temperatures, adequate facilities shall be available for the same.
- b) Where necessary, ambient temperatures shall be controlled to ensure the safety and suitability of food.

3.5.6 Air quality and ventilation

- a) 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.
- b) Food processing areas where operations result in release of fumes, smoke, steam or any vapour shall be equipped with an exhaust system or ventilation that can efficiently and effectively remove these.
- c) Ventilation systems shall ensure that air does not flow from unclean to clean areas and, where necessary, they can be adequately maintained and cleaned.

3.5.7 Lighting

- a) Natural and/or artificial lighting shall be provided in food premises for various operations and other activities within the facility (e.g. sanitary conveniences). The intensity of lighting shall be adequate for the nature of operations. (e.g. sorting, cleaning, grading, inspection and testing require greater intensity of

light). Where necessary, lighting shall be such that the resulting colour is not misleading.

- b) Lighting fixtures shall, especially where food or food contact surface is exposed to open, be shatter proof or protected with shatter-proof covers to ensure that food is not contaminated in the event of breakages. The fixtures shall be designed to avoid accumulation of dirt and be easy to clean.

3.5.8 Power Back up

- a) Suitable power back up facilities e.g generators, invertors etc shall be provided to ensure uninterrupted power supply as necessary for production of safe food.

3.5.9 Storage

- a) Adequate facilities for storage of food, ingredients, packaging material and non-food chemicals shall be provided. These shall be suitably designed and constructed as appropriate to operations (Further details at Clause 4.13).

4. Control of operations

4.1. Time and temperature control

- a) Where time and temperature is critical to the safety of a food, define temperature and time controls for heating, cooling, processing and storage taking into account the nature of food, its shelf life, the processing method, its packaging, intended use of the product. These controls shall reduce any food borne pathogen that may be present in the food to an acceptable level.

4.2 Control of other specific process steps

- a) Define controls over other process steps which contribute to food hygiene which may include cleaning, sorting, chilling, thermal processing, fumigation, irradiation, drying, chemical preservation, vacuum or modified atmospheric packaging, etc.

4.3 Specifications

- a) Define specifications for products at various stages of operations as relevant for ensuring food safety and compliance to regulatory and statutory requirements. These specifications shall be based on sound scientific principles. The monitoring procedures, acceptable limits and analytical methods shall be documented and records maintained.

4.4 Microbiological cross contamination

- a) When processing food, adequate steps shall be taken to prevent the same from microbiological cross contamination.
- b) Raw, unprocessed food shall be effectively separated either physically or by time from ready-to-eat foods, with effective cleaning and where appropriate disinfection. Similarly, this shall also be implemented for vegetarian and non-vegetarian products.
- c) Access to processing areas shall be restricted or controlled. Personnel shall put on clean protective clothing including footwear and wash their hands before entering. In case of high risk products, access to processing areas shall be only via a changing facility.
- d) All surfaces, utensils, equipment, fixtures and fittings shall be thoroughly cleaned and where necessary, disinfected after raw food, particularly meat, poultry, fish, etc. has been handled or processed to prevent contamination.

4.5 Physical and chemical contamination

- a) Foods shall not be contaminated by foreign bodies such as glass, metal particles from machinery, plastic, dust, harmful fumes and hazardous chemicals.
- b) In manufacturing and processing, suitable and effective detection or screening devices (such as filters, sieves, magnets, metal detectors, and metal separators) shall be used where necessary.
- c) If needed, a glass/foreign body control policy shall be defined and adopted to assist in ensuring food safety.

4.6 Incoming materials requirements

- a) Only sound, suitable incoming material like raw materials, ingredients and semi processed products shall be used.
- b) Where appropriate, specifications for raw materials shall be defined including regulatory requirements.
- c) Raw materials shall be inspected, tested or covered by Certificate of Analysis or Certificate of Conformity at appropriate frequencies for verifying conformance to specified requirements prior to acceptance or use.
- d) No raw material or ingredient shall be accepted by an establishment if it is known to contain parasites, undesirable microorganisms, pesticides, veterinary drugs, heavy metals, radioactive substance or toxic, decomposed or extraneous substances which would not be reduced to an acceptable level by normal sorting and or processing.

