

Good Hygiene and Manufacturing Practices Criteria



BHUTAN FOOD AND DRUG AUTHORITY (BFDA)
MINISTRY OF HEALTH (MoH)
THIMPHU 11001

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



FOREWORD

Section 26 to 39 of the Food Rules and Regulations of Bhutan (2017) aims at enhancement of food safety and the orderly development of the food industries by defining minimum requirements for food businesses and procedures for licensing of the food businesses. The licensing of the food business has been designed as per the criteria for Good Hygienic and Manufacturing Practices (GHP/GMP) which is based on the recommended International Code of Practice- General Principles of Food Hygiene of Codex Alimentarius Commission (CAC/RCP 1-1969; revised in 2022) and Bhutan Standard on Food Hygiene-General principles- Code of practice (BTS 139:2020 SARS 00114:2018).

Ensuring compliance with the GHP/GMP Criteria of Bhutan Food and Drug Authority (BFDA) for Food Business will not only fulfill the legal requirements, but also ensure consumer confidence in the food safety system of Food Business and on the inspection services provided by the BFDA officials. In addition, the Food Business can use this document as a guidance document to implement GHP/GMP requirements in their organization and to assess their stand before applying for Food Safety License (FSL). Only upon compliance with the requirements in the criteria, the food business would be granted with a Food Safety License. Thereafter, surveillance inspections would be carried out for the food business to ensure continued compliance with the criteria.

This document is a revised version of Criteria for Good Hygienic and Manufacturing Practices (GHP/GMP) for licensing of Food Business, version 2, September 2017 to address some implementation challenges in the field. The document was developed by the Food Quality and Safety Division, Bhutan Food and Drug Authority, Royal Government of Bhutan.

I hope this manual serves its intended purpose of ensuring food safety and hygiene in the Food Businesses.

Gyem Bidha
Director

1 OBJECTIVE

The objective of this document is to define a set of basic Good Hygienic and Manufacturing Practices (GHP/GMP) that Food Business (FB) needs to implement for production of suitable and safe food. This document shall be used for:

- Food Safety Licensing of Food Businesses;
- Regulatory and monitoring inspection of food businesses and;
- Providing principles and guidance on the application of GHP/GMP to the Food Businesses.

It shall be the responsibility of FBs to ensure compliance to GHP/GMP Criteria throughout the food chain to provide food that is safe and suitable for human consumption. This document can also be used for the purpose of internal and/or external evaluation of FB for 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 FB except street food ¹, temporary food stalls² and primary producers. The document has specified requirements described as 'shall' where compliance with the Criteria is essential.

3 TERMS AND DEFINITIONS

a. Acceptable level

A level of hazard in a food at or below which the food is considered to be safe according to its intended use.

b. Allergen

Allergen is a specific substance or protein found in certain food (such as peanut, milk, wheat product, etc) that can trigger an abnormal response of the immune system and cause symptoms like itching, hives, swelling, nasal congestion, sneezing, coughing, wheezing, difficulty breathing, gastrointestinal issues and in severe cases anaphylaxis.

c. Allergen cross contact

The unintentional incorporation of an allergenic food, or ingredient, into another food that is not intended to contain that allergenic food or ingredient.

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

² BFDA Minimum Standards for Establishment and Operation of Temporary Food Stalls.

d. Competent authority

The government authority or official body authorized by the government that is responsible for the setting of regulatory food safety requirements and/or for the organization of official controls including enforcement.

e. Contaminant

Any biological, chemical or physical agent, foreign matter or other substances not intentionally added to food that may compromise food safety or suitability.

f. Contamination

The introduction or occurrence of a contaminant in the food or food environment.

g. Correction

Immediate action to eliminate a detected non-conformity / non-fulfilment of specified requirements.

h. Corrective action

Any action taken when a deviation occurs in order to re-establish control, segregate and determine the disposition of the affected product if any and prevent or minimize reoccurrence of the deviation.

