

GMP/GHP Basic Criteria for Food

Scope

The requirements as given in this document apply to the entire food processing industry. They do not apply to the hotel and catering industry.

Design and Facilities

Location :

- ▶ Establishment shall 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.
- ▶ Open drains, garbage dumps, water logging; open spaces, such as yards, streets, side or rear lanes and roof tops, should not be used for preparation or storage of food, cleansing or storage of equipment or utensils

Design and layout

- ▶ Basic Infrastructure appropriate to the operations shall be in place. Flow shall be so designed that there is no criss-cross movement of men and material. Entry points for material and personnel shall as far as possible be separate. Food flow should be in one direction, as far as possible.
- ▶ adequate space should be provided for various activities such as raw material receipt & storage, processing, final product storage, change facilities for personnel, foot bath facilities as appropriate to the industry, separate eating area which is located away from process area, toilets/ washrooms, and do not open directly into the processing/ packing/ storage areas.
- ▶ There shall be adequate separation between storage areas (raw material, packaging material and finished goods), processing area, packing area, etc.
- ▶ There shall be provision of appropriate loading and unloading points which facilitate movement of material and provide adequate protection from pests, rain, etc.
- ▶ All requisite “No Objection Certificates (NOC)” from various authorities shall be obtained.

Internal Structures & Fittings

- ▶ Flooring shall be smooth, impervious, with no crevices or damaged. Floors shall be constructed to allow adequate drainage. The junctions with walls shall be such that they are cleanable e.g. coved (shall not be with sharp angles).
- ▶ Roof shall be constructed so as to be gap free, water resistant, and finished so as to minimize build up of dirt and shedding of particles. Overhead fixtures , if any, shall be constructed and finished to minimise the build up of dirt and condensation and the shedding of particles.
- ▶ Walls and partitions shall have a smooth surface. Wall paint shall not be flaking off. There shall be no crevices to harbour pests. If applicable and as appropriate to the operations, the walls up to a desired height shall be impervious and easy to clean.

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- ▶ Windows and Ventilators shall be easy to clean, and where necessary fitted with cleanable insect-proof screens/ louvers. Window glasses shall be shatter-proof. Mesh on windows (ventilator) shall not be cut/ damaged to avoid pest entry.
- ▶ Doors shall have smooth non absorbent surfaces and be easy to clean and disinfect as appropriate. Strip PVC
- ▶ /air curtains/ wire mesh doors with self closing devices shall be fitted at entry/exit points.
- ▶ 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.

Equipment

- ▶ Equipment shall be located so that it permits adequate maintenance and cleaning; functions in accordance with its intended use; facilitates good hygienic practices, including monitoring, if required.
- ▶ 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.
- ▶ These shall be made of materials with no toxic effect in intended use and should not pass on colours, odours or taste to food.

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- ▶ Non food contact surfaces of equipment should be free from unnecessary projections and crevices; and designed and constructed to allow easy cleaning and maintenance.
- ▶ 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. These shall be periodically calibrated & records maintained. The frequency of calibration shall be based on the type of equipment, criticality of the measurement, location & extent of usage.
- ▶ Maintenance programmes shall be in place which shall cover maintenance schedule, responsibilities, methods, tools and gadgets, etc for effective functioning of the equipment .

Containers for waste and inedible substances

- ▶ Containers for waste, by-products and inedible or dangerous substances shall be identifiable, suitably constructed and where appropriate made of impervious material. Those used to hold dangerous substances shall also be lockable.

Facilities

Water supply

- ▶ 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 Indian standard IS 10500:95.
- ▶ In case water is stored in tanks, these shall be such that they prevent contamination of water. They shall be suitably covered to prevent the access by animals, birds, pests and other extraneous matters.
- ▶ 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.
- ▶ The potable water pipes run at a higher level than non potable water pipes and they should not be concealed.

Drainage and waste disposal

- ▶ Drainage systems as relevant to the operations shall be appropriately designed and constructed. The sewage discharge shall comply with the requirements of environmental pollution Board (including ETP, rendering plant, etc. as applicable). No manhole shall be situated inside any food processing area. Rainwater pipes, if inside, shall be constructed of impervious rust-proofing materials. These shall not open in the food processing area.
- ▶ Drains, if any, in the processing area shall be made of impervious rust proofing 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).

Cleaning

- ▶ Adequate facilities, suitable designated, where necessary, should 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.