- e) Imported foods/ raw materials, if used, shall be as per the applicable regulations.
- f) Records of raw materials, food additives and ingredients as well as their source of procurement shall be maintained.

4.7 Packaging

- a) Packaging design and materials shall provide adequate protection for products to minimize contamination, prevent damage and accommodate proper labeling. The materials shall be appropriate for the food to be packed and sufficiently durable to withstand the conditions of processing, handling, storage and transportation. Use of staple pins, strings, rubber bands, shall be discouraged. Glue, if used, shall not come in contact with the food product, and in case it comes in contact, it shall be food grade.
- b) Packaging materials and gases shall be non-toxic and not pose a threat to the safety of food under specified conditions of storage and use. Certificates of conformity from an accredited test laboratory or other evidence shall be used for verification.
- c) Packaging materials shall be stored and handled under hygienic conditions away from raw materials and finished products.
- d) Re-usable packaging, if used, shall be suitably durable, easy to clean and where necessary, disinfect. It shall not have been used for packaging non-food products.

4.8 Water

4.8.1 Water, ice and steam in contact with food

- a) Where used either as an ingredient, for making ice, for washing food, food contact surfaces or hands, only potable water shall be used. Water, ice and steam shall be produced, handled and stored to protect them from contamination.
- b) Steam in direct contact with food and or food contact surfaces shall not contain any agent which is hazardous for food safety.
- c) 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.

4.8.2 Water, ice and steam not in contact with food

- a) For steam production, fire control and other similar purposes not connected with food may not require the use of potable water. In certain processes (e.g. chilling) and in food handling areas where water does not constitute a hazard to the safety of food, the use of potable water may not be required.

4.8.3 Water pipes and storage tanks

- a) 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.

4.9 Management and supervision of operations

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

4.10 Documentation and records

- a) Appropriate records of processing, production and distribution shall be kept and retained for a period of at least one year beyond the shelf life of the product.
- b) At a minimum, records for the following processes shall be maintained:
 - i) Incoming material checks
 - ii) Inspection and test
 - iii) Temperature and time
 - iv) Product recall and traceability
 - v) Storage
 - vi) Cleaning and sanitation, as appropriate
 - vii) Pest control
 - viii) Medical and health
 - ix) Training
 - x) Calibration
 - xi) Complaint and customer feedback
 - xii) Corrective and preventive action

4.11 Product recall and traceability

- a) Effective procedures shall be in place to enable a complete and rapid recall of any implicated lot/ batch of finished food. Where a product has been withdrawn,

other products which are produced under similar condition shall be evaluated for safety and may need to be withdrawn.

- b) 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.
- c) In case of a food recall, records shall be maintained that demonstrate effective identification, recall, subsequent handling and disposal of recalled food. In case of absence of recalls, mock recall shall be conducted at least once annually, and records of the same maintained.

4.12 Storage

- a) Food storage facilities shall be designed and constructed to enable maintenance of cleanliness, ventilation, avoid pest access and harborage; prevent contamination and where necessary, provide suitable conditions of temperature and humidity for minimizing deterioration of food.
- b) Adequate facilities for storage of food, ingredients, packaging material, non conforming material and non-food chemicals (e.g. cleaning materials, lubricants, fuels) shall be provided, and segregated appropriately.
- c) 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/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.
- d) All products in storage shall be clearly identified.
- e) Stocks of raw materials (including packaging material) and ingredients shall be subject to effective stock rotation.
- f) Cleaning materials and hazardous chemical substances shall have restricted access and only to authorized personnel.