i. Cross-contamination

Cross-contamination is the transfer of harmful microorganisms, chemical contaminants including allergens to food from other foods, cutting boards, and utensils when not handled properly.

j. Disinfection

Reduction by means of biological or chemical agents and/or physical methods in the number of viable microorganisms on surfaces, in water or air to a level that does not compromise food safety and/or suitability.

k. Flow diagram

A systematic representation of the sequence of steps used in the production or manufacture of food.

l. Food

Any article or substance, intended for human consumption, whether processed, semi-processed or raw, including water and beverages which may contain any flavouring matter or condiments, except for pharmaceutical drugs, tobacco and cosmetics.

m. Food Business

Any business where harvesting, manufacture, handling, serving, treatment, packaging, grading, labelling, transport, import, export or storage of food is carried out, whether for profit or no.

n. Food handler

Any person who directly handles packaged or unpackaged food, equipment and utensils used for food, or surfaces that come into contact with food and that is expected, therefore, to comply with food hygiene requirements.

o. Food Safety

Assurance that food will not cause adverse health effects to the consumer when it is prepared and/or eaten according to its intended use.

p. Food suitability

Assurance that food is acceptable for human consumption according to its intended use.

q. Foreign matter

Any unwanted or extraneous materials that can contaminate the product and includes physical objects such as dirt, dust, metal fragments, glass shards, plastic pieces and any other material that is foreign to the intended composition of the product.

r. Good Hygiene Practices (GHP)

Fundamental measures and conditions applied at any step within the food chain to provide safe and suitable food.

s. Good Manufacturing Practices (GMP)

Are a set of guidelines and procedures that ensure safe and consistent production, processing and handling of food products. They encompass requirements for facilities, equipment, personnel, hygiene, sanitation, documentation and quality control to prevent contamination, maintain product integrity and protect consumer health.

t. Hazards

A biological, chemical or physical agent in food with the potential to cause an adverse health effect.

u. Licensed FB

Any food business that has been granted Food Safety License (FSL) based on Good Hygiene and Manufacturing Practices (GHP/GMP) criteria by the competent authority (BFDA).

v. Pathogenic Microorganisms

Harmful microorganisms that can cause illness when ingested through contaminated food.

w. Personal hygiene

Practices and behaviors that food handlers should follow to ensure the safety and cleanliness of the food they prepare or serve.

x. Preventive action

Refer to proactive measures taken to identify and eliminate the root causes of the potential issues before they occur aiming to improve processes and prevent nonconformities.

y. Primary packaging

Primary packaging is the material that directly surrounds and comes into direct contact with a product, serving as a protective and functional barrier to maintain its integrity, safety and quality.

z. Product recall

The action of removing or retrieving a defective or potentially harmful product from the market to prevent consumer exposure and mitigate potential risks or adverse effects.

aa. Product withdrawal

The process of removing a product from the distribution chain before it reaches the consumer, typically due to safety concerns or the product's failure to meet established safety requirements, rendering it unsuitable for sale.

bb. Specifications

Specification refers to a comprehensive document that defines specific characteristics, parameters and criteria that a food product, ingredients must satisfy in terms of its composition, production, quality and compliance with regulations.

cc. Spoilage Microorganism

Microorganism that causes food to deteriorate and develop unpleasant odors, taste and textures.

dd. Toxins

Are harmful substances produced by microorganisms that can cause adverse health effects. Example of toxins include bacterial toxins like botulinum toxin produced by *Clostridium botulinum*, which can cause botulism, mycotoxins produced by certain fungi that contaminate the food and can lead to food poisoning.

4 ESTABLISHMENT- DESIGN OF FACILITIES & EQUIPMENT

Objectives:

Depending on the nature of the operations and the risks associated with food establishments, premises, equipment and facilities should be located, designed and constructed to ensure that:

- a) contamination is minimized;
- b) design and layout permit appropriate maintenance, cleaning and disinfection and minimize air-borne contamination;
- c) surfaces and materials, in particular those in contact with food, are non-toxic for their intended use and where necessary, suitably durable, and easy to maintain and clean;
- d) where appropriate, suitable facilities are available for temperature, humidity and other controls; and
- e) there is effective protection against pest access and harbourage.

