

Part-II

(See Regulation 2.1.1(4))

General Requirements on Hygienic and Sanitary Practices to be followed by all Food Business Operators applying for License

The establishment in which food is being handled, processed, manufactured, packed, stored, and distributed by the food business operator and the persons handling them should conform to the sanitary and hygienic requirement, food safety measures and other standards as specified below. It shall also be deemed to be the responsibility of the food business operator to ensure adherence to necessary requirements.

In addition to the requirements specified below, the food business operator shall identify steps in the activities of food business, which are critical to ensure food safety, and ensure that safety procedures are identified, implemented, maintained and reviewed periodically.

1 LOCATION AND SURROUNDINGS

1.1 Food Establishment shall ideally be located away from environmental pollution and industrial activities that produce disagreeable or obnoxious odour, fumes, excessive soot, dust, smoke, chemical or biological emissions and pollutants, and which pose a threat of contaminating food areas that are prone to infestations of pests or where wastes, either solid or liquid, cannot be removed effectively.

1.2 In case there are hazards of other environment polluting industry located nearby, appropriate measures should be taken to protect the manufacturing area from any potential contamination.

1.3 The manufacturing premise should not have direct access to any residential area.

2 LAYOUT AND DESIGN OF FOOD ESTABLISHMENT PREMISES

As far as possible, the layout of the food establishment shall be such that food preparation / manufacturing processes are not amenable to cross-contamination from other pre and post manufacturing operations like goods receiving, pre-processing (viz. packaging, washing / portioning of ready-to-eat food etc).

2.1 Floors, ceilings and walls must be maintained in a sound condition to minimize the accumulation of dirt, condensation and growth of undesirable moulds. They should be made of impervious material and should be smooth and easy to clean with no flaking paint or plaster.

2.2 Doors shall also be made of smooth and non-absorbent surfaces so that they are easy to clean and wherever necessary, disinfect.

2.3 The floor of food processing / food service area shall have adequate and proper drainage and shall be easy to clean and where necessary, disinfect. Floors shall be sloped appropriately to facilitate drainage and the drainage shall flow in a direction opposite to the direction of food preparation / manufacturing process flow.

2.4 Adequate control measures should be in place to prevent insects and rodents from entering the processing area from drains.

2.5 Windows, doors & all other openings to outside environment shall be well screened

with wire-mesh or insect-proof screen as applicable to protect the premise from fly and other insects / pests / animals & the doors be fitted with automatic closing springs. The mesh or the screen should be of such type which can be easily removed for cleaning.

2.6 No person shall manufacture, store or expose for sale or permit the sale of any article of food in any premises not effectively separated to the satisfaction of the licensing authority from any privy, urinal, sullage, drain or place of storage of foul and waste matter.

3 EQUIPMENT & CONTAINERS

3.1 Equipment and containers that come in contact with food and used for food handling, storage, preparation, processing, packaging and serving shall be made of corrosion free materials which do not impart any toxicity to the food material and should be easy to clean and /or disinfect (other than disposable single use types).

3.2 Equipment and utensils used in the preparation of food shall be kept at all times in good order and repair and in a clean and sanitary condition. Such utensil or container shall not be used for any other purpose.

3.3 Every utensil or container containing any food or ingredient of food intended for sale shall at all times be either provided with a properly fitted cover/lid or with a clean gauze net or other material of texture sufficiently fine to protect the food completely from dust, dirt and flies and other insects.

3.4 No utensil or container used for the manufacture or preparation of or containing any food or ingredient of food intended for sale shall be kept in any place in which such utensil or container is likely by reason of impure air or dust or any offensive, noxious or deleterious gas or substance or any noxious or injurious emanations, exhalation, or effluvium, to be contaminated and thereby render the food noxious.

3.5 Equipment shall be so located, designed and fabricated that it permits necessary maintenance and cleaning functions as per its intended use and facilitates good hygiene practices inside the premise including monitoring and audit.

3.6 Appropriate facilities for the cleaning and disinfecting of equipments and instruments and wherever possible cleaning in place (CIP) system shall be adopted.

3.7 Equipment and containers for waste, by-products and inedible or dangerous substances, shall be specifically identifiable and suitably constructed.

3.8 Containers used to hold cleaning chemicals and other dangerous substances shall be identified and stored separately to prevent malicious or accidental contamination of food.