5 Maintenance, cleaning and sanitation

5.1 Establishment and equipment shall be maintained under an appropriate state of repair and condition to;

- a) Facilitate all sanitation procedures
- b) Function as intended particularly at critical steps

c) Prevent contamination of food

5.1.1 Maintenance programs shall be in place which shall cover maintenance schedule, responsibilities, methods, tools and gadgets, etc. and appropriate records maintained. Consumables like lubricants that come in contact with food shall be food grade, and spares shall be non-toxic, non-reactive and impervious.

5.1.2 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.

5.2 Pest Control

- a) 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 drain pipes, etc.
- b) The 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.
- c) The measures shall be documented and records maintained.

5.3 Waste management

- a) 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.

6 Personal hygiene

- a) Personnel working in processing area shall be checked for communicable and infectious diseases at least once in six months by a Government medical doctor. Records of the medical fitness certificate shall be maintained.
- b) Personnel working in processing area shall not have any open cuts or wound/injury, contagious disease, or sickness such as jaundice, diarrhea, vomiting, fever, sore throat with fever, visibly infected skin lesions (boils, cuts, etc.), discharge from ear, eye and nose. The open cuts or wounds shall not come in direct contact with food or food contact surface.

- c) Personnel while working in a food processing area shall maintain a high degree of personal cleanliness and shall wear clean uniform and hair restraint. They shall not wear loose or hanging jewelry, glass bangles, watches, and carry mobile phones in a food processing area. Nails shall be trimmed, kept clean and without nail polish. Street shoes shall not be permitted. Appropriate measure such as passing through a foot dip, using shoe covers, changing to separate foot wear for internal use etc. shall be used.
- d) Personnel shall always wash hands with soap/disinfectant at the start of activities, 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.
- e) No spitting, smoking, eating food and chewing gum, doma and tobacco shall be permitted in the processing areas.
- f) Visitors shall follow the same norms for protective clothing and personal hygiene as those working in the unit.
- g) Personal hygiene practices in simple local language, understood by the personnel and/or pictorial shall be suitably displayed at appropriate places.

7. Quality Control

- a) The quality control program shall include inspection and testing of incoming, in process and finished product (for specifications see Clause 3.3 a).
- b) 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.
- c) The laboratory shall have
 - i) Competent manpower,
 - ii) Appropriate equipment ,
 - iii) Suitable environmental conditions,
 - iv) Methods of sampling and testing,
 - v) Standard reference materials,
 - vi) Documented processes including calibration processes,
 - vii) Process for waste disposal,
 - viii) Quality assurance through in-house or external program,
 - ix) Records of testing, calibration, manpower competence, quality assurance program.

8. Transportation

- a) Food shall be adequately protected during transport to assure food safety.
- b) The transportation or transport containers shall be designed and constructed so that they do not contaminate food (including ingredients) or packaging material. 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.
- c) The temperature, humidity, atmosphere and other necessary conditions, as appropriate to the product shall be maintained.

9. Product information, consumer awareness and complaints

9.1 All incoming, in process and finished products shall be suitably identified for product identification, stage of processing, inspection and test status, etc. so as to avoid inadvertent use. All legal/ statutory requirements shall be clearly given on the label of the final product as per the Food Rules and Regulations of Bhutan (2007). All finished products shall be given a unique batch number. Any special requirements of handling, storage, processing, by customer etc. shall be clearly indicated on labels.

9.2 All complaints shall be analyzed for any improvements with regard to food suitability and food safety.

10 Competence and Training

10.1 All food businesses shall have at least one food handler with a valid Food Handlers License issued by BAFRA.

10.2 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 GMP for the tasks to be performed by them effectively to enable a safe food. Trainings shall be held at required frequencies but at least once in 6 months and records of the same maintained. Trainings can be provided on the job and/or through class room sessions.

10.3

11 Vending Machines

11.1 All requirements of design, operations and hygiene as applicable shall apply to vending machines with a view to ensuring safety and suitability of use.

12 Self Evaluation

12.1 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.