4.1. Location

- a) Food business should not be located where there is a threat to food safety or suitability and hazards cannot be controlled by reasonable measures.
- b) FB shall have:
 - i. Clearly defined boundaries, be away from toxic chemical/odour producing industries which are reasonably likely to contaminate food;
 - ii. Approach road to the site shall be such that it does not compromise food safety;
 - iii. Surrounding areas shall be clean with no garbage accumulation and stagnant water, and not prone to pest infestation and flooding;
 - iv. No uncontrolled vegetation around the premises that may cause cross contamination.
- c) Area near open drains, garbage dumps or logged water and open spaces in and around FB, 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.

4.2. Premises and Rooms

4.2.1 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 layout of premises and the flow of operations, including the movements of personnel and the materials within the buildings, should be unidirectional to minimize or prevent cross-contamination. Entry and exit points for materials and personnel shall be separate.
- 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.

- c) The FB shall have a separate and designated eating area and toilet facilities. These facilities shall be located away from the processing/packaging or storage areas. If these facilities are located inside the building, these facilities should be well separated from production areas by a suitable intervening space such as corridors. There should not be direct access to eating areas or toilets from the processing/ packaging or storage areas.
- d) There shall be adequate separation between storage areas (raw material, packaging material and finished goods), processing area, packing area, utility area etc. to minimize or prevent cross contamination.
- e) 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.
- f) Openings intended for the transfer of materials and products (e.g. transport hoses, conveyors) shall be designed to prevent entry of foreign matter and pests.

4.2.2 Internal Structures and Fittings

Structures within FB should be soundly built of durable materials, which are easy to maintain, clean and, where appropriate, easy to disinfect. They should be constructed of non-toxic and inert materials according to intended use and normal operating conditions. In particular, the following specific conditions should be satisfied where necessary to protect the safety and suitability of food:

- a) Floors shall be made of impervious materials with no crevices or damage that is easy to clean and where necessary disinfect. Floors shall be constructed to allow adequate drainage where necessary.
- b) The floor and wall junction shall be such that they are cleanable e.g. coved (without sharp angles)
- c) Roof and/or ceiling 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 (e.g. lighting) should be constructed to be shatterproof where appropriate and finished to minimize the build-up of dirt and condensation and the shedding of particles.
- d) 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.
- e) 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.
- f) 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 polyvinyl chloride/air curtains/ wire mesh doors/ doors with self-closing devices, etc. to ensure dust, insects, birds and animals are kept out.

- g) The 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. The working surfaces shall be made of smooth (such as free from sharp internal angles or corners; protruding rivets, nuts and bolts, etc.) and non- absorbent materials and inert to food.

4.3. 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 food establishment shall have documented procedure for calibration of equipment specifying frequency.

4.4. Facilities

4.4.1 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 or Bhutan Drinking Water Quality Standard. In case water is stored in tanks, the tanks shall be such that they prevent contamination of water. They shall be suitably covered and locked 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.

4.4.2 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 Department of Environment and Climate Change. 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) Waste bins of adequate size that can be operated without hand contact shall be provided.
- e) 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.

4.4.3 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.

4.4.4 Personnel hygiene facilities and toilets

- a) Adequate means of hygienically washing, drying and sanitizing hands (as relevant), including wash basins, handwashing method poster and supply of adequate water of potable quality shall be provided.
- 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 a 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 room with necessary facilities for personnel shall be provided, as appropriate to the operations.

4.4.5 Temperature Control

Depending on the nature of the food operations undertaken, adequate facilities should be available for heating, cooling, cooking, refrigerating and freezing food, for storing refrigerated or frozen foods, and, when necessary, controlling ambient temperatures to ensure the safety and suitability of food.

4.4.6 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 the 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.