3.9 If required, a waste water disposal system / effluent treatment plant shall be put in place.

3.10 All items, fittings and equipments that touch or come in contact with food must be:

kept in good condition in a way that enables them to be kept clean and wherever necessary, to be disinfected.

Chipped enameled containers will not be used. Stainless steel /aluminum / glass containers, mugs, jugs, trays etc. suitable for cooking and storing shall be used. Brass utensils shall be frequently provided with lining.

4 FACILITIES

4.1 Water supply

4.1.1 Only potable water, with appropriate facilities for its storage and distribution shall be used as an ingredient in processing and cooking.

4.1.2 Water used for food handling, washing, should be of such quality that it does not introduce any hazard or contamination to render the finished food article unsafe.

4.1.3 Water storage tanks shall be cleaned periodically and records of the same shall be maintained in a register.

4.1.4 Non potable water can be used provided it is intended only for cleaning of equipment not coming in contact with food, which does not come into contact with food steam production, fire fighting & refrigeration equipment and provided that pipes installed for this purpose preclude the use of this water for other purposes and present no direct or indirect risk of contamination of the raw material, dairy products or food products so processed, packed & kept in the premise.

4.1.5 Non potable water pipes shall be clearly distinguished from those in use for potable water.

4.2 For Cleaning Utensils / Equipments

Adequate facilities for cleaning, disinfecting of utensils and equipments shall be provided. The facilities must have an adequate supply of hot and cold water if required.

4.3 Washing of Raw materials

Adequate facilities for washing of raw food should be provided. Every sink (or other facilities) for washing food must have an adequate supply of hot and/or cold water. These facilities must be kept clean and, where necessary, disinfected. Preferably, sinks which are used for washing raw foods shall be kept separate and that should not be used for washing utensils or any other purposes.

4.4 Ice and Steam

Ice and steam used in direct contact with food shall be made from potable water and shall comply with requirements specified under 4.1.1. Ice and steam shall be produced, handled and stored in such a manner that no contamination can happen

4.5 Drainage and waste disposal

4.5.1 Food waste and other waste materials shall be removed periodically from the place where food is being handled or cooked or manufactured to avoid building up. A refuse bin of adequate size with a proper cover preferably one which need not be touched for opening shall be provided in the premises for collection of waste material. This shall be emptied and washed daily with a disinfectant and dried before next use.

4.5.2 The disposal of sewage and effluents (solid, liquid and gas) shall be in conformity with requirements of Factory / Environment Pollution Control Board. Adequate drainage, waste disposal systems and facilities shall be provided and they shall be designed and constructed in such manner so that the risk of contaminating food or the potable water supply is eliminated.

4.5.3 Waste storage shall be located in such manner that it does not contaminate the food process, storage areas, the environment inside and outside the food establishment and waste shall be kept in covered containers and shall be removed at regular intervals.

4.5.4 Periodic disposal of the refuse / waste should be made compulsory. No waste shall be kept open inside the premise and shall be disposed of in an appropriate manner as per local rules and regulations including those for plastics and other non environment friendly materials.

4.6 Personnel facilities and toilets

4.6.1 Personnel facilities shall include those for proper washing and drying of hands before touching food materials including wash basins and a supply of hot and /or cold water as appropriate; separate lavatories, of appropriate hygienic design, for males and females separately; and changing facilities for personnel and such facilities shall be suitably located so that they do not open directly into food processing, handling or storage areas.

4.6.2 Number of toilets should be adequate depending on the number of employees (male /female) in the establishment and they should be made aware of the cleanliness requirement while handling food.

4.6.3 Rest and refreshments rooms shall be separate from food process and service areas and these areas shall not lead directly to food production, service and storage areas.

4.6.4 A display board mentioning do's & don'ts for the workers shall be put up inside at a prominent place in the premise in English or in local language for everyone's understanding.

4.7 Air quality and ventilation

Ventilation systems natural and /or mechanical including air filters, exhaust fans, wherever required, shall be designed and constructed so that air does not flow from contaminated areas to clean areas.

4.8 Lighting

Natural or artificial lighting shall be provided to the food establishment, to enable the employees/workers to operate in a hygienic manner. Lighting fixtures must wherever appropriate, be protected to ensure that food is not contaminated by breakages of electrical fittings.