Personnel hygiene facilities and toilets

- ▶ Adequate means of hygienically washing and drying hands (as relevant), including wash basins and supply of adequate water of potable quality shall be provided. Taps shall be non-hand operated.
- ▶ Hand wash basins/ sanitizers should be situated to enable hand washing prior to start of operations.
- ▶ Toilets/ lavatories of appropriate hygienic design at suitable location with adequate natural or mechanical ventilation and natural or artificial lighting shall be provided.
- ▶ Adequate changing facilities for personnel should be provided, as appropriate to the operations

Temperature control

- ▶ 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.
- ▶ Where necessary, ambient temperatures shall be controlled to ensure the safety and suitability of food.

Air quality and ventilation

- ▶ 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.
- ▶ 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.
- ▶ Ventilation systems shall ensure that air does not flow from unclean to clean areas and, where necessary, they can be adequately maintained and cleaned.

Lighting

- ▶ Natural and / or artificial lighting shall be provided in food premises for various operations and other activities within the facility (eg sanitary conveniences). The intensity of lighting shall be adequate on the nature of operations (e.g. sorting, cleaning, grading, inspection and testing require greater intensity of light). Where necessary, lighting should be such that the resulting colour is not misleading.
- ▶ 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 by breakages. The fixtures shall be designed to avoid accumulation of dirt and be easy to clean.

Power Back up

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

Storage

- ▶ 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

Control of operation

Time and temperature control

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.

Control of other Specific process steps

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

Specifications

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. Document monitoring procedures, action limits and analytical methods. Maintain records.

Microbiological cross contamination

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

Physical and chemical contamination

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

Incoming materials requirements

- ▶ Only sound, suitable raw materials or ingredients shall be used.
- ▶ Where appropriate, specifications for raw materials shall be defined including Regulatory requirements.
- ▶ This may be achieved through supplier control, certificates of conformity, incoming inspection and testing etc.
- ▶ Where necessary, laboratory tests (in house or externally conducted) shall be carried out, at appropriate frequencies, to establish conformity.
- ▶ No raw material (including packing material) or ingredient shall be accepted by an establishment if it is known to contain parasites, undesirable micro organisms, pesticides, veterinary drugs, heavy metals or toxic, decomposed or extraneous substances which would not be reduced to an acceptable level by normal sorting and/or processing.
- ▶ Imported Foods/ raw materials, if used, shall be as per the applicable regulations
- g) Records shall be maintained.

Packaging

- ▶ Packaging design and materials shall provide adequate protection for products to minimize contamination, prevent damage and accommodate proper labeling. The materials should 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, should be avoided. Glue if used should not come in contact with the food product.
- ▶ Packaging materials and gases shall be non-toxic and not pose a threat to the safety of food. Certificates of conformity or other evidence may be used for verification.
- ▶ Packaging materials shall be stored and handled under hygienic conditions away from raw materials and finished products.
- ▶ 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.

Water

Water, Ice and steam in contact with food

- ▶ 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.
- ▶ Steam used in direct contact with food and or food contact surfaces shall not contain any agent which is hazardous for food safety.
- ▶ Water that is re-circulated shall be treated and maintained so that it is safe for use, and the treatment process shall be effectively monitored. Re-circulated water which has received no further treatment and water recovered from processing of food by evaporation or drying may be used, provided its use does not constitute a risk to the safety and suitability of food.

Water, Ice and steam not in contact with food

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 (e.g. use of clean sea-water) the use of potable water may not be required.

Water pipes & Storage tanks

Water pipes, either hot or cold, should 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 should be regularly cleaned and disinfected to prevent contamination.

Management and supervision

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.

Documentation and records

- ▶ Appropriate records of processing, production and distribution shall be kept and retained for a period that exceeds the shelf life of the product.
- ▶ At a minimum record for the following processes shall be maintained;
 - ▶ Incoming material checks
 - ▶ Inspection & test
 - ▶ Temperature & time
 - ▶ Product recall & traceability
 - ▶ Storage
 - ▶ Cleaning and sanitation, as appropriate
 - ▶ Pest control
 - ▶ Medical & health
 - ▶ Training
 - ▶ Calibration

Product Recall & Traceability

- ▶ 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 conditions, shall be evaluated for safety and may need to be withdrawn.
- ▶ Recalled products shall be held under supervision until they are destroyed, used for purposes other than human consumption, determined to be safe for human consumption or reprocessed in a manner to ensure their safety.
- ▶ Food establishments should, as far as possible and appropriate, maintain an effective mechanism for identification and traceability of the incoming materials to the supplier and delivery of finished food product to the customer (not the ultimate consumer). This would help in implementation of an effective recall. d) Records of recalled products shall be maintained.