4.4.7 Lighting

- a) Adequate natural or artificial lighting should be provided to enable the food business to operate in a hygienic manner. 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 (recommended 500 lux).
- b) Lighting fixtures shall be shatter-proof or protected with shatter-proof covers to prevent contamination if food and/or food contact surfaces in the event of breakages. The fixtures shall be designed to avoid the accumulation of dirt and be easy to clean.

4.4.8 Power Back up

Suitable power back-up facilities (e.g. generators, invertors etc.,) as appropriate to the nature of food operations and location shall be provided to ensure uninterrupted power supply as necessary for production of safe food.

4.4.9 Storage

- a) Adequate facilities for storage of food, ingredients, packaging material and non- food chemicals (e.g. cleaning materials, lubricants, fuels) shall be provided and segregated appropriately.
- b) 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 that may compromise food quality and safety.

5 TRAINING AND COMPETENCE

Objective:

All those engaged in food operations who come directly or indirectly into contact with food should have sufficient understanding of food hygiene to ensure they have competence appropriate to the operations they are to perform.

- a) All food businesses shall have food handlers with a valid Food Handlers License issued by the competent authority. Where FB does not have food handlers with a valid Food Handlers License, all FHs employed in FB shall be registered with the competent authority within thirty (30) days from the date of employment.
- b) Managers and supervisors shall have appropriate knowledge of food hygiene principles and practices. Suitable training shall be given to all personnel to have the required knowledge and skills in GHP and GMP for the assigned tasks to be performed effectively and to ensure the safety of the food and its suitability for consumption. Such training programme shall be provided at least once in a year and routinely reviewed and updated. Training records should be maintained.

6 FOOD BUSINESS MAINTENANCE, CLEANING AND SANITATION

Objectives:

To facilitate the continuing effective control of food hazards, pests, and other agents likely to contaminate food, it is desirable to establish an effective system to:

- ensure appropriate establishment maintenance;
- ensure cleanliness and, when necessary, adequate disinfection;
- ensure pest control;
- ensure waste management; and;
- monitor effectiveness of cleaning and disinfection, pest control and waste management procedures.

6.1 Maintenance and Cleaning

- a) Establishment and equipment shall be maintained under an appropriate state of repair and condition to:
 - i. Facilitate all sanitation procedures;
 - ii. Function as intended particularly at critical steps;
 - iii. Prevent contamination of food.

- b) Maintenance programmes 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 parts of equipment which directly come in contact with food shall be non-toxic, non-reactive and impervious.
- c) Cleaning and sanitation programmes 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.

6.2 Pest Control

- a) Suitable pest control programme shall be in place and effective to ensure there are no signs of pest infestation including flies, cockroaches, lizards, rats, etc. The pest control programme 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 programmes shall be effective in denying entry, food, shelter to the pest and also destroying the pest.
- b) The chemical pest control activities shall be performed by trained personnel. These shall be continuously monitored for their effectiveness. The FB shall ensure that the pest control chemicals do not contaminate food.
- c) The measures shall be documented, and records maintained.
- d) Animals should, wherever possible, be excluded from the processing and serving areas.

6.3 Waste Management

- a) A suitable waste management system including waste disposal procedure shall be in place.
- b) Waste shall not accumulate in working areas or the adjoining environment in a manner that compromises food safety and suitability.
- c) Waste bins and areas shall be identified, covered, kept appropriately clean and resistant to pest infestation. They should also be located away from processing areas.
- d) These shall be continuously monitored and verified for their effectiveness and rectified, if adequate. The records shall be maintained for the same.

7 PERSONAL HYGIENE

Objectives:

To ensure that those who come directly or indirectly into contact with food:

- maintain appropriate personal health;
- maintain an appropriate degree of personal cleanliness; and
- behave and operate in an appropriate manner.