5 FOOD OPERATIONS AND CONTROLS

5.1 Procurement of raw materials

5.1.1 No raw material or ingredient thereof shall be accepted by an establishment if it is known to contain parasites, undesirable micro-organisms, pesticides, veterinary drugs or toxic items, decomposed or extraneous substances, which would not be reduced to an acceptable level by normal sorting and/or processing.

5.1.2 All raw materials, food additives and ingredients, wherever applicable, shall conform to all the Regulations and standards laid down under the Act.

5.1.3 Records of raw materials, food additives and ingredients as well as their source of procurement shall be maintained in a register for inspection.

5.1.4 All raw materials should be checked & cleaned physically thoroughly.

5.1.5 Raw materials should be purchased in quantities that correspond to storage/ preservation capacity.

5.1.6 Packaged raw material must be checked for 'expiry date'/ 'best before'/ 'use by' date, packaging integrity and storage conditions.

5.1.7 Receiving temperature of potentially high risk food should be at or below 5 0C

5.1.8 Receiving temperature of frozen food should be -18 0C or below.

5.2 Storage of raw materials and food

5.2.1 Food storage facilities shall be designed and constructed to enable food to be effectively protected from contamination during storage; permit adequate maintenance and cleaning, to avoid pest access and accumulation.

5.2.2 Cold Storage facility, wherever required, shall be provided to raw, processed / packed food according to the type and requirement.

5.2.3 Segregation shall be provided for the storage of raw, processed, rejected, recalled or returned materials or products which will be distinguishably marked and secured. Raw materials and food shall be stored in separate areas from printed packaging materials, stationary, hardware and cleaning materials / chemicals.

5.2.4 Raw food, particularly meat, poultry and seafood products shall be cold stored separately from the area of work-in-progress, processed, cooked and packaged products. The conditions of storage in terms of temperature and humidity requisite for enhancing the shelf life of the respective food materials / products shall be maintained.

5.2.5 Storage of raw materials, ingredients, work-in-progress and processed / cooked or packaged food products shall be subject to FIFO (First in, First Out), FEFO (First Expire First Out) stock rotation system as applicable.

5.2.6 Containers made of non-toxic materials shall be provided for storage of raw materials, work-in-progress and finished / ready to serve products. The food materials shall be stored on racks / pallets such that they are reasonably well above the floor level and away from the wall so as to facilitate effective cleaning and prevent harbouring of any pests, insects or rodents.

5.3 Food Processing / Preparation, Packaging and Distribution / Service

5.3.1. Time and temperature control

5.3.1.1 The Food Business shall develop and maintain the systems to ensure that time and temperature are controlled effectively where it is critical to the safety and suitability of food. Such control shall include time and temperature of receiving, processing, cooking, cooling, storage, packaging, distribution and food service upto the consumer, as applicable.

5.3.1.2 Whenever frozen food / raw materials are being used / handled / transported, proper care should be taken so that defrosted / thawed material are not stored back after opening for future use.

5.3.1.3 If thawing is required then only required portion of the food should be thawed at a time.

5.3.1.4 Wherever cooking is done on open fire, proper outlets for smoke/steam etc. like chimney, exhaust fan etc. shall be provided.

5.4 Food Packaging

5.4.1 Packaging materials shall provide protection for all food products to prevent contamination, damage and shall accommodate required labelling as laid down under the FSS Act & the Regulations there under.

5.4.2 For primary packaging (i.e packaging in which the food or ingredient or additive comes in direct contact with the packaging material), only Food grade packaging materials are to be used . For packaging materials like aluminium plastic and tin, the standards to be followed are as mentioned under the FSS Regulations and rules framed there under.

5.4.3 Packaging materials or gases where used, shall be non-toxic and shall not pose a threat to the safety and suitability of food under the specified conditions of storage and use.

5.5 Food Distribution / Service

5.5.1 All critical links in the supply chain need to be identified and provided for to minimize food spoilage during transportation. Processed / packaged and / or ready-to-eat food shall be protected as per the required storage conditions during transportation and / or service.

5.5.2 Temperatures and humidity which are necessary for sustaining food safety and quality shall be maintained. The conveyances and /or containers shall be designed, constructed and maintained in such manner that they can effectively maintain the requisite temperature, humidity, atmosphere and other conditions necessary to protect food

conveyances and / or containers used for transporting / serving foodstuffs shall be non toxic, kept clean and maintained in good condition in order to protect foodstuffs from any contamination.