Storage

- ▶ 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.
- ▶ Adequate facilities for storage of food, ingredients, packaging material and non food chemicals (eg cleaning materials, lubricants, fuels) shall be provided, and segregated appropriately.
- ▶ Food products shall be stored under conditions that prevent spoilage, protect against contamination and minimize damage. Food shall be stored away from the wall not directly on the floor. It should be stored preferably either on pallets / racks or any other manner to facilitate cleanliness, avoid ingress of moisture, etc. Food should be stored in clean areas and stacked in a manner that facilitates ease of movement. Food that requires specific storage conditions eg Temperature and humidity, air circulation etc shall be maintained.

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- ▶ All products in storage should be clearly identified.
- ▶ Stocks of raw materials (including packing material) and ingredients shall be subject to effective stock rotation.
- ▶ Cleaning materials and hazardous chemical substances should have restricted access to authorized personnel.

Maintenance and sanitation

Cleaning and sanitation programmes shall be in place which shall cover cleaning schedule, responsibilities, methods of cleaning, equipment and cleaning aids, etc to effectively control contamination of food. These shall be continuously monitored for their effectiveness. It shall be ensured that cleaning chemicals do not contaminate food.

Pest Control

- ▶ 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 shall include use of insectocutors, traps & bates as appropriate; maintaining cleanliness, covering exposed foods and wastes, blocking drain pipes etc.
- ▶ 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.
- ▶ The measures shall be documented and records maintained.

Waste management

Suitable waste management and waste disposal system shall be in place. Waste shall not accumulate in food processing, storage areas. Waste bins and areas must be covered and kept appropriately clean

Personal hygiene

- ▶ Personnel working in processing area shall be checked for communicable, infectious and loathsome diseases at least once/year.
- ▶ Personnel working in processing area shall not have any open cuts or wound/injury, contagious disease, or sickness such as Jaundice, Diarrhea, fever, etc. The open cuts or wounds shall not come in direct contact with food or food contact surface.
- ▶ Personnel while working in a food processing area shall maintain a high degree of personal cleanliness and shall wear clean uniform, head gear/cap, no loose or hanging jewellery/ glass bangles. Nails shall be trimmed, kept clean and without nail polish. Street shoes shall not be permitted. Appropriate measure such as passing through a foot bath, using shoe covers, changing to separate foot wear for internal use etc. shall be used.

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- ▶ Persons 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.
- ▶ No spitting, smoking, eating food and pan chewing shall be permitted in the processing areas.
- ▶ Visitors shall follow the same norms for protective clothing and personal hygiene as those working in the unit.
- ▶ Personnel Hygiene practices in simple local language / language understood by the personnel/pictorial shall be suitably displayed at appropriate places.

Quality Control

- ▶ The quality control programme shall include inspection and testing of incoming, in process and finished product.
- ▶ Infrastructure shall be available for carrying out testing. In case the same is not available, a proper system for testing in external laboratories shall be in place.

Transportation

- ▶ Food shall be adequately protected during transport to assure food safety.
- ▶ The transportation or transport containers should be designed and constructed so that they do not contaminate food (Including ingredients) or packaging material. These should be kept clean and disinfected. Food and non-food should be suitably segregated during transportation. Where the same conveyance or container is used for transporting different foods or non-foods, effective cleaning and where necessary, disinfection shall take place between loads.
- ▶ The temperature, humidity, atmosphere and other necessary conditions, as appropriate to the product shall be maintained.

Product information and consumer awareness

All incoming, in process and finished products shall be suitably identified for product identification, stage of processing, inspection & 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 W&M, PFA, etc. 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

Competence & Training

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 & 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.

Temporary / mobile premises; vending machines

All requirements of design, operations and hygiene as applicable shall apply to Temporary / mobile premises , vending machines (booths) with a view to ensuring safety and suitability of use.

GUIDELINES FOR ESTABLISHMENT OF COTTAGE/KITCHEN SCALE FOOD

GENERAL

- ▶ These guidelines are for the general public and in particular individual that want to engage in manufacturing of cottage/kitchen scale food products.
- ▶ These guidelines prescribe the minimum good hygienic practice requirements for the facilities, controls to be used in the manufacture, processing and packing of cottage/kitchen food products to ensure that they meet quality
- ▶ A cottage food operation still has to comply with the labelling, adulteration and other provision found in the Agency regulations, as well as other applicable state or federal laws.

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- ▶ The following products listed below Potentially Hazardous Foods/Temperature Controlled for Safety Foods (PHF/TCS) and must have adequate equipment, facilities and personnel with adequate education/training, experience in the manufacturing, processing and packaging of the product(s):
 - ▶ Meat and meat products
 - ▶ Poultry (Chicken, Eggs, Turkey, Duck)
 - ▶ Fish and Fish products
 - ▶ Milk and dairy products
 - ▶ Cooked rice, bean or vegetable
 - ▶ Baked potatoes
 - ▶ Beverages

PERSONNEL

- There should be an adequate number of qualified personnel to perform assigned duties.
- Each personnel engaged in food manufacturing should have
 - Basic education /Adequate Training
 - Experience
- Personnel should wear protective apparel/gears, such as head, face, hand, and arm coverings to protect products from contamination.
- Personnel should practice good sanitation and hygienic habits.