- a) Personnel working in the processing area shall be checked for communicable and infectious diseases once in a year by a Government registered 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. Any person so affected should immediately report illness or symptoms of illness to the management.
- c) Personnel with cuts and wounds shall, where necessary, be assigned to work in areas where they will have no direct contact with food. Where personnel are permitted to continue working, cuts and wounds should be covered by suitable waterproof adhesive bandages and, where appropriate, gloves. Appropriate measures should be applied to ensure bandages do not become a source of contamination.
- d) 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 measures such as passing through a foot dip, using shoe covers, changing to separate footwear for internal use etc. shall be used.
- e) Personnel shall always wash hands with soap/ disinfectant at the start of activities, when returning to work after breaks, 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.
- f) People engaged in food handling activities should refrain from behavior which could result in contamination of food, for example, smoking, spitting, chewing or eating, and sneezing or coughing over unprotected food.
- g) Visitors shall follow the same norms for protective clothing and personal hygiene as those working in the unit.
- h) Personnel hygiene practices in language, understood by the personnel and/or pictorial shall be suitably displayed at appropriate places.

8 CONTROL OF OPERATION

Objectives:

To produce food that is safe and suitable for human consumption by:

- formulating design requirements with respect to raw materials and other ingredients, composition/formulation, production, processing, distribution, and consumer use to be met as appropriate to the food business;
- designing, implementing, monitoring, and reviewing effective control systems as appropriate to the food business.

Control of operation is achieved by having an appropriate food hygiene system in place. The following section describes practices that can assist in the identification and application of appropriate controls, as well as activities that should take place to ensure the operation is under control.

8.1 Time and Temperature Control

- a) Inadequate food temperature control is one of the most common causes of food borne illness or food spoilage. Such controls include time and temperature of cooking, processing and storage. Systems should be in place to ensure that temperature is controlled effectively where it is critical to the safety and suitability of food.
- b) Temperature control systems should take into account:
 - i. the nature of the food, for example, its water activity, pH, and likely initial level and types of microorganisms;
 - ii. the intended shelf-life of the product;
 - iii. the method of packaging and processing; and
 - iv. how the product is intended to be used, for example, further cooking/processing or ready-to-eat

8.2 Control of Other Specific Process Steps

- a) The FB shall define controls over other process steps which contribute to production of food that is safe and suitable for human consumption. These processes may include cleaning, sorting, chilling, thermal processing, fumigation, irradiation, drying, chemical preservation, vacuum or modified atmospheric packaging, etc.
- b) The FB should maintain and display the process flow chart as appropriate.

8.3 Specifications

- a) Define specifications for products at various stages of operations as relevant for ensuring food safety and compliance with 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. Specifications can help ensure that raw materials and other ingredients are fit for purpose and contaminants have been minimized.

8.4 Microbiological Cross Contamination

- a) Systems should be in place to prevent or minimize contamination of foods by microorganisms. Microbiological contamination occurs through a number of mechanisms, but not limited to:
 - i. by direct contact or indirectly by food handlers;
 - ii. by contact with surfaces;
 - iii. from cleaning equipment;
 - iv. by splashing; or
 - v. by airborne particles.
- 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.

8.5 Physical and Chemical Contamination

- a) Foods shall not be contaminated by foreign matter could cause injury or present a choking hazard.
- 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.
- d) Systems should be in place to prevent or minimize contamination of foods by harmful chemicals, e.g. cleaning materials, non-food grade lubricants, chemical residues from pesticides and veterinary drugs such as antibiotics.
- e) Toxic cleaning compounds, disinfectants, and pesticide chemicals should be identified, safely stored in a designated area and used in a manner that protects against contamination of food, food contact surfaces, and food packaging materials.

8.6 Allergen Management

- a) Systems should be in place to take into account the allergenic nature of some foods, as appropriate to the food business. Such a system should be able to effectively control introduction of allergens into the food throughout the various stages of production.
- b) Controls shall be in place to prevent the presence of allergens in foods where they are not labeled. Such control includes separation either physically or by time (with effective cleaning between foods with different allergen profiles). Where allergen cross contact cannot be prevented despite well-implemented controls, consumers should be informed through appropriate means.