5.5.3 Receptacles in vehicles and / or containers shall not be used for transporting anything other than foodstuffs where this may result in contamination of foodstuffs. Where the same conveyance or container is used for transportation of different foods, or high risk foods such as fish, meat, poultry, eggs etc., effective cleaning and disinfections shall be carried out between loads to avoid the risk of cross- contamination. For bulk transport of food, containers and conveyances shall be designated and marked for food use only and be used only for that purpose.

6 Management and Supervision

6.1 A detailed Standard Operating Procedure (SOP) for the processing of food as well as its packing, despatch and storage will be developed for proper management which in turn would help in identifying any problem and the exact point, so that damage control would be faster.

6.2 The Food Business shall ensure that technical managers and supervisors have appropriate qualifications, knowledge and skills on food hygiene principles and practices to be able to ensure food safety and quality of its products, judge food hazards, take appropriate preventive and corrective action, and to ensure effective monitoring and supervision.

7 Food Testing Facilities

7.1A well equipped, laboratory for testing of food materials / food for physical, microbiological and chemical analysis in accordance with the specification/standards laid down under the rules and regulations shall be in place inside the premise for regular / periodic testing and when ever required.

7.2 In case of any suspicion or possible contamination, food materials / food shall be tested before dispatch from the factory.

7.3 If there is no in house laboratory facility, then regular testing shall be done through an accredited lab notified by FSSAI . In case of complaints received and if so required, the company shall voluntarily do the testing either in the in-house laboratory or an accredited lab or lab notified by FSSAI.

8 Audit, Documentation and Records

8.1A periodic audit of the whole system according to the SOP shall be done to find out any fault / gap in the GMP / GHP system.

8.2 Appropriate records of food processing / preparation, production / cooking, storage, distribution, service, food quality, laboratory test results, cleaning and sanitation, pest control and product recall shall be kept and retained for a period of one year or the shelf-life of the product, whichever is more.

9 SANITATION AND MAINTENANCE OF ESTABLISHMENT PREMISES

9.1 Cleaning and Maintenance

9.1.1 A cleaning and sanitation programme shall be drawn up and observed and the record thereof shall be properly maintained, which shall indicate specific areas to be cleaned, cleaning frequency and cleaning procedure to be followed, including equipment and materials to be used for cleaning. Equipments used in manufacturing will be cleaned and sterilized at set frequencies.

9.1.2 Cleaning chemicals shall be handled and used carefully in accordance with the instructions of the manufacturer and shall be stored separately away from food materials, in clearly identified containers, to avoid any risk of contaminating food.

9.2 Pest Control Systems

9.2.1 Food establishment, including equipment and building shall be kept in good repair to prevent pest access and to eliminate potential breeding sites. Holes, drains and other places where pests are likely to gain access shall be kept in sealed condition or fitted with mesh / grills / claddings or any other suitable means as required and animals, birds and pets shall not be allowed to enter into the food establishment areas/ premises.

9.2.2 Food materials shall be stored in pest-proof containers stacked above the ground and away from walls.

9.2.3 Pest infestations shall be dealt with immediately and without adversely affecting the food safety or suitability. Treatment with permissible chemical, physical or biological agents, within the appropriate limits, shall be

carried out without posing a threat to the safety or suitability of food. Records of pesticides / insecticides used along with dates and frequency shall be maintained.

10 PERSONAL HYGIENE

10.1 Health Status

10.1.1 Personnel known, or believed, to be suffering from, or to be a carrier of a disease or illness likely to be transmitted through food, shall not be allowed to enter into any food handling area. The Food Business shall develop system, whereby any person so affected, shall immediately report illness or symptoms of illness to the management and medical examination of a food handler shall be carried out apart from the periodic checkups, if clinically or epidemiologically indicated.

10.1.2 Arrangements shall be made to get the food handlers / employees of the establishment medically examined once in a year to ensure that they are free from any infectious, contagious and other communicable diseases. A record of these examinations signed by a registered medical practitioner shall be maintained for inspection purpose.

10.1.3 The factory staff shall be compulsorily inoculated against the enteric group of diseases as per recommended schedule of the vaccine and a record shall be kept for inspection.