BUILDING/FACILITIES:

Production Area.

- ▶ The apartment provided for production can either be a purpose - built structure or an existing standard kitchen.
- ▶ The apartment must be minimum of 12×12 feet two rooms or a kitchen (12 × 12 Feet) with standard store and must be adequate for the orderly placement of equipment and materials to prevent mix-ups between different materials. iii. Windows and entrance doors should be screened with insect-proof netting and the doors should be self closing to prevent contamination.
- ▶ Adequate ventilation, cooling, lighting should be provided in all areas to facilitate easy identification of materials, cleaning, maintenance and proper operations.

Finished Product Store

All finished products must be stored in a cool dry place following safe, good handling guidelines to prevent adulteration caused by insect, household chemicals, water damage and insanitary condition.

EQUIPMENT

- ▶ The design of equipment should be such as to make it adequate and suitable for its Intended use
- ▶ Its layout and design must aim to minimize the risk of mix-ups and permit effective
- ▶ Cleaning and maintenance in order to avoid cross contamination, build-up of dust,
- ▶ Dirt, food particle or any other contaminant that can affect the quality of the product
- ▶ The parts of the equipment that make contact with products should be made of non-Toxic/non t reactive materials such as food grade stainless steel etc..

RAW/PACKAGING MATERIALS AND SOURCES

- ▶ Raw and packaging materials should be sourced from traceable source..
- ▶ They should be of good quality in order to produce quality products.
- ▶ All incoming materials should be stored under appropriate storage conditions.

QUALITY ASSUARANCE &QUALITY CONTROL

Cottage Food Producing industry are required to send samples from every batch of their finished products to a public analyst for comprehensive analysis and document same in a file while rectifying any anomaly in the parameter reading by carrying out the needed process change(s) for the overall product quality conformity

ENVIROMENTAL SANITATION AND PERSONEL HYGIENE

- ▶ Appropriate sanitation measures should be taken to avoid contamination risks of all kinds.
- ▶ The entire production area(s) should be cleaned frequently and thoroughly in accordance with the standard operational procedure (S.O.P) for cleaning.
- ▶ Equipment should be thoroughly cleaned in strict compliance to the S.O.P
- ▶ Water system toilets and washing facilities should be appropriately located, designed, equipped and the sanitation shall be maintained satisfactory in strict compliance to the S.O.P
- ▶ Eating, Drinking and Smoking should not be permitted when production is ongoing in the production area and storage.
- ▶ All operators should wear appropriate protective garments/gowning.
- ▶ Production staff should undergo food handler's test/medical examination at least once a year.
- ▶ Persons known to be suffering from communicable diseases or with wounds should be excluded from duty until they are certified medically fit again. Wastes should be adequately disposed of in strict compliance to the S.O.P.

DOCUMENTATION

- ▶ The aim of documentation is to define the specification for all materials and methods of manufacture and control, to ensure that all personnel concerned with manufacture know what to do and when to do it. The required documentation includes the following:
 - ▶ Standard Operating Procedure (SOP's) for Production.
 - ▶ Standard Operating Procedure for Cleaning of equipment and production area(s).
 - ▶ Standard Operating Procedures for Waste Disposal.
 - ▶ Food handler's test certificates
 - ▶ Fumigation certificates.

CONSUMER COMPLAINT AND RECALL

All consumer complaints must be thoroughly investigated and documented. Step must be taken to prevent future occurrence. If a recall is decided upon, it should be done quickly using the production batch history through the product distribution records. All records of recalled products must be kept. In event of recall, NAFDAC must be fully notified of all actions at receipt of consumer complaint, during investigation and actual recall activity.

DISTRIBUTION SYSTEM

Record of product distribution network must be properly kept for easy recall of defective products. Distributors' names, addresses, fax, phone, email etc should be obtained.

TRANSPORTATION AND HANDLING

Products should be handled and transported under conditions which prevent deterioration, contamination, spoilage and breakage to ensure that the product quality is maintained up to the time of delivery to the consumer.

LABEL

Product should be labelled adequately in English language and The label should also contain composition/ingredient(s) list, and within the label should be stated the net weight/volume of content, address, lot/batch number, production date, expiry date, direction for use. Note: Nutritional claim(s) are not allowed on the label.

REGISTRATION or LICENSE

FBO should have a Registration Number or License Number according to capacity from competent authority.





Food Safety and Standards
Authority of India



Thank you