8.7 Incoming Materials Requirements

- a) Only sound, safe and suitable incoming materials like raw materials, ingredients and semi-processed products shall be used.
- b) Where appropriate, specifications for incoming materials (local or imported) shall be defined and used as per the applicable legislations.
- c) Raw materials where appropriate, 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) Records of incoming materials and procurement details (e.g. supplier details, date of receipt, quantity, etc.) shall be maintained.

8.8 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. Adhesives/ Glue, if used, shall not come in contact with the food product, and in case it comes in contact it shall be food grade. 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 or test report from an accredited or BFDA recognized laboratory shall be used for verification.
- b) Use of staple pins, strings, rubber bands with the primary packaging shall be restricted. String and rubber bands, if used shall not compromise the safety and suitability of food.
- 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 and/or sterilize. It shall not have been used for packaging non-food products.

8.9 Water

8.9.1 Water, Ice and Steam which comes 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 and documented. 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.

8.9.2 Water, Ice and Steam which does not come in contact with Food

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.

8.9.3 Water Pipes and Storage Tanks

- a) Water pipes, either hot or cold, shall be maintained in good condition and functional to prevent leakage or defects that would result in contamination of food.
- b) Water storage tanks for potable water shall be regularly cleaned at least once in 3 months and where necessary, disinfected at least twice a year to prevent contamination.
- c) The pipelines and tanks shall be properly identified. For e.g. By use of colour.
- d) If the water storage tank is situated in an area that is accessible to unauthorized individuals, it shall be fenced properly and kept under lock and key to prevent contamination.

8.10 Management and Supervision of Operations

All operations shall be monitored and supervised appropriately by Managers/supervisors with sufficient knowledge of food hygiene principles and practices for identification of deviations and taking necessary action as appropriate to their duties. 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.

8.11 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. This shall be in line with the requirement set by the competent authority.

- 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.
- d) Where a product has been withdrawn, other products which are produced under similar conditions shall be evaluated for safety and may need to be withdrawn. Records of withdrawn products shall be maintained.

8.12 Storage

- a) Food products shall be stored:
 - i. Under conditions that prevent spoilage, protect against contamination and minimize damage.
 - ii. away from the wall, ceiling and not directly on the floor. It shall be stored preferably either on pallets / racks or any other manner to facilitate cleaning, avoid ingress of moisture, etc.
 - iii. in clean areas and stacked in a manner that facilitates ease of movement.
 - iv. under specific storage conditions as required e.g. temperature and humidity, air circulation etc. shall be maintained under specific conditions.
- b) All products in storage shall be clearly identified.
- c) Stocks of raw materials (including packaging material) and ingredients shall be subject to effective stock rotation.
- d) Cleaning materials and hazardous chemical substances shall have restricted access and only to authorized personnel.

8.13 Documentation and Records

- a) Appropriate records of processing, production and distribution shall be kept and retained for at least 1 year exceeding 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 status

- ix) Training
- x) Calibration of equipment, as appropriate
- xi) Complaint and Customer feedback
- xii) Corrective and preventive action
- xiii) Emergency preparedness plan

9 QUALITY CONTROL

Objectives:

To ensure that the:

- a) Products are uniform and consistent in quality;
 - b) Products' safety and qualities are evaluated, maintained and improved;
 - c) Products comply with relevant regulatory standards and guidelines set by the competent authority.
-
- a) The quality control programme shall include inspection, sampling and testing of incoming, in process and finished product (for specifications see Clause 8.3 a).
 - b) Infrastructure shall be available for carrying out testing. In case the same is not available, a proper system for testing in National Food Testing Laboratory, Yoeselpang, Thimphu or any accredited or BFDA recognized laboratory 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 programme.
 - d) The FB shall maintain records of testing, calibration, manpower competence and Quality Assurance Programme.