10.1.4 In case of an epidemic, all workers are to be vaccinated irrespective of the scheduled vaccination.

10.2 Personal Cleanliness

10.2.1 Food handlers shall maintain a high degree of personal cleanliness. The food business shall provide to all food handlers adequate and suitable clean protective clothing, head covering, face mask, gloves and footwear and the food business shall ensure that the food handlers at work wear only clean protective clothes, head covering and footwear every day.

10.2.2 Food handlers shall always wash their hands with soap and clean potable water, disinfect their hands and then dry with hand drier or clean cloth towel or disposable paper at the beginning of food handling activities immediately after handling raw food or any contaminated material, tools, equipment or work surface, where this could result in contamination of other food items or after using the toilet.

10.2.3 Food handlers engaged in food handling activities shall refrain from smoking, spitting, chewing, sneezing or coughing over any food whether protected or unprotected and eating in food preparation and food service areas.

10.2.4 The food handlers should trim their nails and hair periodically, do not encourage or practice unhygienic habits while handling food.

10.2.5 Persons working directly with and handling raw materials or food products shall maintain high standards of personal cleanliness at all times. In particular:

- a) they shall not smoke, spit, eat or drink in areas or rooms where raw materials and food products are handled or stored;
- b) wash their hands at least each time work is resumed and whenever

contamination of their hands has occurred; e.g. after coughing / sneezing, visiting toilet, using telephone, smoking etc.

c) avoid certain hand habits - e.g. scratching nose, running finger through hair, rubbing eyes, ears and mouth, scratching beard, scratching parts of bodies etc.- that are potentially hazardous when associated with handling food products, and might lead to food contamination through the transfer of bacteria from the employee to product during its preparation. When unavoidable, hands should be effectively washed before resuming work after such actions.

10.3 Visitors

10.3.1 Generally visitors should be discouraged from going inside the food handling areas. Proper care has to be taken to ensure that food safety & hygiene is not getting compromised due to visitors in the floor area.

10.3.2 The Food Business shall ensure that visitors to its food manufacturing, cooking, preparation, storage or handling areas must wherever appropriate, wear protective clothing, footwear and adhere to the other personal hygiene provisions envisaged in this section.

11 PRODUCT INFORMATION AND CONSUMER AWARENESS

All packaged food products shall carry a label and requisite information as per provisions of Food Safety and Standards Act, 2006 and Regulations made there under so as to ensure that adequate and accessible information is available to the each person in the food chain to enable them to handle, store, process, prepare and display the food products safely and correctly and that the lot or batch can be easily traced and recalled if necessary.

12 TRAINING

12.1 The Food Business shall ensure that all food handlers are aware of their role and responsibility in protecting food from contamination or deterioration. Food handlers shall have the necessary knowledge and skills which are relevant to food processing / manufacturing, packing, storing and serving so as to ensure the food safety and food quality.

12.2 The Food Business shall ensure that all the food handlers are instructed and trained in food hygiene and food safety aspects along with personal hygiene requirements commensurate with their work activities, the nature of food, its handling, processing, preparation, packaging, storage, service and distribution.

12.3 Periodic assessments of the effectiveness of training, awareness of safety requirements and competency level shall be made, as well as routine supervision and checks to ensure that food hygiene and food safety procedures are being carried out effectively.

12.4 Training programmes shall be routinely reviewed and updated wherever necessary.

PART-III

(See Regulation 2.1.2.(1)(5))

Specific Hygienic and Sanitary Practices to be followed by Food Business Operators engaged in manufacture, processing, storing and selling of Milk and Milk Products

In addition to Part-II, the dairy establishment in which dairy based food is being handled, processed, manufactured, stored, distributed and ultimately sold by the food business operator, and the persons handling them should conform to the sanitary and hygienic requirement, food safety measures and other standard as specified below.

I. SANITARY REQUIREMENTS

1. Dairy Establishments shall have the following:

(a) Facilities for the hygienic handling and protection of raw materials and of non-packed or non-wrapped dairy products during loading and unloading, transport & storing including Bulk Milk cooling facilities.

(b) Special watertight, non-corrodible containers to put raw materials or dairy products intended for human consumption. Where such raw materials or dairy products are removed through conduits, these shall be constructed and installed in such a way so as to avoid any risk of contamination of other raw materials or dairy products;

(c) a waste water disposal system which is hygienic and approved ;

(d) facilities for cleaning & disinfecting of tanks used for transporting dairy