10 TRANSPORTATION

Objectives:

During transportation, measures should be taken where necessary to:

- protect food from potential sources of contamination, including allergen cross- contact;
- protect food from damage likely to render the food unsuitable for consumption; and
- provide an environment which effectively controls the growth of pathogenic or spoilage micro-organisms and the production of toxins in food.

- a) Food shall be adequately protected during transport to assure food safety and suitability.
- b) The transportation or transport containers shall be designed and constructed so that they:
 - i) do not contaminate foods or packaging;
 - ii) can be effectively cleaned and, where necessary, disinfected and dried;
 - iii) permit effective separation of different foods or foods from non-food items that could cause contamination where necessary during transport;
 - iv) provide effective protection from contamination, including dust and fumes;
 - v) can effectively maintain the temperature, humidity, atmosphere and other conditions necessary to protect food from harmful or undesirable microbial growth and deterioration likely to render it unsafe or unsuitable for consumption; and
 - vi) allow any necessary temperature, humidity and other environmental conditions to be checked.

11 PRODUCT INFORMATION, CONSUMER AWARENESS & COMPLAINTS

Objectives:

Appropriate information about food should ensure that:

- adequate and accessible information is available to the next FB in the food chain or the consumer to enable them to handle, store, process, prepare and display the product safely and correctly;
- consumers can identify allergens present in foods; and
- the lot or batch can be easily identified and removed/returned if necessary.

Consumers should be given enough information on food hygiene to enable them to:

- be aware of the importance of reading and understanding the label;

- make informed choices appropriate to the individual, including about allergens; and prevent contamination and growth or survival of foodborne pathogens by storing, preparing and using food correctly.

- a) 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.
- b) All legal/ statutory requirements shall be clearly given on the label of the final product as per the Food Rules and Regulations of Bhutan (2017) and its amendments. Bhutan mandatory standard for labelling of prepackaged food (BMS-12:2017) and its amendments shall apply to all prepackaged food.
- c) The licensed FB shall use Food Safety License (FSL) mark on the food label as per the guidelines for use of food safety license mark on the food product label.
- d) All finished products shall be given a unique Batch number for effective traceability and stock rotation.
- e) Any special requirements of handling, storage and processing by all the relevant stakeholders involved in the food supply chain (e.g customer, distributors, etc) shall be clearly indicated on labels. This shall also include information that identifies food allergens in the product as ingredients or where cross-contact cannot be excluded.
- f) All complaints and/or customer feedback shall be analyzed for any improvements with regard to food safety and suitability and the record shall be maintained for the same.

12 VENDING MACHINES

Objectives:

The vending machine should be designed and located in an appropriate area to ensure that:

- a) design and layout permit appropriate maintenance, cleaning and disinfections;
 - b) there is effective protection against pest access and harborage;
 - c) where appropriate, suitable facilities are available for temperature, humidity and other controls.
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- a) All requirements of design, operations and hygiene as applicable shall apply to vending machines with a view to ensuring safety and suitability of use.
 - b) The premises and vending machine should be located, designed, and constructed to avoid, as far as reasonably practicable, the contamination of food and the harboring of pests.

13 SELF-EVALUATION

Objectives:

Self-evaluation shall be done to ensure that:

- a) Relevant regulatory standards and guidelines set by the competent authority are being complied;
- b) Documents and records are properly maintained; and
- c) Continual improvement in the area of food safety and quality are made.

- a) FB shall evaluate themselves periodically to ensure compliance to the food safety requirements for continual improvement and at least once a year for all the requirements of the document. Records of the same shall be maintained.

REFERENCE

FAO and WHO. 1969. General Principles of Food Hygiene. Codex Alimentarius Code of Practice, No. CXC 1-1969. Codex Alimentarius Commission. Rome.

Food Rules and Regulations of Bhutan 2017

Food Act of Bhutan 2005

Food Handlers' Training Manual for Food Processing Units 2014

TECHNICAL WORKING GROUP
Food Quality & Safety Division, Bhutan Food and Drug Authority (BFDA)

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